510(k) Numbe	Contact Name	Applicant Name	Address	Regulation Numbe	Product Code
K011436	Florin Truuvert	Data Critical Corp.	CA	870.2340	DPS
K013311	Stephen Cresswell	Micromedical Industries, Ltd.	Queensland	870.1025	MHX
K020866	Donna K. Templeman	Abbott Diabetes Care, Inc.	CA	862.1345	NBW
K024365	Alex Gonorovsky	Card Guard Scientific Survival, Ltd.	Rehovot	870.2920	DXH
K041901	Joseph Azary	Northeast Monitoring, Inc.	CT	870.2800	MWJ
K042082	William Cameron Powell	MP4 Solutions, LP	TX	884.2740	HGM
K042121	Charles L. Martina	Sigma Intl.	NY	880.5725	FRN
K051857	David Weissburg	Weissburg Associates	WI	868.1400	CCK
K052975	Joel Kent	GE Healthcare	MA	870.2300	MSX
K060298	Keith A. Barritt	Vocel	DC	890.5050	NXQ
K060911	Alex Gonorovsky	Card Guard Scientific Survival, Ltd.	Rehovot	870.2920	DXH
K061994	Joel Kent	GE Healthcare	MA	870.2300	MSX
K062377	Kent E. Dicks	MedApps, Inc.	AZ	862.1345	NBW
K063392	Mark L. Schwartz	IMCO Technologies	WI	892.2050	LLZ
K070426	Shane Goodwin	Aranz Medical Limited	Canterbury	878.4160	FXN
K070599	Geraldine Crean	Tinnitus Otosound Products, LLC	CA	874.3400	KLW
K071995	Alex Gonorovsky	Card Guard Scientific Survival, Ltd.	Rehovot	870.1025	DSI
K072137	Jennifer Reich	Avita Corporation	AZ	870.1130	DXN
K072698	Daniel R. Pionski	Confident Inc.	NC	870.2910	DRG
K080047	Yoram Levy	SHL Telemedicine International Ltd.	Binyamina	870.2920	DXH
K080798	Tae-Woong Koo	Intel Corp.	CA	870.2910	DRG
K081257	Alex Gonorovsky	Card Guard Scientific Survival, Ltd.	Rehovot	870.1025	DSI
K081703	Carlos Gonzalez	Entra Health Systems, Ltd.	CA	862.1345	NBW
K083115	Tae-Woong Koo	Intel Corp.	CA	870.2910	DRG
K083263	Rae Ann Delay	Symcare Personalized Health Solutions, Inc.	PA	862.1345	NBW
K083862	Kent E. Dicks	MedApps, Inc.	AZ	870.2910	DRG
K090037	Martin Jasinski	Medicalgorithmics SP Z.O.O.	NY	870.1025	DSI
K090061		Airstrip Technologies, LP	TX	884.2740	HGM
K090269	Wm Cameron Powell	Airstrip Technologies, LP	TX	884.2740	HGM
K091168	Maria F. Griffin	Infopia Co., Ltd.	NY	862.1345	NBW
K093976	Gregory Moon	Proteus Biomedical Inc.	CA	870.2920	DXH
K100040	Code Cubitt	Zephyr Technoology Corp.	MD	870.1025	MHX
K100066	Malinda Peeples	WellDoc, Inc.	MD		LNX
K100133	Wm Cameron Powell	Airstrip Technologies, LP	TX	870.2300	MWI
K101178	Maureen Glynn	Intel Corp.	CA	870.2910	DRG
K101597	Connie Hertel	Agamatrix, Inc.	NH	862.1345	NBW
K101639	Clay Aneslmo	Card Guard Scientific Survival, Ltd.	CO	870.1025	DSI
K101703	Clay Aneslmo	Card Guard Scientific Survival, Ltd.	CO	870.1025	DSI
K101806	Anders Sonesson	Aidera AB	Goteborg	880.5725	MRZ
K102153	Sailesh Chutani	Mobisante, Inc.	WA	892.1560	IYO
K102251	Alexander Schwiersch	Brainlab, AG	Feldkirchen	882.4560	OLO
K102939	Liu Yi	Andon Health Co., Ltd.	Tianjin	870.1130	DXN
K103276	Maureen Glynn	Intel Corp.	CA	870.2910	DRG
K103544	William H. McGrail	Agamatrix, Inc.	NH	862.1345	NBW
K103785	Lynn Hanigan	MIM Software Inc.	OH	892.2050	LLZ
K110499	Clay Aneslmo	Card Guard Scientific Survival, Ltd.	CO	870.1025	DSI
K110503	Andy Miller	Airstrip Technologies, LP	TX	870.2300	MWI
K110571	Jonathan C. Javitt	Telcare, Inc.	MD	862.1345	NBW
K110872	Jen Ke-Min	Withings	Hsin Chu City	870.1130	DXN
K110919	Linda Stewart	Carestream Health, Inc.	NY	892.2050	LLZ
K111346	Kyle Peterson	Calgary Scientific, Inc.	Alberta	892.2050	LLZ
K111438	Larry Petersen	Reka PTE, LTD.	SC	870.2340	DPS
K111932	Edward Valdez	PositiveID Corp.	FL	862.1345	MBW
K112235	Andy Miller	Airstrip Technologies, LP	TX	870.2300	MWI
K112370	Lauren Bronich-Hall	WellDoc, Inc.	MD	880.5725	MRZ
K112559	Kent E. Dicks	MedApps, Inc.	NY	870.2910	DRG
K112930	Lynn Hanigan	MIM Software Inc.	OH	892.2050	LLZ
K113045	Richard Keen	Zephyr Technoology Corp.	CT	870.1025	MHX
K113070	Jafar Shenasa	Proteus Biomedical Inc.	CA	880.6305	OZW
K113514	Yoram Levy	SHL Telemedicine International Ltd.	Binyamina	870.2920	DXH
K113599	Alexandra Razzhivina	Materialise N.V.	Lueven	892.2050	LLZ
K113656	Nandini Murthy	Reflectance Medical, Inc.	MA	870.2700	MUD
K120115	Yarmela Pavlovic	Orthosize, LLC	PA	892.2050	LLZ
K120314	Lauren Bronich-Hall	WellDoc, Inc.	MD	880.5725	MRZ
K120473	Peggy McLaughlin	Gauss Surgical, Inc.	CA	880.2740	LWH
K120558	Andrea Tasker	Lifescan, Inc.	PA	862.1345	NBW
K120615	Edwad Brehm	Alere	CA	862.1345	CGA

K120672	Thomas Becze	Andon Health Co., Ltd.	NJ	870.1130	DXN
K121165	Alex Curry	Beam Technologies, LLC	KY	872.6855	EFW
K121197	Drew Palin	Preventice, Inc.	MN	870.1025	DSI
K121274	Peggy McLaughlin	Gauss Surgical, Inc.	CA	880.2740	LWH
K121405	Kevin Crossen	Welch Allyn, Inc.	NY	886.1120	HKI
K121470	Liu Yi	Andon Health Co., Ltd.	Tianjin	870.1130	DXN
K121590	Pamela M. Buckman	Capacity Sports, LLC	CA		LXV
K121609	Inger L. Couture	Reciprocal Labs Corp.	WI	868.5630	CAF
K121628	Karl M. Nobert	Epi Mobile Healht Solutions	DC	870.2920	DXH
K121697	Liu Yi	Andon Health Co., Ltd.	Tianjin	870.2700	DQA
K121738	Michael Bartlett	Vital Art and Science Inc.	TX	886.1605	HPT
K121871	Robert Andrew Miller	Airstrip Technologies, LP	TX	870.2300	MWI
K121916	Robert Taylor	Terarecon, Inc	CA	892.2020	LLZ
K121971	Leo Want	Zhongshan Transtek Electronics Co., Ltd.	Sichuan	870.2770	MNW
K122142	Shilpa Mydur	Glooko, Inc.	CA	862.1345	NBW
K122184	Karim Marrouche	Cardiac Designs, LLC	UT	870.2920	DXH
K122260	Matthias Broenner	Aycan Digital Systeme GMBH	Wuerzburg	892.2050	LLZ
K122356	Michael Righter	Alivecor, Inc.	CA	870.2340	DPS
K122458	Lolita Forbes	Cello Partnership	DC	870.2910	DRG
K122645	Nandini Murthy	Reflectance Medical, Inc.	MA	870.2700	MUD
K123082	Michael Pan	Nephosity, Inc.	CA	892.2050	LLZ
K123186	Kyle Peterson	Calgary Scientific, Inc.	Alberta	892.2050	LLZ
K123229	Steve Sidewell	Intouch Health, Inc.	CA	870.2910	DRG
K124000	Kent E. Dicks	MedApps, Inc.	AZ	870.2910	DRG
K130079	Nandini Murthy	Reflectance Medical, Inc.	MA	870.2700	MUD
K130409	Michael Righter	Alivecor, Inc.	CA	870.2340	DPS
K130624	Nicholas Campbell	Globalmed	AZ	892.2050	LLZ
K130676	Kevin Jones	Arrayent Health LLC	CT	870.2910	DRG
K131045	Raymond J. Kelly	Cardiac Designs, LLC	CT	870.1425	DQK
K131209	Ben Chiampa	Teratech, Corp.	MA	892.1550	IYN
K131287	E.J. Smith	Rijuven Corp.	MD	870.1875	DQD
K131338	Nicholas Campbell	Globalmed	AZ	880.6320	PEQ
K971650	Lisa S. Jones	Data Critical Corp.	TX	870.2920	DXH

JUL - 5 2001

K011436

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510(k) Summary of Safety and Effectiveness

May 8, 2001

Submitter

VitalCom Inc.
15222 Del Amo Avenue
Tustin, CA, 92780
USA

Telephone: (714) 546-0147
Fax: (714) 247- 4030

Contact: Ms. Florin Truuvert, Regulatory Affairs Manager

Device Name

Trade Name:	Mobile-PatientViewer™
Common Name:	Patient Data Viewer
Classification Name:	An accessory to an Echocardiograph Monitor Electrocardiograph – 21 CFR 870.2340, Product Code 73DPS.
Classification:	Mobile PatientViewer is an accessory to the Class II, Echocardiograph Monitor

Predicate Device

The predicate device is the VitalCom Remote Viewing Station, RVS (K962473).

Device Description

The Mobile-PatientViewer™, also referred to as MPV, is a wireless hand-held PC-based data viewer that allows physicians and caregivers to have instant remote access to their patients' data from anywhere within the hospital enterprise at any time. The MPV use a proprietary software application program operating on off-the-shelf computers operating under Windows CE or Windows for Pocket PC that supports an IEEE 802.11 wireless LAN.

Indications for Use

The Mobile-PatientViewer is intended to be used by physicians and caregivers to view physiological data and alarm status of those patients being monitored by the PatientNet Central Station, also known as VCOM. The MPV is intended for use from any location within a hospital enterprise.

The MPV is available for sale only upon the order of a physician or licensed health care professional.

Comparison to the Predicate Device

It is VitalCom's conclusion that the Mobile-PatientViewer is substantially equivalent to the Remote Viewing Station (RVS).

- Both MPV and RVS are viewing stations only. The user can not change patient settings. They are read-only monitors.
- Both provide the ability to continuously view a patient's current data (such as physiologic waveforms and other numerical vital sign values), event historical waveform data, and retrospective trended patient data.
- While the RVS is directly connected to the PatientNet Real-Time Network via a proprietary Ethernet LAN. The MPV is connected to the PatientNet Real-Time Network via a wireless LAN connection with the VitalCom Network Data Server (VNDS) which in turn is directly connected to the PatientNet Real Time Network.
- The RVS can be configured to display 8 or 16 patients at a time, whereas the MPV displays one patient at a time.
- Both MPV and RVS operate on off-the-shelf PC-based hardware.

Summary of Performance Testing

The Mobile-PatientViewer has been tested and found to comply with the design control requirement of the 21CFR 820.30 and the product specification listed in the labeling.

The risk analysis, identifying potential hazards and documenting mitigation of hazards has been developed, verified and validated as part of VitalCom's product development and design control procedure. VitalCom Quality System conforms to 21CFR820 and is certified by Intertek Testing Services (ITS) to ISO 9001 standard.

Conclusions
As stated above, VitalCom's conclusion is that the Mobile PatientViewer is safe, effective, complies with the appropriate medical device and information technology standards, and is substantially equivalent to the VitalCom Remote Viewing Station (RVS).

This 510(k) Summary of Safety and Effectiveness may be copied and submitted to interested parties as required by 21CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 5 2001

Ms. Florin Truuvert
Regulatory Affairs Manager
VitalCom Inc.
15222 Del Amo Ave.
Tustin, CA 92780

Re: K011436
Trade Name: Mobile-PatientViewer™
Regulation Number: 870.2340
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: May 8, 2001
Received: May 10, 2001

Dear Ms. Truuvert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you

might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

Applicant
VitalCom, Inc.
15222 Del Amo Avenue
Tustin, CA, 92780
USA

Telephone: (714) 546-0147
Fax: (714) 247- 4030
510(k) Number: K011436

Device Name: Mobile Patient Viewer™

Indication for Use:
The Mobile Patient Viewer, MPV is a Pocket PC-based wireless hand-held personal patient data viewer which allows physicians and caregivers to have instant remote access to their patients' data from anywhere within the hospital enterprise at any time. It is intended to be used by healthcare professionals and clinicians to view physiological ECG data and alarm status of those patient populations being monitored by the PatientNet Central Station.

The MPV is intended for use from any location within a hospital enterprise.

The MPV is available for sale only upon the order of a physician or licensed health care professional.

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Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21CFR801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011436

K013311

510(k) SUMMARY

Submitted by:

JAN 0 3 2002

Micromedical Industries Ltd

Date Prepared:

October 1, 2000

Proposed Device:

PocketView version of Cardioview™ 3000 software

Predicate Device:

Cardioview™ 3000 software

Device Description:

The proposed device is modification to the Cardioview™ 3000 software that allows the 12 Lead Simultaneous Cable to be linked to commercially available personal digital assistants (PDA) running the Windows CE operating system.

Statement of Intended Use:

PocketView ECG software is a version of Cardioview™ 3000 software, a Windows-based program intended to interpret electrocardiograms. PocketView ECG software receives, displays and stores a single or standard 12 Lead Simultaneous ECG recording using a proprietary digital data transmission protocol. The device contains proprietary software algorithms to receive, store, analyze, and interpret the ECG signal. PocketView ECG Software allows the ECG information to be displayed on a commercially available personal digital assistant (PDA) running the Windows CE operating software.

Summary of Technological Characteristics or New Device to Predicate Devices

The technological features of PocketView ECG do not differ significantly from Cardioview™ 3000 software. The predicate device and the modified device are identical with the exception that the modified device has the connectivity feature allowing the ECG information to be displayed on a commercially available personal digital assistant (PDA) running Windows CE operating system.

Discussion of Nonclinical Tests; Conclusions Drawn from Nonclinical Tests

Nonclinical testing was performed to evaluate the modification to the predicate device. Testing verified that the modified device displayed acceptable performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 3 2002

Mr. Stephen Cresswell
MicroMedical Industries, Ltd.
11 Technology Drive
Labrador, Queensland
AUSTRALIA

Re: K013311
Trade Name: PocketView ECG Software
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor
Regulatory Class: Class III (three)
Product Code: MHX
Dated: November 12, 2001
Received: December 4, 2001

Dear Mr. Cresswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

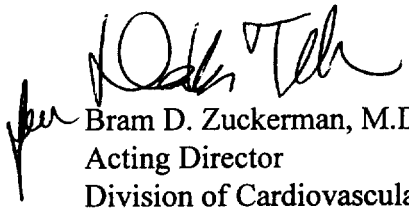
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number: K013311

Device Name: PocketView ECG Software

Indication for Use:

PocketView ECG software is a version of Cardioview™ 3000 software, a Windows-based program intended to interpret electrocardiograms, for use on a personal digital assistant (PDA). PocketView ECG software receives, displays and stores a single or standard 12 Lead Simultaneous ECG recording which is transmitted either locally or transtelephonically using a proprietary digital data transmission protocol. The device contains proprietary software algorithms to receive, store, analyze, and interpret the ECG signal.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____X____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013311

K020866

JUN 11 2002

510(k) Summary

Category	Comments
Sponsor:	TheraSense, Inc. 1360 South Loop Road Alameda, CA 94502
Correspondent:	Donna K. Templeman Manager, Regulatory Affairs 1360 South Loop Road Alameda, CA 94502
Contact Numbers:	Phone: (510) 239-2670 Fax: (510) 239-2799
Device Common Name	Blood Glucose Meter and Data Management Software
Device Proprietary Name	FreeStyle Tracker™ Diabetes Management System
Device Classification Name	Glucose Test System Blood Lancet
Device Classification	Glucose Test System per 21 CFR 862.1345, Class II Device
Predicate Device	TheraSense, Inc., FreeStyle Blood Glucose Monitoring System TheraSense, Inc., FreeStyle Connect Data Management System
Predicate Device Manufacturer(s)	TheraSense, Inc.
Predicate Device Reference(s)	K992684; K000582; K012014; K994433
Predicate Device Proprietary Name(s)	TheraSense, Inc., FreeStyle Blood Glucose Monitoring System TheraSense, Inc., FreeStyle Connect Data Management System
Predicate Device Classification Name(s)	Glucose Test System Data Management Software
Predicate Device Classification(s)	Glucose Test System per 21 CFR 862.1345, Class II Device Data Management Software, no classification exists as of the date of subject device filing.

Date Summary Was Prepared: March 15, 2002.

Description of the Device:

The FreeStyle Tracker Diabetes Management System combines and joins the technologies and capabilities of both the FreeStyle Blood Glucose Monitoring System (blood glucose measurement testing system) and the FreeStyle Connect Data Management System (data management accessory software). Through the use of a Personal Digital Assistant (PDA), the user is able to conveniently log glucose measurements directly to a log history on the PDA. The Tracker System eliminates the necessity for manual data logs and separate tools for calculating values, storing results and producing and maintaining critical medical records. The blood glucose meter and data management system components of the Tracker System can also be used independently as separate features.

The items that comprise the FreeStyle Tracker Diabetes Management System are as follows:

- FreeStyle Tracker Measurement Module
- Personal Digital Assistant (PDA)
- "Hot-sync" Cradle
- FreeStyle Tracker Data Management Software

Additionally, in order to perform a blood glucose test the Tracker System requires the following items. These items are the same as those needed for the current FreeStyle System:

- FreeStyle Test Strips
- FreeStyle Lancing Device
- FreeStyle Lancets
- FreeStyle Control Solution

To perform a blood glucose measurement, the user removes the cover of the Visor PDA expansion slot and inserts the Tracker Measurement Module into the Visor PDA Handspring slot. The user then inserts a test strip into the Measurement Module. The user acquires a blood sample (with the test strip in the meter) by touching the edge of

the test strip to the blood target area, filling the chamber on the strip by capillary action. The Tracker System sounds a tone (beeps) to let the user know that the sample chamber is full and the reaction has begun. The test is complete and the meter displays the glucose reading on the PDA display.

The Tracker Data Management Systems also gives the user the ability to conveniently access and maintain diabetes data through the Visor PDA and/or PC. The user can easily and conveniently track major factors that affects their diabetes health, for example:

- Blood glucose levels
- Insulin usage (via injection or pump)
- Food intake
- Exercise
- Oral medication usage
- State of health

The Tracker DMS will also allow the user to enter personal factors used to maintain their proper glucose level. The following items assist the user to track and modify their lifestyle as it affects their diabetes health:

- Target glucose range
- Usual insulin type
- Typical insulin dose
- Insulin adjustment guidelines (determined by his/her healthcare professional)
- Meal schedule and guidelines (determined by his/her healthcare professional)
- Typical exercise type, duration and intensity

Intended Use:

The TheraSense, Inc. FreeStyle Tracker Diabetes Management System is intended for use in the quantitative measurement of glucose in whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and it is not intended for use on neonates or arterial blood.

Additionally, the TheraSense, Inc. FreeStyle Tracker Diabetes Management System is intended for use in home and clinical setting to aid people with diabetes and healthcare professionals in the review, analysis, and evaluation of historical blood glucose test results to support an effective diabetes management program.

The TheraSense, Inc. FreeStyle Tracker Diabetes Management System is specifically indicated for use on the finger, forearm, upper arm, thigh, calf, and hand.

Technological Characteristics:

The fundamental scientific technology of the FreeStyle System has not been modified to result in the Tracker Diabetes Management System. The Tracker Measurement Module contains the same technology as the FreeStyle Meter in that the Tracker Measurement Module measures the electrical output from the glucose in whole blood reacting with the FreeStyle Test Strip chemistry. The measurement is then converted into glucose concentrations and displayed to the user.

Summary of

Testing:

System and component testing was performed with the Tracker Diabetes Management System to ensure the new device is equivalent to the currently marketed devices (FreeStyle Blood Glucose Monitoring System and FreeStyle Connect Data Management Software). These tests consisted of system, hardware, software, mechanical, packaging, electrical safety (EMC, EMI, and ESD) and clinical (user's study and labeling comprehension) evaluations. The changes to the FreeStyle System have been verified and validated demonstrating that the resultant changes have not affected safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Donna K. Templeman
Manager, Regulatory Affairs
TheraSense, Inc.
1360 South Loop Road
Alameda, CA 94502

JUN 11 2002

Re: k020866
Device Name: FreeStyle Tracker™ Diabetes Management System
Regulation Number: 21 CFR§862.1345
Regulation Name: Glucose Test System
Regulatory Class: II
Product Code: NBW
Dated: June 3, 2002
Received: June 4, 2002

Dear Ms. Templeman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use Statement

510(k) Number (if known): K020866

Device Name: **FreeStyle Tracker Diabetes Management System**

Indication for Use:

The TheraSense, Inc. FreeStyle Tracker Diabetes Management System is intended for use in the quantitative measurement of glucose in whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and it is not intended for use on neonates.

Additionally, the TheraSense, Inc. FreeStyle Tracker Diabetes Management System is intended for use in home and clinical setting to aid people with diabetes and healthcare professionals in the review, analysis, and evaluation of historical blood glucose test results to support an effective diabetes management program.

The TheraSense, Inc. FreeStyle Tracker Diabetes Management System is specifically indicated for use on the finger, forearm, upper arm, thigh, calf, and hand.

(Division Sign-Off)
Division of Clinical Laboratory ...
510(k) Number K020866

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ **OR** **Over-The-Counter Use** ✓

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

CARD GUARD® Scientific Survival LTD.

TM2005 Personal Medical Phone™ Center
Special 510(k) Premarket Notification *510(k) Summary of Safety and Effectiveness*

Submitter: Card Guard Scientific Survival Ltd.,
2 Pekeris St. P.O.B. 527
Rehovot 76100, Israel
Tel: 972-8-9484600
Fax: 972-8-9484605

JAN 1 5 2003

Contact Person: Alex Gonorovsky,
Regulatory Affairs Officer
Tel: 972-8-9484624
E-mail: alexanderg@cardguard.com

Date Prepared: December 02, 2002

1. Definition and Intended Use

The TM2005 Personal Medical Phone™ software system is designed to manage data from remote patients and physicians. The system users are patients, physicians and administrators. Each user has a unique access to database according to his permissions in the system.

The system enables the user to connect to the Internet Server, view and update data according to the user permissions, download data via PDA or PC. This includes ECG, and other patient related data, (such as demographics, doctors, medical history and status, diagnoses, etc.).

An external means (CGTTM) is provided for displaying, measuring, and printing the downloaded ECG.

The system includes a DB Management application and a means to receive data via Internet. It also provides auxiliary tools to enable the administrator to add users, set user permissions, link between users (patients/doctors and a Backup utility).

2. Device Class

The TM2005 Receiving Center system is classified as Class II medical device (21 C.F.R. Par. 870.2920 (1992)).

3. Applicable Standards

No performance standards have been developed under Section 514 of the Federal Food, Drug and Cosmetic Act for telephone ECG and Spirometric transmitter devices.

TM2005 meets the requirements of the following standards and guidances:

- EN1441: 1997 Medical Devices – Risk Analysis
- IEC 1025: 1990 Fault tree analysis (FTA)
- IEC/TR 513: 1994 Fundamental aspects of safety standards for medical electrical equipment
- IEC 601-1, 1996, Medical Electrical Equipment, General Requirements for Safety
- IEC 601-1-1, 1996, Safety Requirements for Medical Electrical Systems
- IEC 601-1-4, 1996, Part 1-4, Programmable Electrical Medical Systems
- IEC 812: 1985 Analysis techniques for system reliability – Procedure for failure mode and effects analysis (FMEA)

- IEC 300-3-9: 1995 Dependability management, Part 3: Application guide, Section 9, Risk analysis of technological systems
- Reviewer Guidance for Computer Controlled Medical Devices, FDA Aug 29, 1991
- ISO/IEC Guide 51: 1990 Guidelines for the inclusion of safety aspects in standards
- ISO 9002 guidelines
- EN-46002
- IEEE Standard for Software Quality Assurance Plan
- FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 29, 1998
- FDA's New 510(k) Paradigm, Alternate Approaches to Demonstrating Substantial equivalence in Premarket Notifications - Final Guidance, CDRH, March 20, 1998.

4. Features

- Runs on Windows 2000 Server; XP Server operating system
- Manual entry of patient and physician detail
- Data processing capabilities
- ECG event recording
- Receiving, storing medical data

5. User Interface

The TM2005 GUI enables access to all categories of data through 3 built-in interfaces:

- Administrator interface
- Physician interface
- Patient interface

6. Substantial Equivalence

The basis of this special 510(k) premarket notification is Card Guard's belief that TM2005 is substantially equivalent to the predicate system: the TM2000 Receiving Center K992164: it has the same intended use and main principles of operation.

The main difference between the systems is that in the TM2000 is essentially a DB server while TM2000 is a web server that supports JSP files. The differences between the systems have no effect on safety, and are intended to improve the system effectiveness.

7. Design Controls and Quality System Regulations

The Card Guard manufacturing facility is in conformance the with design control procedure requirements specified in 21 CFR 20.61, the records are available for review.

The Card Guard's product design procedure, and quality assurance and control policy, formalize the design and production process and assure that all respective requirements are met.

The Pre-Production design control for the original development and subsequent modifications is properly established according to the Quality System Regulation (21 CFR 820.30 Subpart C Design Controls of the Quality System Regulation).

8. Level of Concern and Hazard Analysis

The device Level of Concern criteria were evaluated and the system was determined to be *a moderate level of concern system.*

The rigorous design evaluation and the System Safety and Risk analysis expose potential failures or possible system flaws which could directly or indirectly effect the patient.

9. Conclusions

The system constitutes a safe and reliable means for receiving, storing, displaying, updating, and re-transmitting of patient ECG and other patient related data. Its operation present no adverse health effect or safety risks to patients when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2003

Card Guard Scientific Survival Ltd.
c/o Mr. Alex Gonorovsky
Regulatory Affairs Officer
2 Pekeris Street
Rehovot 76100
Israel

Re: K024365
Trade Name: TM2005 Personal Medical Phone™ Center
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: Class II (two)
Product Code: DXH
Dated: December 1, 2002
Received: December 31, 2002

Dear Mr. Gonorovsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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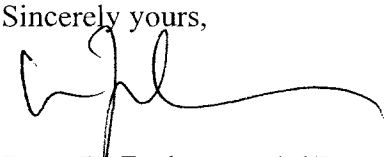
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K024365

CARD GUARD® Scientific Survival LTD.™

Indications For Use
TM2005 Personal Medical Phone™ Center

510(k) Number (if known):

The Personal Medical Phone™ Center is intended for supporting transtelephonic monitoring of Electrocardiography (ECG) parameters of cardiac patients.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovas...

510(k) Number K024365

AUG 3 1 2004

510(k) Summary

Date Prepared [21 CFR 807.92(a)(1)]

July 9, 2004

Submitter's Information [21 CFR 807.92(a)(1)]

Joseph M. Azary
C/o NorthEast Monitoring Inc.
543 Long Hill Avenue
Shelton, CT. 06484

Azary Technologies has received authorization to submit this 510(k) on behalf of the sponsor NorthEast Monitoring Inc. NorthEast Monitoring Inc. located at Two Clock Tower Place, Suite 360, Maynard, MA 01754, is an FDA-registered medical device under establishment# 1224919.

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Device trade names are: NorthEast Monitoring SD360 Digital Recorder, SD360 Digital Holter Recorder

Common Name: Ambulatory ECG Recorder, Ambulatory Electrocardiograph (without analysis)

Classification: Class II, 21 CFR 870.2800, MWJ

Predicate Device [21 CFR 807.92(a)(3)]

- NorthEast Monitoring DR180 II Holter Recorder – K001288

The subject device has the **same** indications for use as the predicate. Both the subject device and predicate device can be used for 3 channel recording. The main differences between the subject device and predicate device are as follows:

- The subject device is smaller and thinner.
- The subject device weighs less.
- The subject device requires only one AA battery (as opposed to two AA batteries required by the predicate).
- The subject device does not have 12 lead capabilities (this was not a heavily used option in the predicate device).
- The LCD screen in the subject device is smaller. The LCD screen of predicate device showed wave-forms, whereas the LCD screen of the subject device shows lead quality as a numeric value.
- The subject device uses SD cards instead of flash cards for memory. The SD cards are smaller, but have the same memory capabilities as the flash cards.

Description of the Device [21 CFR 807.92(a)(4)]

An ambulatory monitor, sometimes called a Holter, is a painless method to monitor the heart beat for a period of time (such as 24 hours, 48 hours, or 72 hours). The Holter is a small recording device that records the heart beat while being worn by the patient.

The physician or technician places electrodes and wires on the patient. The wires are connected to the Holter or digital recorder. Typically the patient is asked to write down a diary of daily activity including the time and character of any symptoms.

The patient can push a patient event button to mark an event. The patient must write down details about the event in their diary so that physician or technician can relate the event to specific symptoms or activities. [redacted]

The NorthEast Monitoring SD360 Digital Recorder is a holter monitor designed to facilitate the ambulatory cardiac monitoring, on the order of a physician, of those patients who may benefit from such monitoring including but not limited to those with complaints of palpitations, syncope, chest pains, shortness of breath, or those who need to be monitored to judge their current cardiac function, such as patients who have recently received pacemakers.

The SD360 Digital Recorder package includes:

- SD360 Digital Recorder
- Operation Manual
- SD Card
- Patient Cable
- Pouch

The data obtained by monitoring is not analyzed at the time of recording. After the recording is complete, the data must later be downloaded to a compatible NorthEast Monitoring holter analysis system to be analyzed. The Holter Analysis Software was cleared by FDA under K930564.

The SD360 is not intended to replace real time telemetry monitoring for patients suspected of having life-threatening arrhythmias.

The SD360 digital recorder is powered by one 1.5 volt AA alkaline battery (MN1500 or the equivalent), one AA rechargeable NiMH (nickel metal hydride) battery, or one AA Eveready Lithium L91 battery. Batteries should not be re-used for a second patient. The batteries are not included; users are instructed to purchase 2 AA batteries.

The device is compatible with standard silver / silver chloride ECG electrodes. Electrodes are not provided with the subject device. The user is instructed to purchase standard silver / silver chloride ECG electrodes.

The SD360 digital recorder uses NorthEast Monitoring SD360 patient cables with either seven leads or five leads for a 3-channel holter recording. The patient cable connects to the recorder via a 9-pin female connector on the recorder. A patient cable is provided with the SD360 Digital Recorder.

The SD360 has a small LCD that is used to display either time of day (during the recording), error messages (during the hookup procedure or during recording), or lead quality (during the hookup procedure).

The data collected by the SD360 digital recorder is stored on a removable SD Card. To store 24 hours in normal mode, the minimum capacity of the SD Card should be 28 megabytes; 56 megabytes are required for 24 hours in high resolution mode. To store 24 hours in 360 samples/sec mode, 112 megabytes are required. To stored 24 hours in 720 samples/sec, 224 megabytes are required. Double all storage requirements for 48 hour recordings, and triple them for 72 hour recordings. The SD360 is provided with an SD memory card with at least 32 megabytes.

The SD360 is packaged in a plastic bag in a cardboard shipping carton. The shipping carton will also include a patient cable and a pouch. The pouch is used by the patient to hold the digital recorder while in use.

The physician or technician can optionally use a PC as an interface to key in patient information. If a PC were used, the patient information would be keyed into the SD card using the NorthEast Monitoring Holter Analysis software (cleared under a separate 510k).

Another option for entering patient information is through the use of a PDA (i.e. Palm Pilot). Patient information such as patient name, sex, date of birth, identification number, scan number, hookup tech name or initials, physician name, indications, and medications.

Physical and Electrical Specifications:

Characteristic	Specification
Dimensions	8.7cm (length) x 6.5cm (width) x 2cm (depth)
Weight	70.9 grams (2.5 oz) without battery 99.3 grams (3.5 oz) with battery
Recording Bandwidth	0.05 to 70 hertz in 180 samples/sec mode; 0.05 to 150 hertz in 360 or 720 samples/sec mode.
Prefilter Sampling Rate	720 samples/sec
Data Stored	In 180 samples/sec mode, data stored at 180 samples/sec (4 sample average), in 360 samples/sec mode, data stored at 360 samples/sec (2 sample average), in 720 samples/sec mode, data stored at 720 samples/sec.
Pacemaker Sensitivity	2 millivolts
Pacemaker Pulse Duration	100 to 2500 microseconds

Intended Use [21 CFR 807.92(a)(5)]

5. Detection of Arrhythmias: The NorthEast Monitoring, Inc. SD360 Digital Recorder is indicated for use in continuous monitoring of cardiac rhythm when intermittent arrhythmia are suspected due to patient symptoms such as palpitations, transient ischemic attacks (TIAs), syncope (fainting), or other such symptoms as determined by the physician.
6. Efficacy of Treatment: The NorthEast Monitoring Inc. SD360 Digital Recorder is indicated for use to determine whether current pharmacological treatment(s) of known arrhythmia is effective by measuring the frequency and duration of the arrhythmia compared to the frequency and duration prior to treatment.
7. Pacemaker Evaluation: The NorthEast Monitoring Inc. SD360 Digital Recorder is indicated for use to evaluate the function of implanted pacemakers to insure that the pacemaker is functioning within prescribed limits.
8. The NorthEast Monitoring SD360 Digital Recorder is to be used by or on the order of a physician.

Technological Characteristics [21 CFR 807.92(a)(6)]

NorthEast Monitoring, Inc. believes that the subject device is substantially equivalent to the predicate device. The subject device has the **same** indications for use as the predicate.

The main technological difference is the device is smaller, thinner, weighs less, uses only one battery, does not have 12 lead capabilities, uses SD cards instead of flash cards for memory, and can be used with a Palm Pilot to enter patient information.

Performance Data [21 CFR 807.92(b)(1)]

The subject device has been subjected to and passed electrical safety and EMC testing requirements.

Conclusion [21 CFR 807.92(b)(3)]

We believe the changes are minor and conclude that the subject device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2004

Azary Technologies, LLC
c/o Mr. Joseph M. Azary
President
543 Long Hill Avenue
Shelton, CT 06484

Re: K041901
Trade Name: Northeast Monitoring SD360 Digital Recorder
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: II (two)
Product Code: MWJ
Dated: July 14, 2004
Received: July 14, 2004

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D. for BDZ
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041901

Device Name: NorthEast Monitoring Inc. SD360 Digital Recorder

Indications For Use:

1. Detection of Arrhythmias: The NorthEast Monitoring, Inc. SD360 Digital Recorder is indicated for use in continuous monitoring of cardiac rhythm when intermittent arrhythmia are suspected due to patient symptoms such as palpitations, transient ischemic attacks (TIAs), syncope (fainting), or other such symptoms as determined by the physician.
2. Efficacy of Treatment: The NorthEast Monitoring Inc. SD360 Digital Recorder is indicated for use to determine whether current pharmacological treatment(s) of known arrhythmia is effective by measuring the frequency and duration of the arrhythmia compared to the frequency and duration prior to treatment.
3. Pacemaker Evaluation: The NorthEast Monitoring Inc. SD360 Digital Recorder is indicated for use to evaluate the function of implanted pacemakers to insure that the pacemaker is functioning within prescribed limits.
4. The NorthEast Monitoring SD360 Digital Recorder is to be used by or on the order of a physician.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for BPZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041901

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 1 2005

Wm. Cameron Powell, M.D.
President
MP4 Solutions, LP
11 Lynn Batts Lane, Suite 100
SAN ANTONIO TX 78218

Re: K042082
Trade/Device Name: AirStrip OB®
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: 85 HGM
Dated: November 26, 2004
Received: November 30, 2004

Dear Dr. Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

AirStrip OB® is intended to be used by Obstetricians for the following purposes:

- To more rapidly and thoroughly respond to a nurse call regarding fetal heart tracings or maternal contraction patterns by viewing the real time waveforms remotely using a mobile device such as a PDA or Smart Phone
- To proactively review a fetal heart or maternal contraction tracing of a patient in Labor and Delivery for whom they are responsible but are unable to be present in the hospital at that time.
- To review the current Labor and Delivery patient census list.
- Provide a request for remote consultation regarding a fetal heart tracing.
- To remotely review other standard or critical real-time numeric data from Labor and Delivery.

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042082

Prescription Use ✓
(Per 21 CFR 801.109)

Premarket Notification 510(k) K042121
Summary of Safety and Effectiveness (p. 1 of 3)

AUG 2 6 2004

SIGMA International

711 Park Avenue • Medina, New York 14103-0756 • 585-798-3901 • Fax: 585-798-3909

SIGMA International General Medical Apparatus, LLC.
Spectrum with or without Master Drug Library

510(k) Summary

Submitter Information

Company Name & Address:
SIGMA International General Medical Apparatus, LLC.
711 Park Avenue
Medina, NY 14103-0756

Contact Name:
Charles Martina
Test Engineer
SIGMA International
(585) 798-3901
(585) 798-3909 Fax

Date Summary Prepared: April 12, 2003

Device Information

Generic Name:
Infusion Pump

Trade or Proprietary Name:
Spectrum with or without Drug Library Work Station

Classification Designation:
Class II, 80FRN Infusion Pump

Device Description Information

The Spectrum with Master Drug Library (device) is an infusion pump having a basic description as identified in Title 21 CFR, Part 880, Section 5725. The Spectrum infusion pump consists of electronic circuitry and mechanical mechanisms that are integrated into a lightweight plastic enclosure. The electrical and mechanical operations are software controlled using discrete microcontroller and processor technology. The motor control / feedback pumping mechanism are of the linear peristaltic design using inlet and exit valves for occlusion control. Infusion therapy fluids and selected intravenous (IV) sets are supplied by the device user. The Spectrum infusion pump is specifically manufactured and calibrated for the application of standard gravity infusion sets of a manufacturer's brand, as indicated by the Spectrum's labeling. The IV set is loaded into

the Spectrum infusion pump. After acceptance of program parameters, the pump is started and fluid is propelled by the rhythmic action of the pumping mechanism against the outside surface of the IV tubing. The pump is controlled to create smooth fluid dynamics, precision volumetric accuracy, and uniformity of flow rate profile. The Spectrum infusion pump is small in comparison to the traditional "Large Volume" infusions pumps currently on the market. However, it is designed to be used in a healthcare facility in an IV pole mounted configuration or carried by the user in an ambulatory manner.

The Master Drug Library (MDL) capability is a software package that allows the generation and management of a patented downloadable drug library into to a target infusion pump. The library may be loaded directly into the infusion pump or uploaded into another computer, Personal Assistants (PDA's), or other transfer apparatus (I.e. "smart" C-pen) for wired or wireless communication to the infusion pump. The MDL software reduces the risk of medication errors by providing programmed delivery profiles and limits for a corresponding drug that is intend for a specific use classification. The MDL software will operate on a popular software systems platform (I.e. Windows) and have the capability (using external peripherals) of printing text / barcode labels that may be used to label and identify drug therapy bags and or patient identification labels. Through the application of the C-pen equipment, scanned patient and IV prescription information can be downloaded into the Spectrum infusion pump. The Spectrum infusion pump has the capability of communicating with a hospital information management system. The Spectrum infusion pump uses coded passwords and redundancy checks to mitigate the acceptance of improper information.

Predicate Device Information

The Spectrum with Master Drug Library is considered to be substantially equivalent (as defined by U.S. FDA regulatory information) to other infusion pumps with software managing systems. The safety and effectiveness related to the predicate devices is comparable to the Spectrum with Master Drug Library. Examples of devices within the same regulatory classification as the Spectrum with Master Drug Library are identified as follows:

Premarket Notification, 510(k) Number	**Device Name**	**Applicant**
K030459	Medley™ System with Medication Management System	ALARIS Medical Systems, Inc.
K011975	Horizon Outlook™ with DoseCom™	B. Braun Medical Inc.

The Spectrum infusion pump may also be used without the Master Drug Library. Predicate devices within the same regulatory classification as the Spectrum are identified as follows:

510(k) Summary (continuation)

Premarket Notification, 510(k) Number	Device Name	Applicant
K950766	SIGMA Model 8000 and 8002 Infusion Pumps	SIGMA International General Medical Apparatus, LLC.
K002211	Colleague® CX Volumetric Infusion Pump	Baxter Healthcare Corporation

Intended Use information for Subject Device

The Spectrum infusion pump is intended to be used for the controlled administration of intravenous fluids. These fluids may include blood, blood products or mixtures of pharmaceutical drugs for required patient therapy. The spectrum is used in conjunction with legally marked intravenous administration sets and medications provided by the user. The Master Drug Library is a software package that will add additional features to the Spectrum infusion pump. The Master Drug Library will permit electronic communications with the Spectrum pump and other external peripheral devices. The intended use of the Spectrum pump includes common drug error prevention, through the stand alone settings features of the pump. This includes drug parameter limits and associated drug name identification. With the Master Drug Library, the intended use is to reduce user errors associated with drug selection, drug dose rates, drug dose concentrations, and patient identification associated with the prescribed drug.

Technological Characteristic Information

The technological characteristics of the Spectrum infusion pump are similar in many respects to the predicate devices. The Spectrum and predicated devices share mechanical and electrical assembly design complexity similarities. Their respective designs contain "state-of-the-art" printed circuit board layout system, proven reliable corrosion resistant pumping mechanisms and microcomputer software control intelligence. The functional characteristics including the user interface, alarm sensing systems, and display technology are of similar technological form. The Master Drug Library features and communication interaction with the Spectrum or other peripherals is also technologically similar in nature to the predicate devices. The technological characteristics of the Spectrum and Spectrum with Master Drug Library are substantially equivalent to the predicate device for intended use. Technological differences between the Spectrum and Spectrum with Master Drug Library do not raise new issues of safety and effectiveness.

Non-Clinical Performance Data Information

The determination of substantial equivalency is also based on non-clinical performance data. The testing conducted on the Spectrum infusion pump was in accordance with recognized performance standards for infusion pumps. In addition, non-clinical testing based on the validation of design requirements has been conducted and is provided as support data for this 510(k) submission. The performance data indicate that the Spectrum and Spectrum with Master Drug Library meets specification requirements and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 6 2004

SIGMA International General Medical Apparatus, LLC
C/O Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
70 Codman Hill Road
Boxborough, Massachusetts 01779

Re: K042121
Trade/Device Name: Spectrum and Spectrum with Master Drug Library
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: August 18, 2004
Received: August 19, 2004

Dear Mr. Reuber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K042121

Device Name: Spectrum, Spectrum with Master Drug Library

Indications for Use

The Spectrum and Spectrum with Master Drug Library is intended to be used for the controlled administration of intravenous fluids. These fluids may include pharmaceutical drugs, blood, blood products and mixtures of required patient therapy. The intended routes of administration consist of the following clinically acceptable routes: intravenous, arterial, subcutaneous, intrathecal, epidural or irrigation of fluid space. The spectrum is intended to be used in conjunction with legally marketed intravenous administration sets and medications provided by the user.

The Spectrum and Spectrum with Master Drug Library is suitable for many user facility applications such as but not limited to hospitals, outpatient care areas, homecare and ambulatory care services.

The Spectrum and Spectrum with Master Drug Library is intended to reduce operator interaction through automated programming thereby helping to reduce errors associated with complex device programming. Parameter programming requires trained healthcare professional confirmation of limits and drug therapy to physician's directive.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K042121

SEP 15 2005

K051857

510(k) SUMMARY

1. 510(k) Owner Name and Address:
   PHASEIN AB
   Svärdvägen 15
   182 33 Danderyd
   Sweden
   Telephone: 46-8-544-98-150
   Fax: 46-8-544-98-169

2. Contact Person:
   David Weissburg
   Weissburg Associates
   Madison, Wisconsin
   Telephone: 1-608-770-0223

3. Date: 6 September 2005
4. Trade Name: VEO Multigas Monitor for Pocket PC
5. Common Name: Multigas Monitor

6. Classification Names:
   a. Carbon dioxide gas analyzer (21 CFR 868.1400, Product Code CCK)
   b. Oxygen gas analyzer (21 CFR 868.1720, Product Code CCL)

7. Substantially equivalent to:
   a. Tidal Wave Model 610, Novametrix Medical Systems Inc. (K963327)
   b. MX300 Portable Oxygen Monitor, Teledyne Analytical Instruments (K024155)
   c. S/5 Multigas Monitor, Datex-Ohmeda-GE (K051092)
   d. Handi, Ceramatec, Inc (K973282)

8. Device description: The VEO Multigas Monitor for Pocket PC combines a miniature mainstream infrared gas analysis bench with an ultra-fast response oxygen fuel cell. The complete multigas analyzer is contained within a transducer that is attached to the breathing circuit via an airway adapter.

9. Intended Use: The VEO Multigas Monitor for Pocket PC is intended to provide monitoring of carbon dioxide and oxygen during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room, and emergency medicine settings for adult and pediatric patients.

10. Comparison to predicates: The VEO Multigas Monitor for Pocket PC combines the gas monitoring capabilities of two predicate devices into one device. The VEO Multigas Monitor for Pocket PC uses the same basic technology concepts used in the predicate devices, while adding improvements derived from advanced electronics and miniaturization. The intended uses of the VEO Multigas Monitor for Pocket PC and its predicates are the same. All the devices consume equivalent amounts of electric power and utilize disposable single-patient-use airway adapters to interface with gases in the breathing circuit. Labeling and materials used are equivalent, except that the VEO Multigas Monitor for Pocket PC displays numeric and graphic information on an off-the-shelf Pocket PC. PHASEIN-approved Pocket PCs have been tested and validated as reliable components of the VEO Multigas Monitor device.

11. Testing vs. predicates: Non-clinical testing in direct comparison to predicates throughout the operating range was conducted using calibrated gas samples and legally marketed anesthesia and ventilation devices.

12. Conclusions from testing: The VEO Multigas Monitor for Pocket PC demonstrated performance, safety and effectiveness equivalent or superior to its predicates in all characteristics. The VEO Multigas Monitor for Pocket PC demonstrated superior performance in response time, accuracy, precision, and reliability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 2005

Phasein AB
C/O Mr. David Weissburg
Weissburg Associates
4213 Winnequah Drive
Madison, Wisconsin 53716

Re: K051857
Trade/Device Name: VEO Multigas Monitor For Pocket PC, Model 400221
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon dioxide gas analyzer
Regulatory Class: II
Product Code: CCK, CCL
Dated: June 30, 2005
Received: July 8, 2005

Dear Mr. Weissburg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: _____

Device Name: VEO Multigas Monitor for Pocket PC
Indications for Use:

The VEO Multigas Monitor for Pocket PC is intended to provide monitoring of carbon dioxide and oxygen during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit, patient room and emergency medicine settings for adult and pediatric patients.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051857

K052975

JAN 20 2006

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5 Web Viewer, Datex-Ohmeda S/5 Pocket Viewer and Datex-Ohmeda S/5 Cellular Viewer with L-WEB04 software

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

October 20, 2005

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5 Web Viewer, Datex-Ohmeda S/5 Pocket Viewer and Datex-Ohmeda S/5 Cellular Viewer with L-WEB04 software

COMMON NAME:

Remote monitoring device

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

Product Code	Classification Name	CFR Section
MSX	System, network and communication, physiological monitors	870.2300

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The revised Datex-Ohmeda S/5 Web Viewer version and S/5 Pocket Viewer version and the new S/5 Cellular Viewer are substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda S/5 Web Viewer and Datex-Ohmeda S/5 Pocket Viewer versions (K033078) currently in distribution.

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Datex-Ohmeda S/5 Web Viewer is a supplementary monitoring application running on a generic PC that is connected to the hospital LAN, either directly or via the Internet. It is based on the World Wide Web and Java technologies, and it is intended to be used for remote viewing of real-time patient information and trends from patient monitors that are connected to the Datex-Ohmeda S/5 Network and Central. The Pocket Viewer is a Web Viewer version running on a Pocket PC PDA that is connected to the hospital LAN via wireless access within the hospital, or via a mobile connection outside the hospital. The PDA uses a standard WLAN (802.11b) or mobile connections (GSM, GPRS, HSCSD, CDMA) to gain access to the Hospital LAN and Web Server. The Cellular Viewer is a Web Viewer version running on a generic cellular phone that is connected to the hospital LAN via a mobile connection. The mobile phone uses standard mobile connections (GSM, GPRS, HSCSD) to gain access to the Hospital LAN and Web Server.
The Web Viewer, Pocket Viewer and Cellular Viewer are not primary alarm sources but decision-making support tools that offer clinicians access to the patient data also outside the patient care area. The network architecture of the S/5 Web/Pocket/Cellular Viewer system consists of the following components:

- Datex-Ohmeda S/5 Network that connects D-O monitors to one or more D O S/5 Centrals
- The Hospital LAN to which the office PCs in the hospital are connected to
- The S/5 Web Server that is connected to both of these networks
- S/5 Web Viewer client programs running in desktop and laptop PCs, S/5 Pocket Viewer client programs running in PDAs and S/5 Cellular Viewers running in generic cellular phones
- Optional VPN (virtual private network) or dial-up solutions enabling remote connection to patient monitoring data with the S/5 Web Viewer, Pocket Viewer and Cellular Viewer

The hospital is responsible for ensuring a secure and functional interface between the Datex-Ohmeda S/5 Network and the Hospital LAN, by utilizing, for example, a gateway, router, switch or firewall, as shown in the figure above. If the Web Viewer clients are not connected to a hospital Intranet, a regular hub can be used instead. Wireless LAN access points are required to connect the Pocket Viewer to the WLAN. For Cellular phones the proper subscriptions with the telephone operators are needed.

INTENDED USE as required by 807.92(a)(5)

Indication for use for S/5 Web Viewer: The Datex-Ohmeda S/5 Web Viewer displays information received from other networked devices. It is comprised of a S/5 Web Server and S/5 Web Viewer clients. The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network and S/5 Web Viewer clients. The S/5 Web Viewer client runs on a generic computer that is connected to the hospital local area network. The Datex-Ohmeda S/5 Web Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5 Web Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Datex-Ohmeda S/5 Web Viewer is not a primary alarm source. The device is for use by qualified medical personnel only.

Indication for use for S/5 Pocket Viewer: The Datex-Ohmeda S/5 Pocket Viewer displays information received from other networked devices. It is comprised of a S/5 Web Server and S/5 Pocket Viewer clients. The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network and S/5 Pocket Viewer clients. The S/5 Pocket Viewer client runs on a generic handheld computer that is connected to the hospital local area network. The Datex-Ohmeda S/5 Pocket Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5 Pocket Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Datex-Ohmeda S/5 Pocket Viewer is not a primary alarm source. The device is for use by qualified medical personnel only.

Indication for use for S/5 Cellular Viewer: The Datex-Ohmeda S/5 Cellular Viewer displays information received from other networked devices. It is comprised of a S/5 Web Server and S/5 Cellular Viewer clients. The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network and S/5 Cellular Viewer clients. The Datex-Ohmeda S/5 Cellular Viewer client runs on a generic cellular phone that is connected to the hospital local area network. The Datex-Ohmeda S/5 Cellular Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5 Cellular Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Datex-Ohmeda S/5 CellularViewer is not a primary alarm source. The device is for use by qualified personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The revised Datex-Ohmeda S/5 Web Viewer version and S/5 Pocket Viewer version and the new S/5 Cellular Viewer are substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda S/5 Web Viewer and Datex-Ohmeda S/5 Pocket Viewer versions (K033078) currently in distribution.

Similarities:

The indications for use for the S/5 Web Viewer is identical to the predicate.

The indications for use for the S/5 Pocket Viewer is identical to the predicate.

The indications for use for the S/5 Cellular Viewer is the same as in predicate S/5 Pocket Viewer except that the term 'generic handheld computer' has been replaced by a term 'generic mobile phone'.

The structure and functionality of the revised Datex-Ohmeda S/5 Web Viewer and S/5 Pocket Viewer and the new S/5 Cellular Viewer corresponds to the structure and functionality of the Datex-Ohmeda S/5 Web Viewer and S/5 Pocket Viewer (predicate). The basic architecture of the revised Datex-Ohmeda S/5 Web Viewer and S/5 Pocket Viewer and the new Cellular Viewer is the same as that of Datex-Ohmeda S/5 Web Viewer and Datex-Ohmeda S/5 Pocket Viewer (predicate).

The revised Datex-Ohmeda S/5 Web Viewer and S/5 Pocket Viewer and the new S/5 Cellular Viewer can show real-time curves, numeric information, graphical and numerical trends and visual alarms from bedside monitors just like the predicate.
The physical network components used by the revised S/5 Web Viewer and S/5 Pocket Viewer and the new S/5 Cellular Viewer are the same as in the predicate.

Differences:
The following functionality has been added to the revised Datex-Ohmeda S/5 Web Viewer, S/5 Pocket Viewer and the new S/5 Cellular Viewer:
User interface changes:

- A new viewer type Cellular Viewer is available
- Up to 30 concurrent Cellular Viewer users
- Entropy parameter numeric values and trends are provided
- User specific configurations are possible through User Configuration Pages
- User can change her/his own password
- No more support for S/5 Light Monitor trends

In addition to the functional changes, the following technical improvements have been implemented in the revised S/5 Web Viewer and S/5 Pocket Viewer:

- The new version supports standard mobile phone technology
- Support for HTTPS tunneling with advanced communication security is available
- PC hardware: A new version of the PC for the Web Server computer has been specified because manufacturing of the earlier one was discontinued

Summary:
The changes above do not effect safety and effectiveness of the system, and the new Datex-Ohmeda S/5 Web Viewer, S/5 Pocket Viewer and S/5 Cellular Viewer, described in this submission, are substantially equivalent to the predicate device.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

Datex-Ohmeda S/5 Web Viewer, Datex-Ohmeda S/5 Pocket Viewer and Datex-Ohmeda S/5 Cellular Viewer with L-WEB04 software has been assessed against the standards below. The device has been thoroughly tested through validation and verification of specifications.

- EN60950: 2000 (IEC60950 3rd edition) – Product Safety
- EN 55022: 1998 (IEC-CISPR 22) – Radio Frequency Interface
- EN 55024: 1998 (IEC-CISPR 24) – Electromagnetic Immunity
- EN 61000-3-2:1995 + A1/A2/A14, Harmonic Currents
- EN 61000-3-3:1995, Voltage Fluctuation and Flicker
- EMC Directive 89/336/EEC (including amendments)
- Low Voltage Directive 73/23/EEC (amended by 93/68/EEC)
- ISO 14971:2000, Medical devices - Risk analysis
- IEC 60601-1-4Medical electrical equipment. Part 1: General requirements for safety4. Collateral Standard: Safety requirements for programmable medical systems.
- CAN/CSA-C22.2 No. 60950-00: Safety on Information Technology Equipment.
- UL: IEC 60950 (1999) Third Edition.

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the revised Datex-Ohmeda S/5 Web Viewer version and S/5 Pocket Viewer version and the new S/5 Cellular Viewer and they are substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda S/5 Web Viewer and Datex-Ohmeda S/5 Pocket Viewer versions (K033078).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 2006

GE Healthcare
c/o Mr. Joel C. Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Road
Needham, MA 02492

Re: K052975
Trade Name: Datex-Ohmeda S/5 Web Viewer, Pocket Viewer and Cellular Viewer with L-WEB04 software
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Monitors Network and Communication System
Regulatory Class: Class II (two)
Product Code: MSX
Dated: December 19, 2005
Received: December 21, 2005

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052975

Device Name: Datex-Ohmeda S/5 Web Viewer, Datex-Ohmeda S/5 Pocket Viewer and Datex-Ohmeda S/5 Cellular Viewer with L-WEB04 software.

Indications for use:

Indication for use for S/5 Web Viewer: The Datex-Ohmeda S/5 Web Viewer displays information received from other networked devices. It is comprised of a S/5 Web Server and S/5 Web Viewer clients. The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network and S/5 Web Viewer clients. The S/5 Web Viewer client runs on a generic computer that is connected to the hospital local area network. The Datex-Ohmeda S/5 Web Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5 Web Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Datex-Ohmeda S/5 Web Viewer is not a primary alarm source. The device is for use by qualified medical personnel only.

Indication for use for S/5 Pocket Viewer: The Datex-Ohmeda S/5 Pocket Viewer displays information received from other networked devices. It is comprised of a S/5 Web Server and S/5 Pocket Viewer clients. The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network and S/5 Pocket Viewer clients. The S/5 Pocket Viewer client runs on a generic handheld computer that is connected to the hospital local area network. The Datex-Ohmeda S/5 Pocket Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5 Pocket Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Datex-Ohmeda S/5 Pocket Viewer is not a primary alarm source. The device is for use by qualified medical personnel only.

Indication for use for S/5 Cellular Viewer: The Datex-Ohmeda S/5 Cellular Viewer displays information received from other networked devices. It is comprised of a S/5 Web Server and S/5 Cellular Viewer clients. The Datex-Ohmeda S/5 Web Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network and S/5 Cellular Viewer clients. The Datex-Ohmeda S/5 Cellular Viewer client runs on a generic cellular phone that is connected to the hospital local area network. The Datex-Ohmeda S/5 Cellular Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Datex-Ohmeda S/5 Cellular Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Datex-Ohmeda S/5 CellularViewer is not a primary alarm source. The device is for use by qualified personnel only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K052975

K060298

12

MAR 2 9 2006

510(k) SUMMARY

Vocel
PILL PHONE Medication Reminder Software Device
510(k) Premarket Notification

Submitter

Vocel
13400 Sabre Springs Parkway
Suite 255
San Diego, CA 92128

Contact Person: Mr. Chris Nelson
Date Prepared: January 27, 2006

Name and Classification of Device

Trade or Proprietary Name:	PILL PHONE
Common Name:	medication reminder system
Classification Name:	daily assist device
Product Code :	unknown

Predicate Devices

The PILL PHONE is substantially equivalent to the ONCELLRX, the MEDPARTNER, and various medication reminder systems marketed by E-Pill, LLC.

Description of the PILL PHONE

The PILL PHONE software device will be sold to users of cell phones (or other communication devices) through their cell phone service. The software will have a feature to send out reminders to a cell phone owner of the dosing schedule that has been programmed into the phone, whether the dosing schedule is for the user, a child, or an elderly parent. The software will also enable the delivery of information about medications, such as indications for use, dosing, side effects, and even photographs of different pills. The PILL PHONE software is a Minor Level of Concern.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2006

Vocel
C/O Mr. Keith A. Barritt
Fish & Richardson, Professional Corporation
1425 K Street, N.W.
Suite 1100
Washington, DC 20005

Re: K060298
Trade/Device Name: Pill Phone
Regulation Number: 890.5050
Regulation Name: Daily activity assist device
Regulatory Class: I
Product Code: NXQ
Dated: February 3, 2006
Received: February 7, 2006

Dear Mr. Barritt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

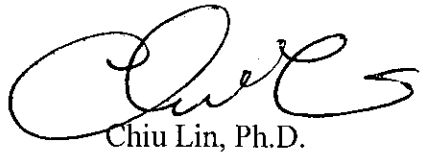
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Dental, Anesthesiology, General
Hospital, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K060298

Device Name: PILL PHONE

Indications For Use:

The PILL PHONE is a medication reminder and information system utilizing software that operates on a user's cell phone or other wireless device. The PILL PHONE will also have the ability to receive multiple question surveys from the PILL PHONE server.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

...ology, General Hospital,
...ical Dental Devices

K060298

AUG 2 2 2006

CARD GUARD Scientific Survival LTD.

CG-6108 Arrhythmia ECG Event Recorder 510(k) Summary of Safety and Effectiveness

K060911 pg 1/2

1. General

Submitter	**Card Guard Scientific Survival Ltd.,**	
Address	2 Pekeris St. P.O.B. 527 Rehovot 76100, Israel	
Contact:	**Alex Gonorovsky, RA Manager**	
Phone:	972-8-9484019	Fax: 972-8-9484044
E-mail:	galex@cardguard.com	
Device		
Trade Name:	CG-6108 Arrhythmia ECG Event Recorder	
Classification:	Transmitters and receivers, electrocardiograph, telephone	
Product Code:	DXH	
Regulation No:	21 CFR 870.2920	
Class:	II	

2. Definition and Intended Use

The CG-6108 system is an Arrhythmia ECG Event Recorder designed for self-testing by patients at home and for analysis by medical professionals at a remote Monitoring Center. It comprises a chest-worn ECG sensor and a handheld device with a proprietary application, configured to process and transmit the ECG recordings.

The chest-worn unit includes 3 electrodes on a harness and it houses a battery, an ASIC and a Bluetooth transceiver for the acquisition, recording, and transmission of the ECG signal.

The ECG signals are transmitted via Bluetooth to the handheld device. When an event is detected it is wirelessly transmitted to the CG Monitoring Center for professional analysis. The handheld device is equipped with shared memory used to record the signal received from the sensor and to allow pre- and post processing options through the use of this memory in a dual memory loop configuration, both running in parallel. One loop is auto-triggered, with programmable thresholds, that starts recording based on specific rhythms and arrhythmias detected or manually activated by the patient. The second, and longer, recording loop is controlled remotely to provide the physician with more information, when requested by the CG Monitoring Center.

The handheld device automatically transmits the recorded ECG, via cellular link, to the Monitoring Center. When cellular service is unavailable the patient can transmit via landline telephone.

3. PMP^4 Medical Application

The PMP^4 Medical Application is designed for wireless mobile platforms, e.g. PDA, SmartPhone and for static platforms, i.e., PC. It is used to receive from the CG-6108 (and other Card Guard's devices), the test results and other medical data, to process and save these test results, and synchronize data and test results with the PMP^4 Medical Center. The Application is a part of a personal medical system solution. The PMP^4 Medical Application performs the following activities:

1. Receives medical test inputs from the external accessories
2. Collects medical test data and other related information as defined for each test
3. Accesses historical test and related data stored on the device
4. Transmits medical test data and additional information to Center for professional evaluation/backup
5. Receives data from Center
6. Enables configuring GPRS data connection (based on mobile phone GPRS/CDMA capabilities), changing user name and password.

K060911 pg 2/2

4. Referenced Standards

No performance standards have been developed under Section 514 of the Federal Food, Drug and Cosmetic Art for wireless ECG event recording devices. The CG-6108 meets the requirements of the following standards:

(1) MDD 93/42/EEC Medical Device Directive Council Directive 93/42/EEC; June 14, 1993
(2) EN 475: Medical devices - Electrically-generated alarm signals ; April 1995
(3) EN 980: Graphical symbols for use in the labeling of medical devices; August 2003
(4) EN 1041: Terminology, Symbols and Information provided with Medical Devices; Information supplied by the manufacturer with medical devices; April 1998
(5) EN ISO 9001: Quality management systems - Requirements; December 2000
(6) EN ISO 13485: Quality systems – Medical devices; August 2000
(7) EN ISO 14971: Medical devices – application of risk management to medical devices; March 2001
(8) EN ISO 10993 Biological evaluation of medical devices Part 1: Evaluation and testing; Dec. 1997
(9) EN 60601-1: Medical electrical equipment; Part 1: General requirements for safety; Sept. 2002
(10) EN 60601-1-2: Medical electrical equipment; Part 1: 2. Collateral Std: EMC; requirements and tests; 2001
(11) EN 60601-1-4: Medical electrical equipment; Part 1: 4. Collateral Std: Programmable electric medical systems; Apr. 01

5. Indications for use

The CG-6108 Arrhythmia ECG Event Recorder is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia.

6. Principles of operation

The CG-6108 Arrhythmia ECG Event Recorder comprises a chest-worn ECG sensor with three electrodes and a handheld device with a proprietary PMP^4 Medical Application, used to process and transmit the ECG recordings. The battery powered chest-worn unit has an ASIC and a transceiver for the acquisition, recording, and transmission of the ECG signal. The ECG signals are transmitted via Bluetooth to the handheld device equipped with the PMP^4 Medical Application, which incorporates an algorithm specially developed for detection of arrhythmia artifacts, e.g. AF. A detected artifact triggers transmission of the signal to the CG Monitoring Center for analysis.

7. Substantial Equivalence

The clearance for the CG-6108 is sought on the grounds of its claimed substantial equivalence (SE) to the following predicate devices:

1. Card Guard's CG-6106 K963811 for its memory loop monitoring principle of operation and the identity of the intended use.
2. Card Guard's CG-6550 K003220 Personal 3-lead ECG Transmitter - for its arrhythmia artifacts detection algorithm (e.g. AF)
3. Card Guard's PMP^4 SelfCheck ECG K042254 - for the BT transmission capability and for interfacing and including the PMP^4 Medical Application - the CG proprietary SW for storing, measuring, displaying and transmitting data gathered from medical sensors.

8. Conclusions

The CG-6108 Arrhythmia ECG Event Recorder constitutes a safe and reliable means for designed for self-testing by patients who experience transient symptoms that may suggest cardiac arrhythmia. Its material composition and operation present no adverse health effect or safety risks when used as intended.

The device is as safe, as effective and performs as well as or better than its cleared predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 2007

Card Guard Scientific Survival Ltd.
c/o Mr. Alex Gonorovsky
Manager, Regulatory Affairs
2 Pekeris St. P.O. Box 527
Rehovot 76101
ISRAEL

Re: K060911
Trade Name: CG-6108 Arrhythmia ECG Event Recorder
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: Class II (two)
Product Code: DXH
Dated: August 4, 2006
Received: August 4, 2006

Dear Mr. Gonorovsky:

This letter corrects our substantially equivalent letter of August 22, 2006 and the subsequent correction letter of March 27, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can

be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zimmerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060911

Device Name: **CG-6108 Arrhythmia ECG Event Recorder**

Indications for Use:

Intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia

Prescription Use ☒ _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B. Symmons

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060911

(Posted November 13, 2003)

K061994

AUG 11 2006

Premarket Notification 510(k) Summary
As required by section 807.92

Web Viewer, Pocket Viewer and Cellular Viewer with L-WEB05 software

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

July 11, 2006

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Web Viewer, Pocket Viewer and Cellular Viewer with L-WEB05 software

COMMON NAME:

Remote monitoring device

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

Product Code	Classification Name	CFR Section
MSX	System, network and communication, physiological monitors	870.2300

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 2006

GE Healthcare
c/o Joel Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Road
Needham, MA 02492

Re: K061994
Trade/Device Name: Cellular Viewer, Pocket Viewer, and Cellular Viewer
Regulation Number: 21 CFR 870.2300
Regulation Name: Network and Communicaiton Physiological System
Regulatory Class: Class II
Product Code: MSX
Dated: July 11, 2006
Received: July 14, 2006

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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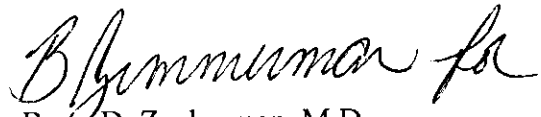
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: **Web Viewer, Pocket Viewer and Cellular Viewer with L-WEB05 software.**

Indications for use:

Indication for use for Web Viewer: The Web Viewer displays information received from other networked devices. It is comprised of a Mobile Care Server and Web Viewer clients. The Mobile Care Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network or Unity Network and Web Viewer clients. The Web Viewer client runs on a generic computer that is connected to the hospital local area network (LAN). The Web Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Web Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Web Viewer is not a primary alarm source. The device is for use by qualified medical personnel only.

Indication for use for Pocket Viewer: The Pocket Viewer displays information received from other networked devices. It is comprised of a Mobile Care Server and Pocket Viewer clients. The Mobile Care Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network or Unity Network and Pocket Viewer clients. The Pocket Viewer client runs on a generic handheld computer (PDA) that is connected to the hospital local area network (LAN). The Pocket Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Pocket Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Pocket Viewer is not a primary alarm source. The device is for use by qualified medical personnel only.

Indication for use for Cellular Viewer: The Cellular Viewer displays information received from other networked devices. It is comprised of a Mobile Care Server and Cellular Viewer clients. The Mobile Care Server maintains and coordinates the network connections between the devices in the Datex-Ohmeda Network or Unity Network and Cellular Viewer clients. The Cellular Viewer client runs on a generic cellular phone that is connected to the hospital local area network (LAN). The Cellular Viewer can be used for viewing or otherwise processing of information from several bedside monitors or other networked devices. The Cellular Viewer can be used for patients in the hospital and it is meant for consultation and remote monitoring use. The Cellular Viewer is not a primary alarm source. The device is for use by qualified personnel only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061994

PREMARKET NOTIFICATION 510(k) SUMMARY
As required by §807.92

Device Name – as required by 807.92(a)(2):

510(k) Number:	**K062377**
Trade Name:	**MedApps™ Remote Patient Monitoring System**
Common/Classification Name:	**Transmitters and Receivers, Physiological Signal, Radiofrequency**
Classification Regulation:	**870.2910**
Device Class:	**Class II**
Product Code (Procode):	**DRG**
Premarket Notification submitter:	
Company Name:	**MedApps, Inc.**
Company Address:	7975 North Hayden Road, Suite B-200, Scottsdale, AZ 85258
Contact:	**Kent E. Dicks, President and CEO**
Preparation Date:	August 14, 2006
Revision Date:	April 3, 2007

A. LEGALLY MARKETED PREDICATE DEVICE – as required by 807.92(a)(3)

Legally marketed predicate device are:

K061328	Think Positive (t+) Diabetes Management System
K050929	The Hermes System

The submitted device is intended to be an accessory device to the LifeScan OneTouch® Ultra® Blood Glucose Monitoring System (K024194/K043197).

B. DEVICE DESCRIPTION – as required by 807.92(a)(4)

The MedApps Wellness System ("System") is designed to be used by patients to send their data from the LifeScan OneTouch Ultra glucometer to a central server for subsequent storage and display.

The System is comprised of a "Hub" (cell phone software) and the MedApps Engine, which runs on a central server.

The Hub is a software program that runs on a cell phone and takes in data from the OneTouch Ultra and then transmits it to the central server for storage and processing.

The MedApps Engine is a software program that runs on a common Web / Internet secure server platform. The MedApps Engine picks up the stored data sent to it by the Hub and through a set of business rules set by the healthcare providers, determines if a follow-up Interactive Voice Response (IVR) call is required to be made to the patient to collect additional Behavioral information from the patient.

Once all the data is collected, then it is stored in a repository for access by the healthcare provider.

The Hub will utilize the OneTouch Ultra integrated Short-range low power wireless transmission (Bluetooth V1.2) or a FDA approved accessory to the medical devices that to transmits the medical device data via Bluetooth to a compatible cellular telephone, such as the Nokia 6620, or other /compatible cellular phones.

C. INTENDED USE – as required by 807.92(a)(5)

The MedApps Wellness System is intended for use in non-clinical settings to collect and transmit historical data to healthcare professionals to help support effective management of patients.

The System is not intended to provide automated treatment decisions, nor is it to be used as a substitute for a professional healthcare judgment. All patient medical diagnosis and treatment are performed under the supervision and oversight of an appropriate healthcare professional.

D. INDICATIONS FOR USE

The MedApps Wellness System model D-PAL acts as an accessory to FDA cleared devices, which collects and transmits stored patient data via wireless connections from medical devices to a cellular phone (Hub) and forwards to a central server for review of historical data about a patient over time to benefit the Healthcare Practitioner.

The following medical devices and measuring systems are fully validated for this intended use at this time:

- LifeScan OneTouch ® Ultra® Blood Glucose Monitoring System (K024194 / K043197)
- Polytel PWR-08-03 Remote Module (K070559 pending clearance)

The MedApps Wellness System is not intended to provide automated treatment decisions or to be used as a substitute for professional healthcare judgment. All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

The MedApps Wellness System is not intended for emergency calls, and may not be used for transmission or indication of any real-time alarms or time-critical data.

Clinical judgment and experience are required to check and interpret the measurements collected and transmitted.

This device is not for use in systems which substitute for medical care.

This device is not intended for patients requiring direct medical supervision or emergency intervention.

E. LEVEL OF CONCERN – as requested by recent FDA guidance

The FDA guidance document "***Guidance For The Content of Premarket Submissions For Software Contained In Medical Devices***," May 11, 2005, clearly identifies that all manufacturers of software devices are responsible for determining a **Level of Concern** for their device(s).

MedApps, Inc. believes that this device, because of its functional characteristics and intended uses, has a **MODERATE LEVEL OF CONCERN**. See Exhibit 4, Level of Concern.

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY – as required by 807.92(a)(6)

Feature	**Think Positive K061328**	**The Hermes K050929**	**MedApps (Submission Device)**
Indications of Use	Enables healthcare providers to monitor and manage chronic conditions of patients remotely	Same	Same
Intended Use	Telemedicine System	Same	Same
Intended Users	Home users and Healthcare providers	Same	Same
Site of Use	Home, Clinic	Same	Same
Data Collection Software	Think Positive Proprietary Software	The Hermes Proprietary Software	MedApps Proprietary Software
Data Collection Software Functionality	Transmit data from Sensor devices to Central Database	Same	Same
Communication method of hub with Central Server	Via Cellular Phone	Same	Same

Feature	Think Positive K061328	The Hermes K050929	MedApps (Submission Device)
Types of sensors which can be interfaced (wired or wirelessly) to receiver hub	Glucose Levels	Same	Same
Implementation method of collecting data from sensors	Short range radio system using Bluetooth and Cellular technology	Same	Same
Sensor Software	Sensor Software unchanged	Same	Same
Connectivity	Short range radio system using Bluetooth and Cellular technology	Same	Same
Communication method of hub with devices	Short range radio system using Bluetooth and Cellular technology	Same	Same
Communications Protocol	Bluetooth V1.2	Same	Same
Communication Frequency	2.402 to 2.480 GHz	Same	Same
Power Source	Wall power plug for hub (120 VAC/50-60) and batteries in devices	Same	Same
Display	On devices and hub, and monitors connected to central server	Same	Same
Communication with Patients	On screen display	Same	On screen display of Readings and Interactive Voice Response (IVR)

G. NON-CLINICAL PERFORMANCE DATA TESTING AND REVIEW – as required by 807.92(b)(1)

Non-Clinical Testing
The submitted device has undergone significant verification and validation testing. Alpha validation testing included testing of all executable code and functionality and confirmation that all identified hazards have been adequately addressed by software functionality, the user interface, documentation or user SOP.

Alpha validation activities included exhaustive validation scripts of all Software Design Specifications (SDS), which was summarized and discussed to provide a preliminary record of performance data. Additionally, the submitter duplicated the operational environment of a sophisticated user and provided the complete record of those executed scripts as operational performance data. The output of these two performance data records documents that **MedApps Wellness System** met its required requirements and design specifications as intended.

H. SUBSTANTIAL EQUIVALENCE SUMMARY

The submitted device, **MedApps Wellness System**, has the same indications for use as the predicate devices, *Think Positive (t+) Diabetes Management System and The Hermes System.*

I. CONCLUSIONS

The performance and usability testing and validation studies document that **MedApps Wellness System** is substantially equivalent to the predicate *Think Positive (t+) Diabetes Management System and The Hermes System.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MedApps, Inc.
c/o Mr. Kent E. Dicks
President/CEO
7975 North Hayden Road, Suite B-200
Scottsdale, AZ 85258

JUL - 3 2007

Re: k062377
Trade/Device Name: MedApps™ Remote Patient Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: June 26, 2007
Received: June 27, 2007

Dear Mr. Dicks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k062377

Device Name: MedApps™ Remote Patient Monitoring System

Indication For Use:

The MedApps Remote Patient Monitoring System model d-PAL acts as an accessory to FDA cleared devices, which collects and transmits stored patient data via wireless connections from medical devices to a cellular phone (Hub) and forwards to a central server for review of historical data about a patient over time to benefit the Healthcare Practitioner.

The following medical devices and measuring systems are fully validated for this intended use at this time:

- LifeScan OneTouch ® Ultra® Blood Glucose Monitoring System (k024194/k043197)
- Polytel PWR-08-03 Remote Module (k070559)

The MedApps Remote Patient Monitoring System is not intended to provide automated treatment decisions or to be used as a substitute for professional healthcare judgment. All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

The MedApps Remote Patient Monitoring System is not intended for emergency calls, and may not be used for transmission or indication of any real-time alarms or time-critical data. Clinical judgment and experience are required to check and interpret the measurements collected and transmitted. This device is not for use in systems which substitute for medical care. This device is not intended for patients requiring direct medical supervision or emergency intervention.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _X_ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K062377

K06 3392

DEC 1 2 2006

The Image Management Company

510(k) Summary

In accordance with the provisions of the Safe Medical Device Act of 1990, IMCO Technologies is providing a summary of safety and effectiveness information regarding the IMCO-STAT™ software

1.1 Company Identification

IMCO Technologies
N27W23957 Paul Road
Pewaukee WI 53072
Contact: Mark Schwartz, President and CEO
Telephone: 262-523-4445
Fax: 262-523-1141
Email: mschwartz@imco-tech.com

1.2 Official Correspondent

Mark Schwartz, President and CEO
IMCO Technologies
N27W23927 Paul Rd
Pewaukee WI 53072
Telephone: 262-523-4445
Fax: 262-523-1141
Email: mschwartz@imco-tech.com

1.3 Date of Submission

November 7, 2006

1.4 Device Name

Classification Name:	System, Image Processing, Radiological
Common/Usual Name:	Soft-copy reading system
Proprietary Name:	IMCO-STAT™

1.5 Substantial Equivalence

The IMCO-STAT™ system has the same intended uses and technical characteristics as the Medical Insight EasyViz system (K051809) and Marotech, Inc . Marosis PACS System (K012844).

www.imco-tech.com

IMCO Technologies
N27 W23957 Paul Road, Pewaukee, WI 53072
PH: 800/300-7734 262/523-4445 FX: 262/523-1141

Product Name	IMCO Stat	Medical Insight EasyViz	Marosis PACS
Graphical UI	Yes	Yes	Yes
Windows O.S. - Client	Yes	Yes	Yes
Uses Standard Monitor	Yes	Yes	Yes
Scales Image to Display	Yes	Yes	Yes
Image Input	DICOM 3.0	DICOM 3.0	DICOM 3.0
Images stored on remote Window server	Yes	Yes	Yes
Network Protocol	TCP-IP	TCP-IP	TCP-IP
Compression	JPEG 2K	Proprietary	JPEG 2K
Wireless Capability	Yes	Yes	No
Support Tablet PC, PDA, etc	Yes	Yes	No
Annotation	Yes	Yes	Yes
Image Measurement	Yes	Yes	Yes
Cine tool	Yes	Yes	Yes
Comparison Mode	Yes	Yes	Yes
Review Report from RIS	No	Yes	Yes
Designed for Use Inside and Outside Radiology	Yes	Yes	Yes
Flip / Rotate of Images	Yes	Yes	Yes
User Log In	Yes	Yes	Yes
Multiple Layout Options	Yes	Yes	Yes
WWL control & Pre-sets	Yes	Yes	Yes
Patient & Study Browser	Yes	Yes	Yes
Print to Paper Capability	No	Yes	Yes

1.6 Device Description and Intended Use

IMCO-STAT™ is a software device that receives digital images and data from existing imaging equipment using DICOM 3.0 communication protocols. Images and data are stored on the IMCO-STAT™ server in DICOM 3.0 Part 10 and JPEG format.

IMCO-STAT™ is designed to send reports, images, audio and video data to other workstations, Personal Digital Assistants (PDA) or Tablet PCs in wired or wireless environments. This is accomplished using an executable client application on a receiving entity with the appropriate hardware.

The images may be embedded for reference in a DICOM image comprised report data, for distribution across a network and storage in a Picture Archive Communication System (PACS) with the original exam series data. Wavelet files can also be created and stored utilizing the same process. The algorithms used to create JPEG and wavelet images follow known and accepted protocols.

IMCO-STAT™ uses standard off-the-shelf hardware and commercially available computer platforms and operating systems. The software communicates using the standard TCP/IP stack. The network used to support the TCP/IP stack is superfluous to IMCO-STAT™

1.7 General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and indications for use. The optional hardware components specified are off-the-shelf computer components

Validation and Effectiveness:

Testing of the software and related hardware has been performed by programmers, non-programmers, quality control individuals and potential customers.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Substantial Equivalence

As stated previously, IMCO-STAT™ is substantially equivalent to EasyViz software package and Marosis PACS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Mark L. Schwartz
President / CEO
IMCO Technologies
N27W23957 Paul Road #101
PEWAUKEE WI 53072

DEC 1 2 2006

Re: K063392
Trade/Device Name: IMCO-STAT™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 7, 2006
Received: November 9, 2006

Dear Mr. Schwartz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

IMCO™ TECHNOLOGIES

The Image Management Company

INDICATIONS FOR USE

510(k) Number (if known): K063392

Device Name: IMCO-STAT™

Sponsor Name: IMCO Technologies

Indications for Use:

IMCO-STAT™ is a software device that receives digital images and data from existing imaging equipment using DICOM 3.0 communication protocols. Images and data are stored on the IMCO-STAT™ server in DICOM 3.0 Part 10 and JPEG format.

IMCO-STAT™ is designed to send reports, images, audio and video data to other workstations, Personal Digital Assistants (PDA) or Tablet PCs in wired or wireless environments. This is accomplished using an executable client application on a receiving entity with the appropriate hardware.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Prescription Use ☒ (21 CFR 801 Subpart D) And/Or Over-The-Counter Use ☐ (21 CFR 807 Subpart C)

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation

David Krug

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063392

IMCO Technologies
N27 W23957 Paul Road, Pewaukee, WI 53072
PH: 800/300-7734 262/523-4445 FX: 262/523-1141
www.imco-tech.com

K070426

510(k) Summary of Safety and Effectiveness

JUN 29 2007

Submitter:	ARANZ Medical Limited
Address:	Ground Floor, St Elmo Courts 47 Hereford Street, PO Box 3894 Christchurch 8013
Phone:	+64 3 3746120 ext 217
Fax:	+64 3 3746130
Contact:	Shane Goodwin
Trade name:	Silhouette
Common name:	Wound measurement and documentation system
Classification name:	Surgical camera and accessories (21 CFR 878.4160)
Class:	Class I (general controls)
Predicate Devices:	Verge Videometer (Verg Incorportated) Visitrak (Smith & Nephew)
Device Description:	Silhouette consists of a camera connected to a PDA, for the measurement and tracking of wounds
Indications for Use:	Silhouette is indicated for wound measurement and documentation and can be used on all external wound types.
Intended Use:	The intended use of the Silhouette system is to measure and document the progression of external wounds over time. The Silhouette system is comprised of a camera (SilhouetteCamera) connected to a PDA running a software application (SilhouetteMobile Software) to capture and document images taken by the user. A software accessory (SilhouetteServer) on a PC may be used to transfer images and documentation to a third-party patient information database. The system is non-contact with respect to the patient.
Comparison to Predicates:	Silhouette is substantially equivalent the predicate devices, considered in light of the comparison of the indications for use, the intended use, the workflow of the devices and the technological principles being applied. Standard wound measurements made with Silhouette are more accurate than those made with the predicate devices. These differences do not raise questions safety and effectiveness over the predicate devices.
Date of Summary:	17 January 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 9 2007

Aranz Medical Limited
% Shane Goodwin
Regulatory Scientist
St. Elmo Courts
Ground Floor
47 Hereford Street
P.O. Box 3894
Christchurch, New Zealand

Re: K070426
Trade/Device Name: Silhouette Wound Measurement and Documentation System
Regulation Number: 21 CFR 878.4160
Regulation Name: Surgical camera and accessories
Regulatory Class: I
Product Code: FXN
Dated: June 18, 2007
Received: June 20, 2007

Dear Shane Goodwin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

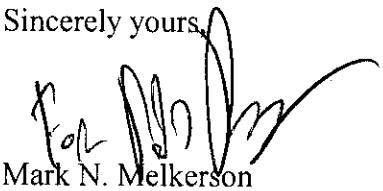
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070426

Device Name: Silhouette Wound Measurement and Documentation System

Indications For Use:

Silhouette is indicated for wound measurement and documentation and can be used on all external wound types.

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070426

K070599

JUL 13 2007

510K Summary

APPLICANT:	Tinnitus Otosound Products, LLC
ADDRESS:	880 First Street, Suite 403 Los Angeles, CA 90012
CONTACTS:	Geraldine Crean, Ph.D. Regulatory Liaison, Tinnitus Otosound Products, LLC gerldinecrean@yahoo.com 310-927-6151 310-273-8217 Anthony Materna, Ph.D. CEO, Tinnitus Otosound Products, LLC tmaterna@top_llc.net 213-626-0927
DATE OF SUBMISSION:	February 28, 2007
TRADE OR PROPRIETARY NAME:	Customized Sound Therapy
COMMON OR UNUSUAL NAME(S):	CST
CLASSIFICATION NAME:	Tinnitus Masker Device (TMD) Described in 21 CFR 874.3400 Class II, product code KLW

PREDICATE DEVICE(S)

Manufacturer:	Petroff Audio Technologies, Inc.
Tradename:	Dynamic Tinnitus Mitigation System, DTM-6
510K Number:	K974501

Manufacturer:	Neuromonics (formerly TiniTech)
Tradename:	TinniTech ANMP System
510K Number:	K030791

SUBSTANTIAL EQUIVALENCE

Customized Sound Therapy is claiming substantial equivalence to two devices.

1. Equivalence to the Dynamic Tinnitus Mitigation System, DTM-6, manufactured by Petroff Audio Technologies Inc. 510K number K974501.

2. Equivalence is also claimed to the TinniTech ANMP System, manufactured by Neuromonics (formerly TiniTech). 510K number K030791

DEVICE DESCRIPTION

The Tinnitus Otosound Products LLC (TOP-LLC), Customized Sound Therapy (CST), falls under devices described in 21 CFR 874.3400 Class II, product code KLW. The device is a CD comprised of software with two components: a graphic user interface and cmusic program. The software can be used on a notebook or desktop computer with at least Windows XP (SP2) having at least a 1.2 GHz Pentium III CPU (or equivalent), 256 MB of RAM, 1 GB of free disk space, a CD drive, and an available USB port.

The Customized Sound Therapy software produces, and transfers sounds to a sound wave file. This sound file can be stored on any commercially available computer hard drive or portable audio device (PAD) like an iPod.

DESCRIPTION OF DEVICE DESIGN

The CST software consists of specialized programs for creating the CST sounds, which are matched as closely as possible to the tinnitus sensation experienced by the patient. The CST software is based on the cmusic acoustic compiler and a proprietary graphic user interface developed specifically for use during sound matching with CST [1; Chapter 3, pp. 150-214; Appendix D, pp. 490-546]. Under control of a qualified audiologist or other qualified professional, the CST software writes the matching sound on the hard drive of the computer. A copy of this sound is transferred to a commercially available portable audio device for use by the patient during therapy. The volume control on the PAD is used to match that apparent level of the CST sound to the patient's tinnitus sensation as subjectively judged by the patient.

The system is intended to provide relief from the disturbance of tinnitus in an attempt to provide temporary relief of the effect of tinnitus

INTENDED USE

The TOP-LLC CST is intended for use by a qualified healthcare professional such as an otolaryngologist, an audiologist, or other qualified professional. It is intended to mask or intermittently mask the patient's tinnitus as part of a tinnitus management program.

Patients receive a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) to rule out medically or surgically treatable diseases for which tinnitus is a symptom before proceeding with CST. Initial hearing and tinnitus tests are conducted by a qualified audiologist familiar with the treatment of tinnitus; subsequent management of the treatment is carried out by an audiologist or other qualified professional.

INDICATIONS FOR USE

The CST system is a CD with software that enables qualified professional to identify, with the patient's verbal input, the sounds that most closely match the patient's tinnitus. The device is indicated to mask and intermittently mask tinnitus as part of a tinnitus management program. The target population for the device is adults (18 years and over) who present with tinnitus, that may or may not be accompanied with hearing loss at the higher frequencies, and who are participating in a tinnitus management program.

RISKS AND WARNINGS FOR SAFE USE

The software packaging and the CD are clearly marked with two warnings; 1) the sounds on the discs should not be played at uncomfortable levels, and 2) the CST system should not be used if such use prevents the user from hearing sounds warning of danger (like the beeping of oncoming vehicles).

The following caution statement is also on the software packaging and the CD:

Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of this device.

DEVICE CHARACTERISTICS

The CST device consists of computer software, which identifies, produces and transfers custom sounds, CST, from a desktop or laptop to a PAD. The CST software is based on the cmusic acoustic compiler (standard in generating computer music) that includes a proprietary graphic user interface developed specifically for use during sound matching with CST [1]. CST software will be use with standard computer and audio equipment that is commercially available. The standard commercially available components are intended for use as designated by the manufacturer.

CONCLUSIONS

CST is equivalent to tinnitus masking devices already approved for marketing.

REFERENCES

[1] Moore, F. R. *Elements of Computer Music* (Prentice-Hall, 1990)

[2} Folmer, R.L. Long-term reductions in tinnitus severity. BMC Ear, Nose, and Throat Disorders, 2002, 2(3): 1-9.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2007

Tinnitus Otosound Products, LLC
c/o Geraldine Crean, Ph.D.
880 First Street, Suite 403
Los Angeles, CA 90012

Re: K070599
Trade/Device Name: Customized Sound Therapy (CST)
Regulation Number: 21 CFR 874.3400
Regulation Name: Tinnitus masker
Regulatory Class: Class II
Product Code: KLW
Dated: May 22, 2007
Received: May 24, 2007

Dear Dr. Crean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M. B. Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070599

Indications for Use

510(k) Number: [redacted] K070599

Device Name: Customized Sound Therapy (CST)

Indicaitons For Use:

The CST system is a CD with software that enables a qualified healthcare professional to identify, with the patient's verbal input, the sounds that most closely match the patient's tinnitus. The device is indicated to mask and intermittently mask tinnitus as part of a tinnitus management program. The target population for the device is adults (18 years and over) who present with tinnitus, that may or may not be accompanied with hearing loss at the higher frequencies, and who are participating in a tinnitus management program.

Perscription Use: __X__ AND/OR Over-The Counter Use____

(Part 21 CFR 801 Subpart D) (12 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Drug Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Page 1 of 1

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K070599

CARD GUARD
Scientific Survival LTD.

CG-6108 Continuous ECG Monitor and Arrhythmia Detector 510(k) Summary of Safety and Effectiveness

K071995
1/3

Submitter	**Card Guard Scientific Survival Ltd.,**	
Address	2 Pekeris St. P.O.B. 527 Rehovot 76100, Israel	
Contact:	**Alex Gonorovsky, RA Manager**	
Phone:	972-8-9484019	Fax: 972-8-9484044
E-mail:	galex@cardguard.com	
Device		
Trade Name:	CG-6108 Continuous ECG Monitor and Arrhythmia Detector	
Classification:	detector and alarm, arrhythmia	
Product Code:	DSI	
Regulation No:	870.1025	
Class:	II	

DEC 18 2007

1. Definition

The CG-6108 Continuous ECG Monitor and Arrhythmia Detector system is designed for self-testing by patients at home and for analysis by medical professionals at a remote Monitoring Center. It comprises a chest-worn ECG sensor and a handheld device with a proprietary application, configured to process and transmit the ECG recordings.

The chest-worn unit includes 3 electrodes on a harness and it houses a battery, an ASIC and a Bluetooth transceiver for the acquisition, recording, and transmission of the ECG signal.

The ECG signals are transmitted via Bluetooth to the handheld device. When an event is detected it is wirelessly transmitted to the CG Monitoring Center for professional analysis. The handheld device is equipped with shared memory used to record the signal received from the sensor and to allow pre- and post processing options through the use of this memory in a dual memory loop configuration, both running in parallel. One loop is auto-triggered, with programmable thresholds that starts recording based on specific rhythms detected or manually activated by the patient. The second, and longer, recording loop is controlled remotely to provide the physician with more information, when requested by the CG Monitoring Center.

The handheld device automatically transmits the recorded ECG, via cellular link, to the Monitoring Center. When cellular service is unavailable the patient can transmit via landline telephone.

2. Medical Application

The Application is designed for wireless mobile platforms, e.g. PDA, SmartPhone and for static platforms, i.e., PC. It is used to receive from the CG-6108, the test results and other medical data, to process and save these test results, and synchronize data and test results with the Medical Center. The Application is a part of a personal medical system solution. The Medical Application performs the following activities:

1. Receives medical test inputs from the external accessories
2. Collects medical test data and other related information as defined for each test
3. Accesses historical test and related data stored on the device
4. Transmits medical test data and additional information to Center for professional evaluation/backup
5. Receives data from Center
6. Enables configuring GPRS data connection (based on mobile phone GPRS/CDMA capabilities), changing user name and password.

K071995
2/3

3. Referenced Standards

No performance standards have been developed under Section 514 of the Federal Food, Drug and Cosmetic Art for wireless ECG event recording devices. Following are reference standards:

(1) Arrhythmia Detector and Alarm Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: October 28, 2003
(2) ANSI/AAMI-EC 57:1998, Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms
(3) ANSI/AAMI EC38:1998 Ambulatory Electrocardiograph
(4) IEC 60601-2-27 2005 Medical electrical equipment - Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment
(5) EN 475: Medical devices - Electrically-generated alarm signals ; April 1995
(6) EN 980: Graphical symbols for use in the labeling of medical devices; August 2003
(7) EN 1041: Terminology, Symbols and Information provided with Medical Devices; Information supplied by the manufacturer with medical devices; April 1998
(8) EN ISO 9001: Quality management systems - Requirements; December 2000
(9) EN ISO 13485: Quality systems – Medical devices; August 2000
(10) EN ISO 14971: Medical devices – application of risk management to medical devices; March 2001
(11) EN ISO 10993 Biological evaluation of medical devices Part 1: Evaluation and testing; Dec. 1997
(12) EN 60601-1: Medical electrical equipment; Part 1: General requirements for safety; Sept. 2002
(13) EN 60601-1-2: Medical electrical equipment; Part 1: 2. Collateral Std: EMC; requirements and tests; 2001
(14) EN 60601-1-4: Medical electrical equipment; Part 1: 4. Collateral Std: Programmable electric medical systems; 2001

4. Indications For Use

The CG-6108 Continuous ECG Monitor and Arrhythmia Detector is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors a one lead ECG, automatically generates an alarm triggered by an arrhythmia detection algorithm or generates an alarm manually triggered by the patient, and transmits the recorded data transtelephonically to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.

5. Principles of operation

The CG-6108 system comprises a chest-worn ECG sensor with 3 electrodes and a handheld device with a Medical Application, used to process and transmit the ECG recordings. The battery powered chest-worn unit has an ASIC and a transceiver for acquisition, recording, and transmission of the ECG signal. The ECG signals are transmitted via Bluetooth to the handheld device equipped with the Medical Application, which incorporates an algorithm for AF detection. A detected event triggers transmission of the signal to the CG Monitoring Center for analysis.

6. Substantial Equivalence

The clearance for the CG-6108 is sought on the grounds of its claimed substantial equivalence (SE) to the following predicate devices:

1. Card Guard's CG-6108 Arrhythmia ECG Event Recorder K060911 for the complete physical identity and the identity of the intended use and technical specifications. The CG-6108 Continuous ECG Monitor and Arrhythmia Detector is physically identical to the CG-6108 ECG Event Recorder K060911.
2. Cardiac Telecom Corp's Heartlink, Model II K982803 for Product Code DSI (Reg. Number 870.1025).

K071995
3/3

7. Conclusions

The CG-6108 device constitutes a safe and reliable means for self-testing by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device is at least as safe, effective, and reliable as the cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 2007

Card Guard Scientific Survival, Inc.
c/o Mr. Gregory Levine
Arnold & Porter, LLP
555 12 St NW
Washington DC 20004

Re: K071995
Trade/Device Name: Card Guard CG-6108 Continuous ECG Monitor and Arrhythmia Detector
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: II (special controls)
Product Code: DSI, DXH
Dated: October 26, 2007
Received: October 26, 2007

Dear Mr. Levine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071995

Device Name: **CG-6108 Continuous ECG Monitor and Arrhythmia Detector**

Indications for Use:

The CG-6108 Continuous ECG Monitor and Arrhythmia Detector is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors a one lead ECG, automatically generates an alarm triggered by an arrhythmia detection algorithm or generates an alarm manually triggered by the patient, and transmits the recorded data transtelephonically to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.

Prescription Use [X] _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071995

(Posted November 13, 2003)

510(K) SUMMARY

K072137

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name: AViTA Corporation

Address:	9F , No. 78 , SEC. 1 , Kwang-Fu Rd., San-Chung, Taipei County., Taiwan , 241
Phone:	+886-2-8512-1568
Fax:	+886-2-8512-1347
Contact:	Mr. Casper Chen / Vice President of R&D

DEC 07 2007

2. Device Name :

Trade Name:	AViTA Bluetooth Blood Pressure Monitor , Model no.: BPM656ZB
Common Name:	Non-Invasive Blood Pressure Monitor
Classification name	System , Measurement , Blood-Pressure , Non-Invasive

3. DEVICE CLASS The **AViTA Bluetooth Blood Pressure Monitor (Model no.: BPM656ZB)** has been classified as

Regulatory Class: II
Panel: 74
Product Code: DXN
Regulation Number: 2ICFR 870.1130

4. Predicate Device: The predicate device is the A&D Medical UA-767PBT Digital Blood Pressure Monitor(K040371) marketed by A & D ENGINEERING, INC..

5. Intended Use: The device is arm type Blood Pressure Monitor that applies oscillometric method to measure human Systolic, Diastolic blood pressure and heart rate The measurement results are displayed on the LCD and transmitted to Bluetooth enabled devices, such as a PC , a PDA or a printer.

The devise is designed for adult.

6. Device Description: The **AViTA Bluetooth Blood Pressure Monitor (Model no.: BPM656ZB)** is designed to measure the systolic and diastolic blood pressure, and pulse rate (heart of an individual).

The device uses an inflated cuff which is wrapped around the upper arm. The cuff is inflated by an electrical air pump. The systolic and diastolic blood pressures are determined by oscillometric method. The deflation rate is controlled by a preset mechanical valve at a constant rate. At any moment of measurement, the user can deflate the cuff. The measurement results are displayed on the LCD and transmitted to a Bluetooth enabled devices, such as a PC, a PDA, a printer, or and access point.

7. Performance Summary: In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included EN-1060-1, EN-1060-3, ANSI/AAMI SP-10, IEC 60601-1 and IEC 60601-1-2 requirements.

8. Conclusions:

The **AViTA Bluetooth Blood Pressure Monitor (Model no.: BPM656ZB)** has the same intended use and similar technological characteristics as the A&D Medical UA-767PBT Digital Blood Pressure Monitor(K040371) marketed by A & D ENGINEERING, INC.. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, The **AViTA Bluetooth Blood Pressure Monitor (Model no.: BPM656ZB)** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 07 2007

AViTA Corporation
c/o Ms. Jennifer Reich
2904 Boldt Drive
Flagstaff, AZ 86001

Re: K072137
Trade/Device Name: AViTA Bluetooth Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN, DRG
Dated: November 6, 2007
Received: November 8, 2007

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K072137**

Device Name: AViTA Bluetooth Blood Pressure Monitor ,
Model no.: BPM656ZB
AViTA Corporation

Indications For Use:

The **AViTA Bluetooth Blood Pressure Monitor** (Model no.: BPM656ZB) is intended to measure the blood pressure (systolic and diastolic) and pulse rate by oscillometric method. The measurements are conducted by using an cuff which is wrapped around the upper arm. At the end of each measurement, the results will be displayed on LCD. **AViTA BPM656ZB** through its Bluetooth wireless communication port can also transfer the measurement results to other electronic devices, such as a PC , a PDA or a printer.

The device is indicated for adult in home use. The arm circumference range shall be between 9 inches (23 cm) to 17 inches (43 cm). The end users should not have common arrhythmias, such as atrial or ventricular premature beats or atrial fibrillation.

Prescription Use _____ AND/OR Over-The-Counter Use V
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

B Zimmerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072137

CONFIDANT

NOV 16 2007

510(K) SUMMARY K072698

In accordance with 21 CFR 807.92, the following information constitutes Confidant's summary for the Confidant 2.5 System.

SUBMITTER'S NAME:	Confidant International, LLC
ADDRESS:	2530 Meridian Parkway, Suite 300
CONTACT PERSON:	Daniel R. Plonski
CONTACT PERSON TITLE:	Director of Product Management
TELEPHONE NUMBER:	(919) 806-4323
FAX NUMBER:	(919) 806-4802
DATE OF SUBMISSION:	September 20, 2007

1 Identification of device

Proprietary Name: Confidant 2.5
Common Name: Physiological Transmitter and Receiver
Classification Status: Class II per regulations 870.2910
Product Codes: DRG

2 Equivalent devices

Confidant Inc. believes that Confidant 2.5 is substantially equivalent to the following legally marketed devices:

Confidant 2.0 K062215 Confidant Inc.	Honeywell HomMed Genesis OTC Monitor System K061087 Honeywell HomMed, LLC

3 Description of the device

Confidant 2.5 is an accessory device that collects data from a range of supported home-monitoring devices. The data is collected from the supported devices and sent to a central database server, using standard wireless technologies. Upon receipt of newly submitted patient data, the Confidant Server software will generate and send one or more feedback messages directly to the patient's cell-phone. The feedback messages are selected by the system based on the patient's currently submitted and recent historic data.
Confidant 2.5 currently supports several models of glucose meters, non-invasive blood pressure cuffs and weight scales.

K072698

4 *Intended use*

Confidant 2.5 is intended for personal use by out-of-hospital patients as a means to retrospectively collect and record physiologic measurements from home monitoring devices (including blood glucose meters, blood pressure cuffs and weight scales). The data is transmitted to a database server where customized messages are generated by the system and returned to the patient. The returned messages contain objective observations and motivational information intended to help the patient better understand and manage their health.

Confidant 2.5 is an accessory device that collects data from a range of supported home-monitoring devices. The data is collected from the supported devices and sent to a central database server, using standard wireless technologies. Upon receipt of newly submitted patient data, the Confidant Server software will generate and send one or more feedback messages directly to the patient's cell-phone. The feedback messages are selected by the system based on the patient's currently submitted and recent historic data.

Confidant 2.5 does not provide diagnosis of any disease or medical condition.

Confidant 2.5 is not intended to provide automated treatment decisions, or to be used as a substitute for professional healthcare judgment. All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

Confidant 2.5 is not intended for emergency calls or for transmission or indication of any real-time alarms or time-critical data. This device is not intended as a substitute for direct medical supervision or emergency intervention.

Confidant 2.5 is intended for over-the-counter use.

2530 Meridian Parkway, Ste 300 Durham, NC 27713
(W) 919.806.4620 (F) 919.806.4802

5 *Technological characteristics, comparison to predicate device.*

Confidant 2.5 utilizes the same technology as one or both of the predicate devices (Confidant 2.0, K062215 and/or Honeywell HomMed Genesis OTC Monitor System, K061087) including:

- The same supported monitoring devices
- The same operating features
- The same fundamental technology

6 *Discussion of functional and safety testing.*

Testing of Confidant 2.5 included electrical safety and EMC testing of the Confidant Connector component; software testing of the Confidant Collector and Confidant Server components; and low-level, device compatibility testing with each of the supported monitoring devices. The test results demonstrate that Confidant 2.5 is in compliance with the applied standards and that it performed within its specifications and functional requirements.

7 *Conclusion*

Based on the comparison of intended use, supported monitoring devices, operational features and technology and the results of electrical safety. EMC, device compatibility and performance testing, it is our conclusion that Confidant 2.5 is as safe, as effective and performs as well as the legally marketed predicate devices.

2530 Meridian Parkway, Ste 300 Durham, NC 27713
(W) 919.806.4620 (F) 919.806.4802

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 6 2007

Confidant International, LLC
c/o Mr. Daniel R. Plonski
Director of Product Management
2530 Meridian Parkway, Suite 300
Durham, NC 27713

Re: K072698
Device Name: Confidant 2.5
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: September 20, 2007
Received: September 24, 2007

Dear Mr. Plonski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B/Zimmerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072698

Device Name: Confidant 2.5

Indications For Use: Confidant 2.5 is intended for personal use by out-of-hospital patients as a means to retrospectively collect and record physiologic measurements from home monitoring devices (including blood glucose meters, blood pressure cuffs and weight scales). The data is transmitted to a database server where customized messages are generated by the system and returned to the patient. The returned messages contain objective observations and motivational information intended to help the patient better understand and manage their health.

Confidant 2.5 is an accessory device that collects data from a range of supported home-monitoring devices. The data is collected from the supported devices and sent to a central database server, using standard wireless technologies. Upon receipt of newly submitted patient data, the Confidant Server software will generate and send one or more feedback messages directly to the patient's cell-phone. The feedback messages are selected by the system based on the patient's currently submitted and recent historic data.

Confidant 2.5 does not provide diagnosis of any disease or medical condition.

Confidant 2.5 is not intended to provide automated treatment decisions, or to be used as a substitute for professional healthcare judgment. All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

Confidant 2.5 is not intended for emergency calls or for transmission or indication of any real-time alarms or time-critical data. This device is not intended as a substitute for direct medical supervision or emergency intervention.

Confidant 2.5 is intended for over-the-counter use.

Prescription Use _____ **AND/OR Over-The-Counter Use** ___X___
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072698

JUL 11 2008

510(K) SUMMARY

CardioSen'C

510(k) Number K 080047

Applicant's Name: SHL Telemedicine International Ltd.
90 Igal Alon St.
Tel Aviv 67891
ISRAEL
Tel (972)3-561-2212
Fax (972)3-624-2414

Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: CardioSen'C

Classification: **Name**: Telephone electrocardiograph transmitter and receiver
Product Code: DXH
Regulation No: 21 CFR 870.2920
Class: II
Panel: Cardiovascular

Device Description: The CardioSen'C is a personal, battery powered, hand-held personal ECG transmitter, enabling an individual to immediately transmit a 12-lead ECG and a rhythm strip from a remote location, to a physician's office, hospital or monitoring center.

The ECG data can be transmitted in real time via two communication methods. The CardioSen'C produces an ECG frequency modulated acoustical tone that can be coupled with and transmitted by a standard or a cellular telephone. The ECG data can also be transmitted digitally through the cellular network. Either one of these two transmissions methods permits the transfer of a 12-lead ECG and rhythm strip to the medical professional capable of interpreting the data.

SHL
TeleMedicine International Ltd.

Intended Use Statement:

The CardioSen'C device is intended to condition an electrocardiographic signal so that it can be transmitted acoustically via telephone and/or digitally over cellular network to a remote location. The CardioSen'C device is designed to be used by a patient to transmit a 12 lead ECG and rhythm strip in real-time to a physician's office, hospital or other medical receiving center.

Predicate Devices:

The CardioSen'C is substantially equivalent to the following predicate devices:

- CardioBeeper ® CB 12/12, 12 Lead Personal ECG Transmitter, cleared under K002310;
- River – 1, ECG Event Recorder and Transmitter, cleared under K063609.

Performance Data:

The CardioSen'C device has been tested according to various standards and guidance documents, such as ANSI/AAMI EC11-1991 (Diagnostic Electrocardiographic Devices), IEC 60601-2-25 (1993) +A1:1999 requirements for the safety of electrocardiographs, etc. Further IVD study has shown that the system meets its design specifications and is safe and effective for its intended use.

Conclusions:

The CardioSen'C device has the same intended use and is capable of transmitting the electrocardiographic signal acoustically via customary telephones as the CardioBeeper® CB 12/12. Further, the CardioSen'C can transmit digitally over cellular network to a remote location as the River -1 device. The results of tests studies and analyses performed with the CardioSen'C device demonstrate that the CardioSen'C device is as safe and effective as its predicate devices without raising any new safety and\or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2008

SHL TeleMedicine International LTD
c/o Qsite
Mr. Yoram Levy
31 Haavoda St.
Binyamina, 30500
ISRAEL

Re: K080047
CardioSens'C
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DXH
Dated: June 22, 2008
Received: June 27, 2008

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SHL
TeleMedicine
International Ltd.

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K080047

Device Name: CardioSen'C

Indications for Use: The CardioSen'C device is intended to condition an electrocardiographic signal so that it can be transmitted acoustically via telephone and/or digitally over cellular network to a remote location. The CardioSen'C device is designed to be used by a patient to transmit a 12 lead ECG and rhythm strip in real-time to a physician's office, hospital or other medical receiving center.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of Cardiovascular, Respiratory and Neurological Devices
510(k) Number

(Division Sign-Off)
Division of Cardiovascular Devices

K080798

510(k) Summary
As required by 21 CFR §807.92(c)

Submitter

JUN 27 2008

510(k) Owner:	Intel Corporation
Address:	1900 Prairie City Road, FM7-197, Folsom, CA 95630
Telephone:	(408) 765-2060
Contact Person:	Tae-Woong Koo
Date Prepared:	March 19, 2008

Device Information

Trade Name:	Intel® Health Guide PHS6000
Common Name:	Remote Patient Monitoring System
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG)

Substantial Equivalence is claimed to the following devices:

1. Philips Medical Systems' M3810A TeleMonitoring System with M3812B TeleStation **(K023749)**
2. Health Hero Network's Health Buddy® Appliance **(K063612)**
3. WEBVMC, LLC's RemoteNurse™ Patient Monitoring system **(K041308)**

Device Description

The Intel® Health Guide PHS6000 is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. It collects measurements captured on commercially available wireless or tethered medical devices designed for home use, stores and displays the collected information on the LCD screen, and transmits the information to a secure host server. Caregivers can review the transmitted information and select education and reminders for patients using a caregiver software interface to the host server. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also optionally engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.

The Intel® Health Guide PHS6000 system consists of the:

(1) Intel® Health Guide PHS6000 hardware:

The physical component of the Intel® Health Guide PHS6000 is an electronic device contained in a plastic enclosure with a touch screen, video camera with privacy screen, microphones, speakers and a reminder light which is mounted into the top of the case. On the back of the device is a power socket, a headphone socket, a

Broadband (high-speed) internet socket for connection to a broadband network. The device has medical device sockets for connection to specific physiological monitors, and may optionally have a phone socket for modem connection to a standard phone line.

(2) Intel® Health Guide software application:

The software application captures, stores, and transmits information to a secure website via a standard telephone line or a LAN/WAN connection.

(3) Intel® Care Management Suite software application:

The application allows caregivers to review patient vital signs on the secure website. The Intel® Care Management Suite allows for predefining upper and lower limits and, when either limit is exceeded, the system emails and/or pages the caregiver.

(4) Processor software application:

The processor software application manages the interface between the Intel® Health Guide PHS6000 software application and the secure website.

The Intel® Health Guide PHS6000 is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention. The device is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

Indications for Use

The Intel® Health Guide PHS6000 is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. It collects measurements captured on commercially available wireless or tethered medical devices designed for home use, stores and displays the collected information on the LCD screen, and transmits the information to a secure host server. Caregivers can review the transmitted information and select education and reminders for patients using a caregiver software interface to the host server. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also optionally engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.

The Intel® Health Guide PHS6000 is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. It is contraindicated for patients requiring direct medical supervision or emergency intervention. It is intended for patients who are willing and capable

of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

Technological Characteristics

The Intel® Health Guide PHS6000 is substantially equivalent to the predicate devices in terms of data collection software functionality, operating system for the patient device, communication method of patient device with central server, types of sensors which can be interfaced to the patient device, implementation method of collecting data from sensors, sensor software, connectivity, communication protocol, power source, and display method.

Safety and Efficacy

The Intel® Health Guide PHS6000 does not rely on an assessment of clinical performance data. The device conforms to FDA's recognized consensus standards and relies on its conformity to demonstrate the safety and efficacy. The device introduces no new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2008

Digital Health Group
c/o Ms. Maureen Glynn
Director of Regulatory Affairs
Intel Corporation
1900 Prairie City Road FM7-197
Folsom, CA 95630

Re: K080798
Trade/Device Name: Intel® Health Guide PHS6000
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitters and Receivers
Regulatory Class: Class II
Product Code: DRG
Dated: June 10, 2008
Received: June 12, 2008

Dear Ms. Glynn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

510(k) Number: K080798

Device Name: Intel® Health Guide PHS6000

Indications for Use:

The Intel® Health Guide PHS6000 is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. It collects measurements captured on commercially available wireless or tethered medical devices designed for home use, stores and displays the collected information on the LCD screen, and transmits the information to a secure host server. Caregivers can review the transmitted information and select education and reminders for patients using a caregiver software interface to the host server. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also optionally engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.

The Intel® Health Guide PHS6000 is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. It is contraindicated for patients requiring direct medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080798

MAY 29 2008

CARD GUARD

CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector
510(k) Summary of Safety and Effectiveness

- IEC 60601-2-27 2005 Medical electrical equipment - Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment
- EN 475: Medical devices - Electrically-generated alarm signals ; April 1995
- EN 980: Graphical symbols for use in the labeling of medical devices; August 2003
- EN 1041: Terminology, Symbols and Information provided with Medical Devices; Information supplied by the manufacturer with medical devices; April 1998
- EN ISO 9001: Quality management systems - Requirements; December 2000
- EN ISO 13485: Quality systems – Medical devices; August 2000
- EN ISO 14971: Medical devices – application of risk management to medical devices; March 2001
- EN ISO 10993 Biological evaluation of medical devices Part 1: Evaluation and testing; Dec. 1997
- EN 60601-1: Medical electrical equipment; Part 1: General requirements for safety; Sept. 2002
- EN 60601-1-2: Medical electrical equipment; Part 1: 2. Collateral Std: EMC; requirements and tests; 2007
- EN 60601-1-4+A1 2000: Medical electrical equipment; Part 1: 4. Collateral Std: Programmable electric medical systems;

Indications for Use, Intended Use

The CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors patient ECG, automatically generates an alarm triggered by an arrhythmia detection algorithm, or generates an alarm manually triggered by the patient, and transmits the recorded data transtele-phonically to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.

Principles of operation

The chest-worn ECG sensor transmits signals via Bluetooth to the handheld device equipped with the Medical Application, which incorporates an algorithm specially developed for detection of AF events. A detected artifact triggers transmission of the signal to the CG Monitoring Center for analysis.

Substantially Equivalent Devices

The clearance for the CG-6108 ACT-3L is sought on the grounds of its claimed substantial equivalence (SE) to the following predicate devices:

1. Card Guard's CG-6108 Continuous ECG Monitor And Arrhythmia Detector K071995 for being the parent model
2. Card Guard's CG-6550 Personal ECG Transmitter K990478 for the 3 leads/3 channel design.

Conclusions

All Verification, Validation and Testing (VV&T) documents - although not included in this dossier, constitute a part of the device DMR and are available upon request

The Truthful and Accurate Statement complies with 21 CFR 807.87(j).

We trust that the submitted information will enable the reviewer to process the material promptly. The time factor is crucial for Card Guard's commercial interests.

This dossier contains one paper copy of the 510(k) submission together with an electronic copy that is an exact duplicate of the paper copy.

CARD GUARD

CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector
510(k) Summary of Safety and Effectiveness

Submitter	**Card Guard Scientific Survival Ltd.,**	
Address	2 Pekeris St. P.O.B. 527 Rehovot 76100, Israel	
Contact:	**Alex Gonorovsky, RA Manager**	
Phone:	972-8-9484019	Fax: 972-8-9484044
E-mail:	galex@cardguard.com	
Device		
Trade Name:	CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector	
Classification:	detector and alarm, arrhythmia	
Product Code:	DSI DXH	
Regulation No:	870.1025	
Class:	II	

Device Definition

The CG-6108 ACT-3L is designed for self-testing by patients at home and for analysis by medical professionals at a remote Monitoring Center. It comprises a chest-worn ECG sensor and a handheld device with a proprietary application, configured to process and transmit the ECG recordings.

The chest-worn unit has 3 electrodes on a harness and it houses a battery, an ASIC and a Bluetooth transceiver for the acquisition, recording, and transmission of the ECG signal.

The ECG signals are transmitted via Bluetooth to the handheld device. When an event is detected it is wirelessly transmitted to the CG Monitoring Center for professional analysis. The handheld device is equipped with shared memory used to record the signal received from the sensor and to allow pre- and post processing options through the use of this memory in a dual memory loop configuration, both running in parallel. One loop is auto-triggered, with programmable thresholds that starts recording based on specific rhythms detected or manually activated by the patient. The second, and longer, recording loop is controlled remotely to provide the physician with more information, when requested by the CG Monitoring Center.

The handheld device automatically transmits the recorded ECG, via cellular link, to the Monitoring Center. When cellular service is unavailable the patient can transmit via landline telephone.

Medical Application

The Application is designed for wireless mobile platforms, e.g. PDA, SmartPhone and for static platforms, such as PC. It is used to receive from the CG-6108 the test results and other medical data, to process and save these test results, and synchronize data and test results with the CG Medical Center. The Application is a part of a personal medical system solution. It performs the following activities:

1. Receives medical test inputs from the external accessories
2. Collects medical test data and other related information as defined for each test
3. Accesses historical test and related data stored on the device
4. Transmits medical test data and other information to Center for professional evaluation/backup
5. Receives data from Center
6. Enables configuring GPRS data connection (based on mobile phone GPRS/CDMA capabilities), changing user name and password.

Referenced Standards

- Arrhythmia Detector and Alarm Guidance for Industry and FDA Staff Class II Special Controls Guidance
- ANSI/AAMI-EC 57:1998, Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms
- ANSI/AAMI EC38:1998 Ambulatory Electrocardiograph

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2008

Card Guard Scientific Survival Ltd.
c/o Mr. Alex Gonorovsky
Manager, Regulatory Affairs
2 Pekeris St.
P.O. Box 527
Rehovot 76101 ISRAEL

Re: K081257
CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class II (two)
Product Code: DSI
Dated: March 26, 2008
Received: May 2, 2008

Dear Mr. Gonorovsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081257

Device Name: **CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector**

Indications for Use:

The CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors patient ECG, automatically generates an alarm triggered by an arrhythmia detection algorithm, or generates an alarm manually triggered by the patient, and transmits the recorded data transtelephonically to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.

Prescription Use [X] _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K081257

(Posted November 13, 2003)

EntraHealth Systems, USA
338 Galloway Valley Ct.
Alpine, CA 91901

K081703

JAN - 8 2009

SUMMARY OF SAFETY AND EFFECTIVENESS
In accordance with 21CFR part 807.92

DEVICE NAME: Myglucohealth Models MGH-1 and MGH-BT1

PREDICATE DEVICE HMD Biomedical "Evolution" blood glucose monitor (reference K072369)

DESCRIPTION: Reference CLASSIFICATION: 862.1345: Blood glucose monitoring systems that include a monitor, control solution and test strips with biosensor.

INTENDED USE:
Systems are intended for the quantitative measurement of the concentration of glucose in whole blood that can be taken from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh by diabetic patients or health care professionals. Results are plasma calibrated to allow for easy comparison to lab method. The Myglucohealth glucose monitoring systems are not to be used for the diagnosis of diabetes or for neonatal use. Alternate site testing should be done during steady-state times when glucose is not changing rapidly.

SUBSTANTIAL EQUIVALENCE STATEMENT:
The Myglucohealth blood glucose monitoring system is **equivalent in safety and effectiveness** to the HMD Biomedical "Evolution" device by virtue of the following:

1) Similar materials of construction including use of the same PCB, software and strips. Case design is different, however the MGH-BT1 monitor is tested and found to be in compliance to:
   - ISO 15197
   - CB test scheme to IEC/EN 61010-1:2001 and 61010-2-101: 2002

2) Equivalent manufacturing methods as both the MGH and predicate (Evolution) systems (including monitor, control solution and strips) are manufactured by the same entity.

3) Although unlike the predicate, the Myglucohealth MGH-BT1 system provides for the wireless uploading of data from the monitor via Bluetooth transmission to a Bluetooth paired PC or cell phone. However, the wireless transfer of data has been validated and demonstrates a 100% correlation to actual monitor data. A significant number of users of varying demographic ages, gender, education and background were studied.

4) The intended use of the MGH monitors is the same as the predicate device.

Therefore, there are no substantive differences between the products defined in this 510(k) sub-mission and the predicate device.

Signed: _____ Dated: June 4, 2008

Carlos Gonzalez
Regulatory Affairs Consultant to Entra Health Systems, USA
p: (413) 513-6343

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Entra Health Systems, Ltd.
c/o Carlos Gonzalez
7833 Knollbrook Dr.
Pleasanton, CA 94588

JAN - 8 2009

Re: k081703
Trade Name: Myglucohealth Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Monitoring System
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX
Dated: December 23, 2008
Received: December 29, 2008

Dear Mr. Gonzalez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): K081703

Device Name: ***Myglucohealth Glucose Monitoring Systems***

Indication For Use:

The Myglucohealth glucose monitoring system provides a quick and easy way for diabetic patients to measure and self-monitor blood glucose levels. The system is comprised of the MGH-BT1 (w/Bluetooth wireless download capability) or the MGH-1 (w/o Bluetooth) blood glucose meter, control solution and test strips that carry a biosensor used for the quantitative measurement of the concentration of glucose in capillary whole blood that can be taken from the fingertip, ventral palm, hand, upper arm, forearm, calf and/or thigh by diabetic patients or health care professionals. The results obtained are plasma calibrated to allow for easy comparison to the laboratory method. Further, results from either meter may be uploaded to a memory device through a standard RS32 connection, or, with the –BT1 model, wirelessly transmitted to a bluetooth capable PC or Cell phone. The Myglucohealth glucose monitoring systems are not to be used for the diagnosis or screening of diabetes or for neonatal use. Alternate site testing should be done during steady-state times when glucose is not changing rapidly.

Prescription Use ___x___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _x_. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K081703

K083115

510(k) Notification Submission – Special 510(k)
Modification to Intel® Health Guide PHS6000

510(k) Summary
As required by 21 CFR §807.92(c)

NOV 2 6 2008

Submitter

510(k) Owner:	Intel Corporation
Address:	1900 Prairie City Road, FM7-197, Folsom, CA 95630
Telephone:	(408) 765-2060
Contact Person:	Tae-Woong Koo
Date Prepared:	October 20, 2008

Device Information

Trade Name:	Modification to Intel® Health Guide PHS6000
Common Name:	Remote Patient Monitoring System
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG)

Substantial Equivalence is claimed to the following device:
Intel Corporation's Intel® Health Guide PHS6000 (**K080798**)

Device Description

The Intel® Health Guide PHS6000 is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. It collects measurements captured on commercially available wireless or tethered medical devices designed for home use, stores and displays the collected information on the LCD screen, and transmits the information to a secure host server. Caregivers can review the transmitted information and select education and reminders for patients using a caregiver software interface to the host server. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also optionally engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.

K083115

510(k) Notification Submission – Special 510(k)
Modification to Intel® Health Guide PHS6000

The Intel® Health Guide PHS6000 system consists of the:

(1) Intel® Health Guide PHS6000 hardware:

The physical component of the Intel® Health Guide PHS6000 is an electronic device contained in a plastic enclosure with a touch screen, video camera with privacy screen, microphones, speakers and a reminder light which is mounted into the top of the case. On the back of the device is a power socket, a headphone socket, a Broadband (high-speed) internet socket for connection to a broadband network. The device has medical device sockets for connection to specific physiological monitors, and may optionally have a phone socket for modem connection to a standard phone line.

(2) Intel® Health Guide software application:

The software application captures, stores, and transmits information to a secure website via a standard telephone line or a LAN/WAN connection.

(3) Intel® Care Management Suite software application:

The application allows caregivers to review patient vital signs on the secure website. The Intel® Care Management Suite allows for predefining upper and lower limits and, when either limit is exceeded, the system emails and/or pages the caregiver.

(4) Processor software application:

The processor software application manages the interface between the Intel® Health Guide PHS6000 software application and the secure website.

The Intel® Health Guide PHS6000 is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention. The device is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

510(k) Notification Submission – Special 510(k)
Modification to Intel® Health Guide PHS6000

Indications for Use

The Intel® Health Guide PHS6000 is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. It collects measurements captured on commercially available wireless or tethered medical devices designed for home use, stores and displays the collected information on the LCD screen, and transmits the information to a secure host server. Caregivers can review the transmitted information and select education and reminders for patients using a caregiver software interface to the host server. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also optionally engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.

The Intel® Health Guide PHS6000 is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. It is contraindicated for patients requiring direct medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

Technological Characteristics

The Intel® Health Guide PHS6000 is substantially equivalent to the predicate device in terms of data collection software functionality, operating system for the patient device, communication method of patient device with central server, types of sensors which can be interfaced to the patient device, implementation method of collecting data from sensors, sensor software, connectivity, communication protocol, power source, and display method.

Safety and Efficacy

The Intel® Health Guide PHS6000 does not rely on an assessment of clinical performance data. The device conforms to FDA's recognized consensus standards and relies on its conformity to demonstrate the safety and efficacy. The device introduces no new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 6 2008

Intel Corporation
c/o Mr. Tae-Woong Koo, Ph.D.
Manager of Medical Regulatory Affairs
Digital Health Group
1900 Prairie City Road, FM7-197
Folsom, CA 95630

Re: K083115
Trade/Device Name: Intel® Health Guide PHS6000
Regulation Number: 21 CFR 870.2910
Regulation Name: Physiological Signal Radiofrequency Transmitters and Receivers
Regulatory Class: Class II
Product Codes: DRG, LFR, CGA
Dated: November 18, 2008
Received: November 20, 2008

Dear Dr. Koo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

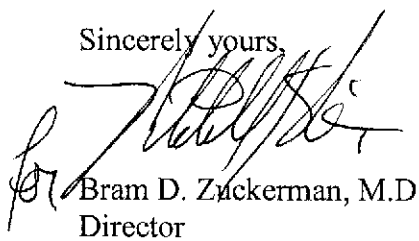
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

510(k) Number: K083115

Device Name: Modification to Intel® Health Guide PHS6000

Indications for Use:

The Intel® Health Guide PHS6000 is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. It collects measurements captured on commercially available wireless or tethered medical devices designed for home use, stores and displays the collected information on the LCD screen, and transmits the information to a secure host server. Caregivers can review the transmitted information and select education and reminders for patients using a caregiver software interface to the host server. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also optionally engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.

The Intel® Health Guide PHS6000 is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. It is contraindicated for patients requiring direct medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 11/26/08
Division of Cardiovascular Devices

510(k) Number K083115

MAR 1 3 2009

K083263

510(k) Summary

Date

March 9, 2008

Contact

Rae Ann DeLay
Director, Quality, Regulatory and Health Care Compliance
SymCare Personalized Health Solutions, Inc.
200 Lawrence Drive
West Chester, PA 19380
Phone: (484) 686-4650
Email: rdelay@its.jnj.com.

Device Name

SymCare Diabetes Management Program

Common Name

Accessory to glucose test system

Classification

862.1345 – Glucose Test System – Class II
862.2100 – Calculator/Data Processing Module for Clinical Use – Class I

Predicate Devices

- MCT-Diabetes™ by MyCare Team Inc. cleared most recently via 510(k) K073699
- Think Positive (t+) Diabetes Management System by e-San Limited cleared most recently via 510(k) K061328

Device Description

The SymCare Diabetes Management Program (DMP) is an online tool that helps patients to manage their diabetes and communicate their blood glucose readings to their healthcare providers, healthcare providers manage their diabetes patient population, and insurance companies manage their diabetes patient and health care provider populations. The DMP enables a blood glucose meter to connect via a Bluetooth accessory, the Polymap Wireless Polytel® GMA Glucose Meter Accessory (GMA), to a cellular phone. Once the mobile phone has gathered the data from the meter, it transmits the data to a centralized repository database. The data is analyzed to recognize health patterns, show trends, and offer personalized health information.

Continued on next page

510(k) Summary, Continued

Indications

The SymCare Diabetes Management Program is intended for use in home settings to aid people with diabetes and healthcare professionals in the review, analysis and evaluation of historical blood glucose test results to support effective diabetes management. It is intended for use as an accessory to blood glucose meters with data management capabilities. This system is intended for use by people 18 years of age and older. The SymCare Diabetes Management Program is not intended to provide treatment decisions or to be used as a substitute for professional healthcare judgment. All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

Technological Characteristics

The SymCare Diabetes Management Program, like the predicate devices, is an internet-based software device.

Nonclinical Tests

Extensive software verification and validation testing was conducted and demonstrated compliance to requirements and design specifications.

Clinical Tests

A study to measure the usability of the SymCare DMP was conducted. The study demonstrated:

- comprehension of the study doctors, medical team members, and participants with the DMP,
- appropriate human factors related to the DMP, and
- ease of use of the DMP.

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, SymCare Personalized Health Solutions, Inc., concludes that the new device, the SymCare Diabetes Management Program, is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 3 2009

Symcare Personalized Health Solutions, Inc .
c/o Rae Ann DeLay
Director, Quality, Regulatory & Health Care Compliance
200 Lawrence Drive
West Chester, PA 19380

Re: k083263
Trade/Device Name: Symcare Diabetes Management Program
Regulation Number: 21CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, JQP
Dated: February 27, 2009
Received: March 2, 2009

Dear Ms. DeLay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): k083263

Device Name: SymCare Diabetes Management Program

Indication For Use:

The SymCare Diabetes Management Program is intended for use in home settings to aid people with diabetes and healthcare professionals in the review, analysis and evaluation of historical blood glucose test results to support effective diabetes management. It is intended for use as an accessory to blood glucose meters with data management capabilities. This system is intended for use by people 18 years of age and older. The SymCare Diabetes Management Program is not intended to provide treatment decisions or to be used as a substitute for professional healthcare judgment. All patient medical diagnoses and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K083263

K083862
P. 1/7

PREMARKET NOTIFICATION 510(k) SUMMARY
As required by 21 CFR §807.92(c)

JUN - 5 2009

Submitter

510(k) Owner:	MedApps, Inc.
Owner / Operator:	10027842
Registration:	3005916763
Address:	7975 North Hayden Road, Suite A-200, Scottsdale, AZ 85258
Telephone:	480-305-6323
Fax Number:	480-393-1892
Contact Person:	Kent Dicks
Contact Person Title:	President / CEO
Date Prepared:	December 23, 2008

Device Information

Trade Name:	MedApps 2.0 - Remote Patient Monitoring System
Common Name:	Remote Patient Monitoring System
Classification Status:	Class II per regulations 870.2910
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG)

A. LEGALLY MARKETED PREDICATE DEVICE

Legally marketed predicate device are:

K080798	Intel Health Guide PHS6000
K072698	Confidant 2.5
K062377	MedApps Remote Patient Monitoring System (D-PAL)

B. DEVICE DESCRIPTION

The MedApps 2.0 - Remote Patient Monitoring System consists of a patient device, MedApps HealthPAL, which is a mobile Over-The-Counter wireless communication hub that connects to commercially available wireless and tethered Glucose Meters, Scales, Blood Pressure Monitors and Pulse Oximeters. The HealthPAL stores and displays the information on the OLED screen, and transmits the information to the MedApps secure host server called "HealthCOM" using off the shelf FCC approved wireless / cellular connectivity (including, but not limited to GSM, CDMA and WiMax). Healthcare professionals can review the transmitted information within the MedApps HealthCOM system, set thresholds to flag readings based on specific thresholds being exceeded. In addition, the MedApps Interactive Voice Response (IVR) has the ability to contact the patient remotely and use pre-approved ("canned") educational or reminder messages. ("Your nurse would like to talk to you, can I connect you now", "We haven't received a reading from you today, please send us your readings").

The HealthCOM system allows the patient to login and create a personal account. The patient can specify / authorize which Personal Health Record (PHR) or Electronic Health Record (EHR / EMR) they would like to send / view their data within, outside of the HealthCOM system.

The MedApps 2.0 - Remote Patient Monitoring System uses MedApps Accessories that help the patient in usability of the product, including HealthLINK which docks the HealthPAL, and HealthPOD which connects to off the shelf medical devices via their data port to transmit data via wireless or RF technology (including, but not limited to bluetooth, zigbee, ANT, ULP, etc.).

The MedApps 2.0 - Remote Patient Monitoring System consists of:

(1) MedApps HealthPAL hardware:

The physical component of the MedApps HealthPAL is an electronic device contained in a plastic enclosure with an OLED screen, built-in M2M cellular chip, speaker, smart cable connection, smart cables, wireless, LED Lights to indicate activity, timer button to remind the patient to take their reading in X minutes, last reading button, volume up and down buttons.

(2) MedApps HealthPAL software application:

The software application captures, stores and transmits information to the MedApps HealthCOM server, via the embedded communication chip / platform.

The software application takes in additional information via the embedded wireless module from other medical devices that are wireless enabled, and that have been paired to the MedApps HealthPAL.

The software application has many additional functions including:

- Download of the users profile from the server to configure the HealthPAL remotely.
- Ability to "talk" to the patient with verbal acknowledgments of readings from all attached medical devices, time settings, volume control, educational content and reminders, in any language that is loaded to the device.
- Timer set that was activated by the user at a set timeframe to do whatever they wanted to be reminded to do.
- Control the OLED screen to show certain information including, battery status, volume level, transmission status, message waiting indicator, medical device last reading, activity icons / messages and more as it pertains to provide ease of use and easier adoption for the patient.
- Battery charging, isolation circuits, and interfaces to individual medical devices / protocols via the smart cables.

- For complete comparison of predicate devices see paragraph D - TECHNOLOGICAL CHARACTERISTICS SUMMARY table below. Additionally, please reference Exhibit 08 - System Requirements Specifications (FDA-SRS-8009) document for complete software / system functionality.

(3) MedApps HealthLINK hardware / software:

The HealthLINK hardware / software plugs into off the shelf Glucose Meters, Scales, Blood Pressure Monitors and Pulse Oximeters, and transmit the data via wireless to a receiver that it is already paired with. This functionality was cleared in the MedApps D-PAL submission K062377 in July 2007.

(4) MedApps HealthPOD hardware / software:

The HealthPOD hardware / software is an extension of the HealthPAL functionality that is outlined in this submission. HealthPOD acts as a "docking" station for the HealthPAL in order to recharge batteries, take in additional connections to off the shelf Glucose Meters, Scales, Blood Pressure Monitors and Pulse Oximeters, via smart cables (per validated in HealthPAL software), add a backup communication method via phone line (POTS line), and communicate via wireless to HealthPAL or additional HealthPODs.

(5) MedApps HealthCOM software application:

The software application allows caregivers to set thresholds and review patient data on the secure HealthCOM website.

The HealthCOM software also allows the patient to establish an account and to direct / authorize their data to be directed to an outside, validated Personal Health Record (PHR), Electronic Health Record (EHR or EMR).

(6) MedApps IVR software application:

The software application calls the patient on any phone that is designated in their user profile, and executes an approved ("canned") script to gather information. ("Your nurse would like to talk to you, can I connect you now", "We haven't received a reading from you today, please send us your readings").

In addition, the MedApps IVR application will send out Email, SMS / Text Messages, Paging, IM and many other forms of communications in order to contact patients or caregivers. This will include reminders and alerts, based on parameters / thresholds set in the HealthCOM system.

C. INDICATIONS FOR USE

The MedApps 2.0 - Remote Patient Monitoring System consists of a patient device, MedApps HealthPAL, which is a mobile Over-The-Counter wireless communication hub that connects to commercially available wireless and tethered Glucose Meters, Scales, Blood Pressure Monitors and Pulse Oximeters. The HealthPAL stores and displays the information on the OLED screen, and transmits the information to the MedApps secure host server called "HealthCOM" using off the shelf FCC approved wireless / cellular connectivity (including, but not limited to GSM, CDMA and WiMax). Healthcare professionals can review the transmitted information within the MedApps HealthCOM system, set thresholds to flag readings based on specific thresholds being exceeded. In addition, the MedApps Interactive Voice Response (IVR) has the ability to contact the patient remotely and use pre-approved ("canned") educational or reminder messages. ("Your nurse would like to talk to you, can I connect you now", "We haven't received a reading from you today, please send us your readings").

The MedApps 2.0 - Remote Patient Monitoring System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention.

D. TECHNOLOGICAL CHARACTERISTICS SUMMARY – as required by 807.92(a)(6)

Feature	**Intel Health Guide PHS6000** **K080798**	**Confidant 2.5** **K072698**	**MedApps Submission** **K083862**
Indications of Use	Enables healthcare providers to monitor and manage chronic conditions of patients remotely	Same	Same
Intended Use	Telemedicine System	Same	Same
Intended Users	Home users and Healthcare providers	Same	Same
Site of Use	Home (HealthPAL), Clinic (HealthCOM)	Same	Same
Data Collection Software	Intel Care Management Suite Software	The Hermes Proprietary Software	MedApps Proprietary Software

Feature	Intel Health Guide PHS6000 K080798	Confidant 2.5 K072698	MedApps Submission K083862
Data Collection Software Functionality	Transmit data from Sensor devices to Central Database	Same	Same
Communication method of hub with Central Server	Via DSL or Phone Line Connection	Via Cellular Phone	Via Embedded Cellular Technology
Types of sensors which can be interfaced (wired or wirelessly) to receiver hub	Medical Devices designed for Home: Glucose Scale Blood Pressure Pulse Ox Peak Flow	Medical Devices designed for Home: Glucose Scale Blood Pressure	Medical Devices designed for Home: Glucose Scale Blood Pressure Pulse Ox
Maximum number and type of measurement devices that can be connected to the devices	Determined by vital sign devices that are designed for Home use, and have a data port. (Wireless or Wired)	Same	Same
Maximum data throughput under worst case conditions	Multiple readings are stored on the medical devices and act as a backup if data needs to be re-sent to the server	Same	Same
Time Delay in the processing of data collected and transmitted	Readings stored in the medical devices can be sent up to the server when the connection is restored.	Same	Same
Implementation method of collecting data from sensors	Short range radio system using Bluetooth and Wired (tethered) cables.	Short range radio system using Bluetooth	Short range radio system using Bluetooth and Wired (tethered) cables.
Sensor Software	Sensor Software unchanged	Same	Same
Connectivity	Short range radio system using Bluetooth and Wired (tethered) cables.	Short range radio system using Bluetooth	Short range radio system using Bluetooth and Wired (tethered) cables.
Communication method of hub with devices	Short range radio system using Bluetooth and Wired (tethered) cables.	Short range radio system using Bluetooth	Short range radio system using Bluetooth and Wired (tethered) cables.

Feature	Intel Health Guide PHS6000 K080798	Confidant 2.5 K072698	MedApps Submission K083862
Communications Protocol	Bluetooth V2.0 and Wired (Tethered)	Bluetooth V2.0	Bluetooth V2.0 and Wired (Tethered)
Communication Frequency	Bluetooth : 2.402 to 2.480 GHz	Bluetooth : 2.402 to 2.480 GHz GSM: 850 / 900 / 1800 / 1950 Mhz	Bluetooth : 2.402 to 2.480 GHz GSM: 850 / 900 / 1800 / 1950 Mhz
Power Source	Wall power plug (120 VAC/50-60)	Wall power plug (120 VAC/50-60) and Rechargeable Batteries in Device	Wall power plug (120 VAC/50-60) and Rechargeable Batteries in Device
Display	On devices and hub, and monitors connected to central server	Same	Same
Communication with Patients	On screen display	Same	On screen display of Readings, Voice Output and Interactive Voice Response (IVR)
Use of Thresholds / Algorithms for determining how Thresholds are set and changed	Thresholds are set by Healthcare professionals in Server Software	Same	Same
Information presented to the user, if it is different from that presented by the measurement devices	On screen display	Same	On screen display of Readings, Voice Output and Interactive Voice Response (IVR)
Messages and Instructions that can be sent to the User.	On screen display	Same	On screen display of Readings, Voice Output and Interactive Voice Response (IVR)

Data Collection:
The 2 predicates and the MedApps solution connect to medical devices (designed for home use) via either through wired (cable) or wireless (bluetooth). The data is collected from the devices and sent up to the central server via various communication methods.

Telecommunication Platform to Central Server:
Intel Health uses DSL connectivity (wired point of care), Confidant uses an off the shelf Cell Phone (Cellular), and MedApps uses an embedded Machine to Machine (M2M) module that transmits the data via cellular connectivity.

Patient Feedback Technology:
On the 2 predicates and MedApps, data and messages are displayed on a screen for the patient to read and acknowledge. The MedApps solution also uses an Interactive Voice Response (IVR) system in order to call up the patient and ask them a question, or remind them to take their readings.

Backend Data Storage:
All systems (2 predicates and MedApps), have a backend system that allows data to be stored, and for Healthcare professionals to have the ability to monitor the patients data.

E. NON-CLINICAL PERFORMANCE DATA TESTING AND REVIEW – as required by 807.92(b)(1)

Non-Clinical Testing
The submitted device has undergone significant verification and validation testing. Alpha validation testing included testing of all executable code and functionality and confirmation that all identified hazards have been adequately addressed by software functionality, the user interface, documentation or user SOP.

Alpha validation activities included exhaustive validation scripts of all Detail Design Specifications (DDS), which was summarized and discussed to provide a preliminary record of performance data. Additionally, the submitter duplicated the operational environment of a sophisticated user and provided the complete record of those executed scripts as operational performance data. The output of these two performance data records documents that **MedApps 2.0 - Remote Patient Monitoring System** met its required requirements and design specifications as intended.

F. SUBSTANTIAL EQUIVALENT

The MedApps Remote Patient Monitoring System 2.0 is substantially equivalent to the predicate devices in terms of data collection software functionality, operating system for the patient device, communication method of patient device with central server, types of sensors which can be interfaced to the patient device, implementation method of collecting data from sensors, sensor software, connectivity, communication protocol, power source and display method.

G. SAFETY AND EFFICACY

The MedApps Remote Patient Monitoring System 2.0 does not rely on an assessment of clinical performance data. The device conforms to FDA's recognized consensus standards and relies on its conformity to demonstrate its safety and efficacy. The device introduces no new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2009

MedApps, Inc.
c/o Mr. Kent Dicks
President & CEO
7975 North Hayden Road, Suite A-200
Scottsdale, AZ 85258

Re: K083862
Trade/Device Name: MedApps 2.0 Remote Patient Monitoring System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II
Product Code: DRG
Dated: March 31, 2009
Received: April 1, 2009

Dear Mr. Dicks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MedApps, Inc.
STATEMENT OF INDICATIONS FOR USE

EXHIBIT 01

510(k) Number: K083862

Preparation Date: December 23, 2008

Device Name: **MedApps 2.0 - Remote Patient Monitoring System**

Indications For Use:

The MedApps 2.0 - Remote Patient Monitoring System consists of a patient device, MedApps HealthPAL, which is a mobile Over-The-Counter wireless communication hub that connects to commercially available wireless and tethered Glucose Meters, Scales, Blood Pressure Monitors and Pulse Oximeters. The HealthPAL stores and displays the information on the OLED screen, and transmits the information to the MedApps secure host server called "HealthCOM" using off the shelf FCC approved wireless / cellular connectivity (including, but not limited to GSM, CDMA and WiMax). Healthcare professionals can review the transmitted information within the MedApps HealthCOM system, set thresholds to flag readings based on specific thresholds being exceeded. In addition, the MedApps Interactive Voice Response (IVR) has the ability to contact the patient remotely and use pre-approved ("canned") educational or reminder messages. ("Your nurse would like to talk to you, can I connect you now", "We haven't received a reading from you today, please send us your readings").

The MedApps 2.0 - Remote Patient Monitoring System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

Donna R. Mitchell

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083862

510(k) Summary December 1, 2008

K090037
P1/3

1. Submitter Name and Address

Medicalgorithmics LLC	245 West 107th St., Suite 11A New York, NY 10025, USA
Contact Person	Martin Jasinski, phone (917) 9419581, fax (817) 5829527

2. Device

Trade name:	PocketECG – Medicalgorithmics Real-Time ECG Monitor and Arrhythmia Detector
Classification name:	Arrhythmia Detector and Alarm
Product code:	DSI
Regulation no:	870.1025
Class:	Class II, Special Controls

3. Substantial Equivalence

The selected predicate devices are:

1. CardioNet's Ambulatory ECG Monitor, K072558 (Reg. Number 870.1025 Product Code DSI)
2. Card Guard's CG-6108 Continuous ECG Monitor and Arrhythmia Detector, K071995 (Reg. Number 870.1025, Product Code DSI)

4. Device Description

PocketECG – Medicalgorithmics Real-Time ECG Monitor and Arrhythmia Detector is an ambulatory ECG monitor which analyzes electrographic signal, classifies all detected heart beats and recognizes rhythm abnormalities. All detection results, including annotations for every detected heart beat and ECG signal are transmitted via cellular telephony network to a remote server accessible by a Monitoring Center for reviewing by trained medical staff. The data transmission is automatically triggered when abnormalities are detected, or periodically in case of normal ECG.

The patient worn transmitter streams via Bluetooth link the ECG signal to a Windows Mobile operated PDA (Personal Digital Assistant) device with mobile phone capabilities. The PDA runs Medicalgorithmics proprietary software which detects the ECG annotations and manages the data transmission. The PDA device stores entire ECG on its storage card.

K090037
p 2/3

5. Indications for Use and contradictions

The indications for use for the PocketECG monitor are as follows:

1. Patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease
2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath)
3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.
4. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)
5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring
6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias
7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.
8. Data from the device may be used by another device to analyze, measure or report QT interval. The device is not intended to sound any alarms for QT interval changes.

Contradictions:

1. Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
2. Patients who the attending physician thinks should be hospitalized.

6. Technological comparison to predicate devices

The first technology difference between the subject device is that the predicate devices use customized PDA size monitors, while the subject device uses of-the-shelf PDA with the following minimum requirements:

1. Windows Mobile 5.x or 6.x Operating System,
2. built in GSM/CDMA modem,
3. built in Bluetooth module for communication with the ECG Transmitter,
4. replaceable Storage Card slot for cards of minimum 1 GB capacity,
5. USB port

Example PDAs meeting the above criteria are:
HTC Touch:
http://www.htc.com/www/product.aspx?id=362

K090037
P 3/3

Hewlett Packard iPAQ hw6940
http://h10010.www1.hp.com/wwpc/us/en/sm/WF06a/215348-215348-64929-314903-215381-1822489.html

The second technological difference between the subject device and the predicate devices is that the subject device uses an arrhythmia analysis algorithm developed by Medicalgorithmics while the predicate devices use arrhythmia analysis algorithm licensed from Mortara (K072558) or their proprietary algorithms (K071995).

The third technological difference between the subject device and the predicate devices is that the subject device uses its own ECG sensor and transmitter, while the predicate devices use their own manufactured ECG sensors.

7. Referenced standards

The Medicalgorithmics ECG Monitor and Arrhythmia Detector, PocketECG meets the requirements of following performance standards in accordance with FDA Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm.

- IEC 60601-1:1999 "Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995"
- IEC 60601-1-2:2001/A1:2004 "Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests" Class B
- AAMI/ANSI EC38:2007 Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
- AAMI / ANSI EC57:1998/(R)2003 Testing and Reporting Performance Results of Cardiac Rhythm and ST-Segment Measurement Algorithms

Quality management system - Medical devices is in conformance with the standards: PN-EN ISO 9001:2001 and PN-EN ISO 13485:2005.

8. Substantial Equivalence Conclusion

Medicalgorithmics ECG Monitor and Arrhythmia Detector, PocketECG is safe, effective and substantially equivalent to the predicate devices as supported by the descriptive information and the performance testing. The subject device is composed of off-the-shelf, certified devices and components fully complying with the US safety and EMC standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2009

MedicAlgorithmics, Sp. Z O.O.
c/o Mr. Martin Jasinski
MedicAlgorithmics, LLC
245 West 107th St, Suite 11A
New York, NY 10025

Re: K090037
Trade/Device Name: MedicAlgorithmics Real-Time ECG Monitor and Arrhythmia Detector, Model PocketECG
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (special controls)
Product Code: DSI, MLO
Dated: March 31, 2009
Received: May 8, 2009

Dear Mr. Jasinski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090037

Device Name: PocketECG-Medicalgorithmics Real-Time ECG Monitor and Arrhythmia Detector

Indications For Use:

The indications for use for the PocketECG monitor are as follows:

1. Patients who have a demonstrated need for cardiac monitoring. These may include but are not limited to patients who require monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease
2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath)
3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susana R. Cruz

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K090037

4. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)
5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring
6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias
7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.
8. Data from the device may be used by another device to analyze, measure or report QT interval. The device is not intended to sound any alarms for QT interval changes.

Contradictions:

1. Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
2. Patients who the attending physician thinks should be hospitalized.

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number_____

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2009

Airstrip Technologies, LP
c/o Mr Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, N W
BUFFALO MN 55313

Re K090061
Trade/Device Name AirStrip OB® Remote Data Viewing software
Regulation Number 21 CFR §884 2740
Regulation Name Perinatal monitoring system and accessories
Regulatory Class II
Product Code HGM
Dated January 8, 2009
Received January 9, 2009

Dear Mr Job

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to. registration and listing (21 CFR Part 807), labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter

21 CFR 876 xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884 xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892 xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K090061

Device Name AirStrip OB® Remote Data Viewing software

Indications for Use

AirStrip OB® is intended to be used by Obstetricians for the following purposes

- To more rapidly and thoroughly respond to a nurse call regarding fetal heart tracings or maternal contraction patterns by viewing the real time waveforms remotely using a Windows-based handheld device
- To proactively review a fetal heart or maternal contraction tracing of a patient in Labor and Delivery for whom they are responsible but are unable to be present in the hospital at that time
- To review the current Labor and Delivery patient census list
- Provide a request for remote consultation regarding a fetal heart tracing
- To remotely review other standard or critical real-time numeric data from Labor and Delivery

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K090061

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801 109)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2009

Airstrip Technologies, LP
c/o Mr. Mark Job
Reviewer
Regulatory Technology Services, LLC
1394 25th Street, N.W.
BUFFALO MN 55313

Re: K090269
Trade/Device Name: AirStrip OB® Remote Data Viewing software
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: February 2, 2009
Received: February 3, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K090269

Device Name AirStrip OB® Remote Data Viewing software

Indications for Use

AirStrip OB® is intended to be used by Obstetricians for the following purposes:

- To more rapidly and thoroughly respond to a nurse call regarding fetal heart tracings or maternal contraction patterns by viewing the real time waveforms remotely using a Windows-based handheld device
- To proactively review a fetal heart or maternal contraction tracing of a patient in Labor and Delivery for whom they are responsible but are unable to be present in the hospital at that time.
- To review the current Labor and Delivery patient census list.
- Provide a request for remote consultation regarding a fetal heart tracing.
- To remotely review other standard or critical real-time numeric data from Labor and Delivery.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K090269

K091168

510(k) Summary **Attachment #4**

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.
The assigned 510(K) Number is not applicable.

MAY 27 2010

Date: May 21, 2010

1. Submitter:

Submitted by:	Infopia Co.,ltd. #891, Hogye-dong, Dongan-Gu Anyang, Kyunggi 431-080, Korea Phone: 82-31-460-0400 Fax: 82-31-0401
Contact:	Bryan Oh Phone: 1-321-267-9911 Fax: 1-321-267-5582

2. Device:

Propriety Name	Glucophone™ Blood Glucose Monitoring System
Common Name	Blood Glucose Test System
Classification Name:	System, test, blood glucose, over the counter Glucose Oxidase Single (specified) analyte controls
Classification:	Class II, 21 CFR 862.1345,
Product Code:	NBW, CGA, JJX

3. Predicate Device:

GlucoPack™ Blood Glucose Monitoring System(HealthPia America Corp.)
K052469
GlucoLab™ Blood Glucose Monitoring System(Infopia co., Ltd.)
K051285

4. Description:

The Glucophone™ Meter device combined with Cell Phone (Motorola v3) is used along with the Glucophone™ Test Strip to measure the glucose level in capillary whole blood.

Test Principle

The principle of the test relies upon a specific type of glucose in the blood sample, the glucose oxidase reacts to electrodes in the test strip. The test strip employs an electrochemical signal generating an electrical current that will stimulate a chemical reaction. This reaction is measured by the Meter and displayed as your blood glucose result.

5. Indications for use:

Glucophone™ Blood Glucose Testing System is for the quantitative measurement of the concentration of glucose in capillary whole blood that can be taken from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh by diabetic patients or healthcare professionals in the home and in clinical setting. Glucophone™ Blood Glucose Testing System is for testing outside the body (in vitro diagnostic use only). GlucoPhone™ Blood glucose Testing system is for use with a cellular phone. GlucoPhone™ Blood glucose Testing system is not for neonatal use and not for diagnosis or screening of diabetes. Alternate site testing is for use during times of steady state.

6. Comparison of Technological Characteristics with Predicate:

The technological characteristics of the new device (Glucophone™) in comparison to two predicate devices (GlucoPack™, GlucoLab™):

The modified Glucophone™ device has the same technological characteristics as the current legally marketed predicate devices: 1. same in the meter device technology with GlucoPack™ Glucose Monitoring System (K052469) By HealthPia America Corp. and 2. same in the strip technology with GlucoLab™ Blood Glucose Monitoring System (K051285) By Infopia co., Ltd..

7. Performance Data:

Clinical: The clinical performance evaluation using the Glucophone™ Blood Glucose Monitoring System components were conducted for the purpose of validating consumer use and professional accuracy. Test results showed substantial equivalence.

Non-clinical: Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the Glucophone™ Blood Glucose Monitoring System with respect to two predicate devices. Testing involved the verification

of software requirement specifications, product requirement specifications and user interface requirement specifications from the risk analysis. The device passed all of the tests based on pre-determined Pass/Fail criteria.

8. Conclusion

The data from the clinical and non clinical tests show that the Glucophone™ Blood Glucose Monitoring System is as safe and effective as the legally marketed predicate devices, the GlucoPack™ and GlucoLab™.

Therefore we conclude that the Glucophone™ Blood Glucose Monitoring System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Infopia Co., Ltd.
C/O Maria Griffin
MDI Consultants, Inc.
55 Northern Blvd. Suite 200
Great Neck, NY 11021

MAY 27 2010

Re: k091168
Trade/Device Name: Glucophone™ Blood Glucose Testing System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: May 21, 2010
Received: May 24, 2010

Dear Ms. Griffin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K091168

Device Name: Glucophone™ Blood Glucose Testing System

Indication For Use:

Glucophone™ Blood Glucose Testing System is for the quantitative measurement of the concentration of glucose in capillary whole blood that can be taken from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh by diabetic patients or healthcare professionals in the home and in clinical setting. Glucophone™ Blood Glucose Testing System is for testing outside the body (in vitro diagnostic use only). GlucoPhone™ Blood glucose Testing system is for use with a cellular phone. GlucoPhone™ Blood glucose Testing system is not for neonatal use and not for diagnosis or screening of diabetes. Alternate site testing is for use during times of steady state.

Prescription Use _____ And/Or Over the Counter Use X .
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k)

K093976
p1/7

510(k) Summary

1.4.1 -- 510(k) Owner

Proteus Biomedical
2600 Bridge Parkway, Suite 101
Redwood City, CA 94065
(650) 632-4031 (tel)
(650) 632-4071 (fax)

MAR 2 5 2010

1.4.2 -- Contact Person

Gregory Moon, MD

1.4.3 -- Date Summary Prepared

February 10, 2010

1.4.4 -- Name of Device

Trade name:	Raisin™ Personal Monitor
Common name:	Physiological Data and Event Logging Device
Classification name:	Cardiovascular Transmitter and Receiver (Product Code DXH)

1.4.5 -- Predicate Devices

HealthePod™ (K083174)
Actiheart® (K052489)
Actiwatch-Score® (K991033)

1.4.6 -- Device Description and Technologic Characteristics

The Raisin™ Personal Monitor (RPM) is a miniaturized, ambulatory, battery-operated data-logging device that is worn on the torso to record heart rate, activity, and patient-logged events.

Patient-logged events can be extrinsic (e.g., dosing of a medication) or intrinsic (e.g., a symptom) and are time-stamped using a manual button on the device, in order to contextualize the physiologic measures. Subjective meaning of these events is assigned by the user. In addition to quantification of physical motion, signals from the device's accelerometer are used to determine body position relative to gravity. Electrode-to-electrode impedance is also measured to assess whether the device is attached properly to the user. RPM recorded data are transferred via Bluetooth telemetry to a general computing device for display and conversion for export to other programs. The RPM is available in two form factors to accommodate individual comfort preferences: one-piece and two-piece. The functionality, intended use, duration and location of wear, and fundamental scientific technologies are exactly the same between the two RPM form factors.

1.4.6.1 -- Basic technologies

Parameter	Sensor Technology	Method
Heart rate	Biopotential low-frequency amplifier	Digitized R wave
Activity	Accelerometer	Digitized accelerometer output
Body angle	Accelerometer	Double integration of accelerometer output
Patient event logging	Patient activated button	Digital pulse
Inter-electrode impedance	Biopotental high-frequency amplifier	Digitized impedance from small auxiliary current

1.4.6.2 – Physical Characteristics

Parameter	Value
Shape	One-piece: ovoid
	Two-piece: triangular
Size	One-piece: 115 x 54 x 12 mm
	Two-piece: 95 x 84 x 10 mm
Weight	50 g
	20 g
Battery type	Rechargeable lithium ion
Moisture susceptibility	Waterproof
Memory	4 MB
Storage temperature	-25 °C to +75 °C
Relative humidity	10% to 90%, not condensing

1.4.6.3 – Theory of Operation

The Raisin™ Personal Monitor acquires, time-stamps and logs digital data corresponding to physiologic signals and patient-marked events. Heart rate, quantified using R-wave frequency, is sensed via three adhesive skin electrodes on the base of the data recorder. Activity data are provided by a 3-axis accelerometer integrated into the RPM. Subjects can mark subjectively defined, personally relevant events by depressing a button on the data recorder. Raisin™ Personal Monitor data are periodically uploaded to a general computing device via Bluetooth telemetry for display and export.

1.4.7 -- Intended Use

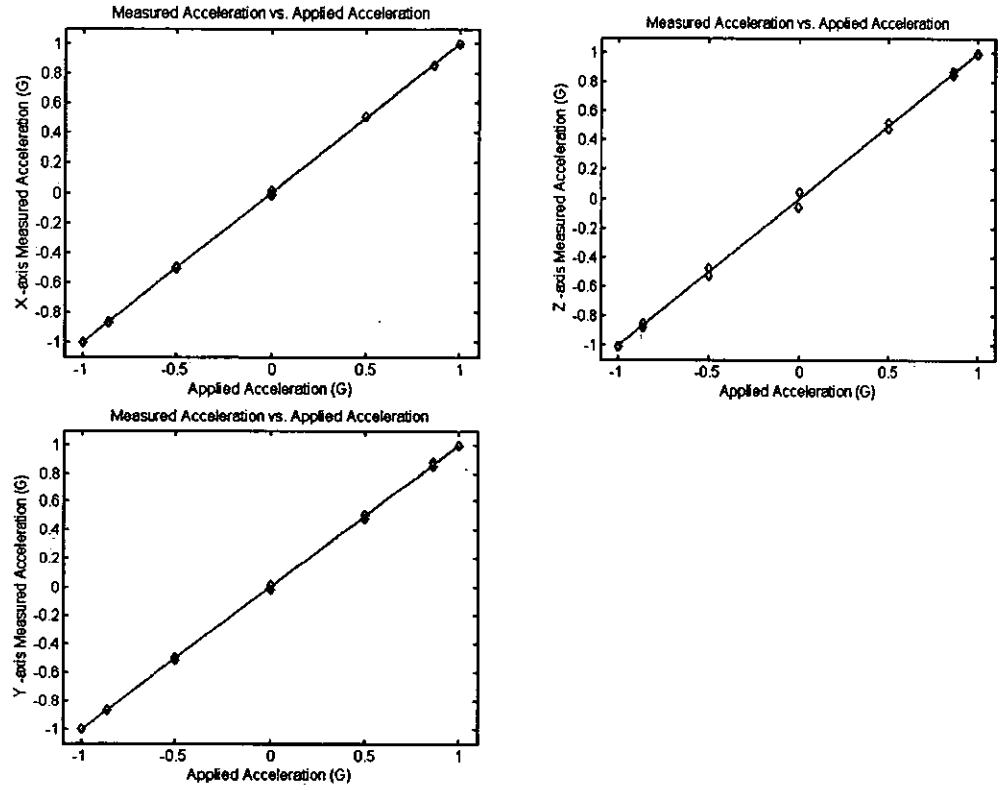
The Raisin™ Personal Monitor is a miniaturized, wearable data-logger for ambulatory recording of heart rate, activity, body angle relatively to gravity, and time-stamped, patient-logged events. The Raisin™ Personal Monitor enables unattended data collection for clinical and research

applications. The Raisin™ Personal Monitor may be used in any instance where quantifiable analysis of event-associated heart rate, activity, and body position is desirable.

1.4.8 -- Summary of Non-Clinical Performance Data

The three-axis accelerometer provides motion and position data and is validated against a known acceleration applied against each of its three axes.

The figure below shows bench validation of the accelerometer in all three of its axes.



The biopotential low-frequency amplifier is used to quantify heart rate by measuring R-wave frequency. The table below shows R-wave detection validation results, based upon a modified Hamilton-Tompkins algorithm, tested using guidelines set forth in the ANSI/AAMI EC 13 standard.

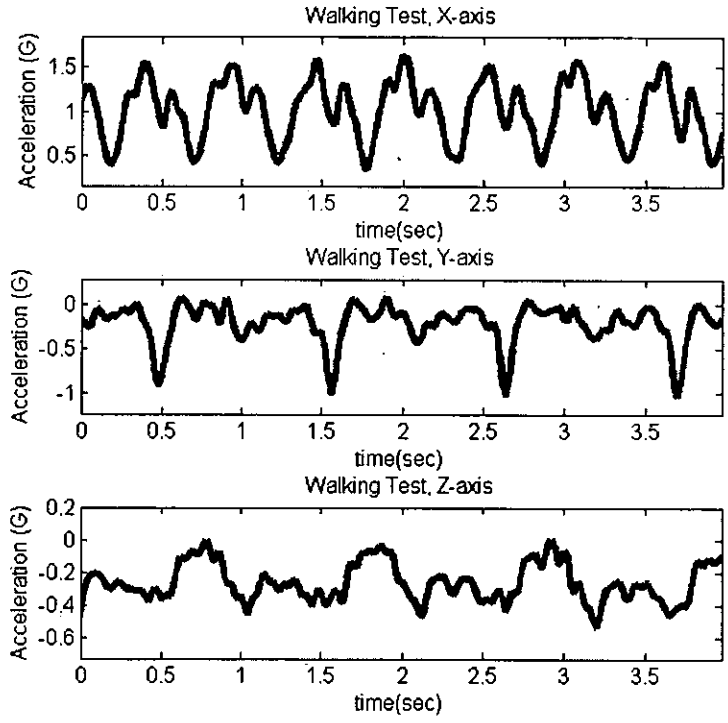
Test Description	Expected Results (bpm)	Algorithm Results (bpm)
Default ECG waveform	80	80.0
T-wave rejection R-wave amplitude of 1 mV T-wave amplitude of 0.4 mV	80	80.0
Ventricular bigeminy	80	79.9
Slow alternating ventricular bigeminy	60	60.5
Rapid alternating ventricular bigeminy	120	119.8
Bidirectional systoles	90	90.1
Default ECG waveform Pacing pulse with 2 mV amplitude, 2 ms width	80	80.0

The table below shows validation testing results of R-wave detection during arrhythmia. Raisin™ Personal Monitor-reported R-wave locations were compared with annotated R-wave locations in all 48 test files from the MIT-BIH arrhythmia database.

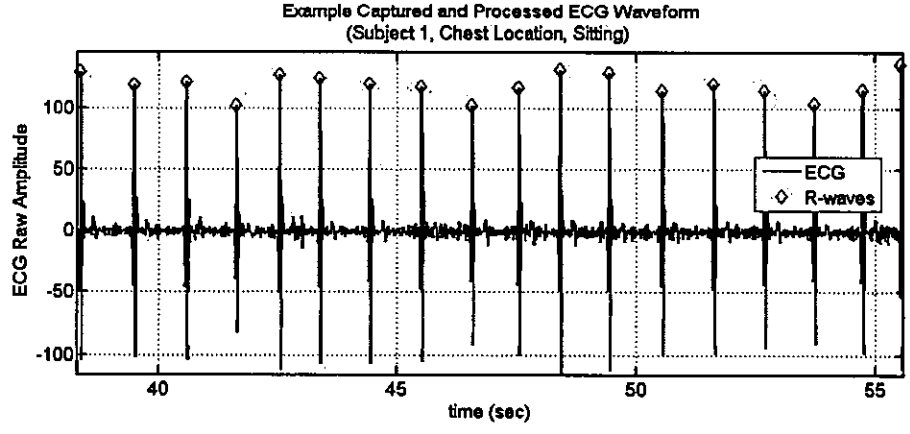
Metric	Median	Standard Deviation
Positive Detection Accuracy	99.7%	5.9%
False Positive Rate	0%	1.7%

1.4.9 -- Summary of Clinical Performance Data

The three-axis accelerometer was also validated clinically by assessing subject movement, in this case walking, to assess capture of expected features. The figure below demonstrates data from a representative walking test.



The figure below shows a representative subject ECG captured by the RPM, with the automatically identified R-waves highlighted.



The table below shows robust R-wave detection accuracy when heart rate data were collected from different body locations.

	Anterior Chest	Xyphoid	Stomach	Lateral Chest
Subject 1	100	99.72	-	-
Subject 2	99.30	99.00	99.24	99.61
Subject 4	99.14	98.58	99.31	98.05
Subject 5	99.14	99.37	98.66	98.81
Average R-wave detection accuracy	**99.40**	**99.17**	**99.07**	**98.82**

1.4.10 -- Conclusions

The Raisin™ Personal Monitor (RPM) is a small, ambulatory, battery-operated data-logging device that is worn on the chest surface to record heart rate, activity, body angle relative to gravity, and patient-logged events. Patient-logged events are used to contextualize the physiologic measures. The RPM's functionality has been validated in non-clinical and clinical testing as summarized above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 2 5 2010

Proteus Biomedical, Inc.
c/o Gregory Moon, M.D.
Director of Clinical Affairs
2600 Bridge Parkway, Suite 101
Redwood City, CA 94065

Re: K093976
Trade/Device Name: Raisin™ Personal Monitor
Regulatory Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: II (two)
Product Code: 74 DXH
Dated: February 26, 2010
Received: March 2, 2010

Dear Dr. Moon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093976

Indications for Use

510(k) Number (if known): K093976

Device Name: Raisin™ Personal Monitor

Indications for use:

The *Raisin™ Personal Monitor* is a miniaturized, wearable data-logger for ambulatory recording of heart rate, activity, body angle relatively to gravity, and time-stamped, patient-logged events. The *Raisin™ Personal Monitor* enables unattended data collection for clinical and research applications. The *Raisin™ Personal Monitor* may be used in any instance where quantifiable analysis of event-associated heart rate, activity, and body position is desirable.

Prescription Use ✓ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093976

Premarketing Notification

Traditional 510(k) Submission

DEC - 3 2010

Submission date:	December 31, 2009
Submitter	Zephyr Technology Corporation 1 Annapolis Street Suite 200 Annapolis, Maryland 21401
Contact Person:	Code Cubitt Chief Operating Officer Telephone: +1 (443) 569 3603 Fax: +1 (443) 926 9402
Common Name:	Ambulatory Patient Monitor
Trade Name:	BioHarness
Classification Name:	21CFR 870 1025
Establishment Registration Number:	
Product code:	MHX
Device Class:	Class II

1 GENERAL INFORMATION

This document contains the Premarket Notification for Zephyr Technology Corporation's BioHarness product. The BioHarness is an ambulatory patient monitor and provides remote vital signs monitoring for subjects in healthcare, occupational and home settings.

Zephyr's recommended classification for the BioHarness is as a class II medical device under regulation 21 CFR 870.1025 with product code MHX. The BioHarness product is a new medical device based on a legacy non-medical product already marketed by Zephyr. The intended use and technological characteristics of the BioHarness are the same as that of an existing legally marketed medical device manufactured by Hidalgo Ltd, the Equivital EQ-10 Vital Signs Physiological Monitor (K061993).

Zephyr Technology Corporation is a developer and manufacturer of real-time monitoring solutions for defense, emergency responder, training and research markets. Based in Annapolis, Maryland, Zephyr leverages a world class team of engineers, scientists, physiologists and business experts. Local universities and government labs augment Zephyr's internal development in specialized areas such as materials science, garment and textile design, sports science, physiological monitoring and software / web applications. Zephyr Technology Ltd, a wholly-owned R&D subsidiary of Zephyr Technology Corporation, is located in Auckland, New Zealand.

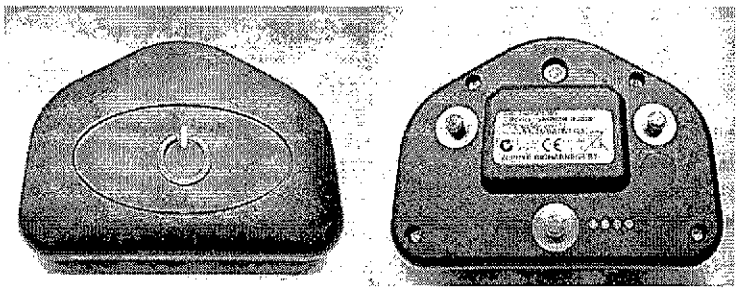
3/12

2 PROPOSED LABELLING

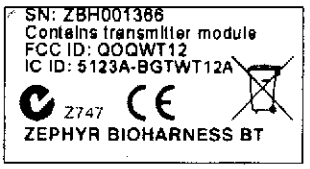
2.1 User Documentation

The user manual is available. "Zephyr Technology BioHarness Bluetooth User Manual"

Images of labels on the device are shown below.



Front and rear view of BioHarness device



Rear label

2.2 Carton Label

The BioHarness ships in a package 25.5cm x 16.5cm x 4.5cm. The figures below show the package labelling.

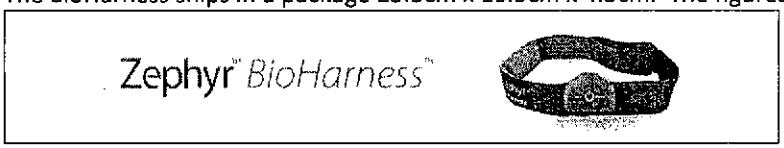


Figure 3.2.1 – BioHarness Carton Top

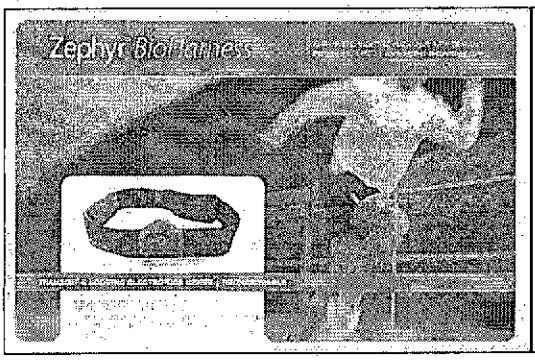


Figure 3.2.2 – BioHarness Carton Front

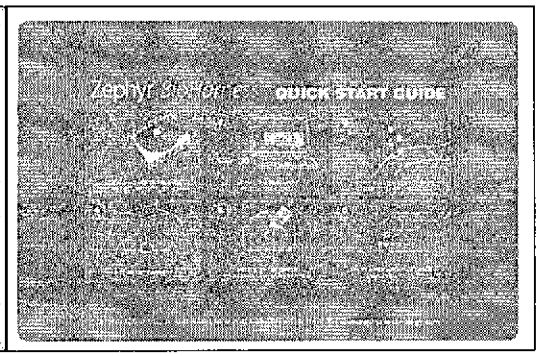


Figure 3.2.3 – BioHarness Carton Rear

Figure 3.2.4 – BioHarness Carton Bottom

3 SUBSTANTIAL EQUIVALENCE

The BioHarness and the Hidalgo Equivital EQ-10 Vital Signs Physiological Monitor are each ambulatory physiological monitoring devices capable of storing and transmitting multiple physiological parameters. Each of these devices is composed of two main components, a chest strap and a battery-powered electronics module. Both chest straps are used to sense heart electrical activity, thoracic movement and skin temp.

The physiological monitoring device presented in this 510(k) submission (BioHarness) is substantially equivalent to the physiological monitor marketed as the Hidalgo Equivital EQ-10 Vital Signs Physiological Monitor (K061993). Additional predicate devices include:

Respironics	Actiheart	K052489
VivoMetrics	LifeShirt Real Time	K043604
GMP|Wireless Medicine	LifeSync	K030795

A summary of similarities and differences between BioHarness and predicate devices are presented in the table below.

Table 5.1: Comparison To Predicate

Function	BioHarness	Predicate 1	Predicate 2
Heart Rate	A single-ended amplifier senses heart electrical activity through a chest strap with conductive fabric electrodes. The device filters and converts signal to digital form. The output is a digital value that corresponds to heart beats per minute.	Hidalgo Equivital EQ-10 K061993 Heart rate is derived from ECG sensed through a chest belt. A secondary measurement of R wave is also available.	Respironics Actiheart K052489 A differential amplifier senses and amplifies ECG through electrodes. The output is a digital value that corresponds to heart beats per minute.
Respiration Rate	Respiration rate is inferred from thoracic movement sensed by a chest strap containing a proprietary capacitive sensor. The thoracic movement waveform is amplified, digitized and analyzed to determine respiration rate.	Hidalgo Equivital EQ-10 K061993 Respiratory breathing frequency is inferred from thoracic cavity movement sensed by a chest belt containing an expansion sensor.	VivoMetrics LifeShirt Real Time K043604 Respiratory rate is derived from signals sensed via torso vest with embedded respiratory inductive plethysmography bands.
Skin Temperature	Measurement of skin temperature on the chest is performed with an integrated infrared thermometer.	Hidalgo Equivital EQ-10 K061993 Skin surface temperature.	
Activity/Body Orientation	The signal from an internal tri-axis accelerometer is digitized and analyzed using proprietary algorithms to determine activity and body orientation.	Hidalgo Equivital EQ-10 K061993 Activity and motion detection using a tri-axis accelerometer.	Respironics Actiheart K052489 The signal from an internal tri-axis accelerometer is used to detect motion.
Bluetooth Telemetry	An internal Bluetooth communications module is used to transmit digital physiological data.	Hidalgo Equivital EQ-10 K061993 Transmission of ECG data over Bluetooth.	GMP|Wireless Medicine LifeSync K030795 Transmission of ECG data over Bluetooth link.

4 510(K) EXECUTIVE SUMMARY

1.	Submitter:	Zephyr Technology Corporation 1 Annapolis Street Suite 200 Annapolis, Maryland 21401
2.	Contact Person:	Code Cubitt Chief Operating Officer Telephone: +1 (443) 569 3603 Fax: +1 (443) 926 9402
3.	Date submitted:	December 31, 2009
4.	Trade Name:	BioHarness
5.	Common Name:	Ambulatory Patient Monitor
6.	Classification Name:	21CFR 870 1025 Product code: MHX
7.	Predicate Device	Hidalgo Equivital EQ-10 (K061993) VivoMetrics LifeShirt Real Time (K043604) Respironics Actiheart (K052489) GMP|Wireless Medicine LifeSync K030795
8.	Substantial Equivalence Statement	The Zephyr Technology BioHarness is substantially equivalent in intended use to the Hidalgo Equivital EQ-10. The intended use and application of the proposed device are substantially equivalent to the legally marketed predicate device currently on the market.
9.	Device description	The BioHarness is a compact physiological monitor that consists of two components: 1. A chest strap with conductive fabric skin electrodes and a thoracic expansion sensor. 2. A battery-powered electronics module that attaches to the chest strap.

6/12

The device provides both storage and real-time transmission of the user's Heart Rate and Respiration Rate. The device uses heart electrical activity signals and respiratory breathing frequency inferred from thoracic movement to derive the Heart Rate and Respiration Rate.

The device also provides the following physiological measures:

- An indication of the user's activity level based on acceleration measured by an internal triaxial accelerometer.
- Body orientation
- Thoracic skin temperature.
- Alerts if physiological conditions exceed predefined thresholds.

An accessory cradle is provided to recharge the internal battery and transfer internally stored data to a computer.

The transmitted data provided by the device over Bluetooth may be integrated into third party monitoring applications.

10. Intended use

The BioHarness is a physiological monitoring telemetry device intended for monitoring of adults in the home, workplace and alternate care settings. The device consists of a chest strap and an electronics module that attaches to the strap. The device stores and transmits vital sign data including heart rate, respiration rate, thoracic skin temperature, body orientation and activity.

The BioHarness collects and transmits measurements captured during both sedentary as well as rigorous activity for Heart Rate, Skin Temperature, Posture and Activity. Breathing rate values are accurately transmitted only during sedentary periods.

The BioHarness is indicated for use as a general patient monitor to provide physiological information as part of an occupational welfare monitoring system, and for general research and performance measurement purposes.

11. Technological characteristics

Substantial equivalence has been measured by review and comparison of performance data for the following. The technological characteristics compare to the following predicates:

Function	Predicate 1	Predicate 2
Heart Rate	Hidalgo Equivital EQ-10 K061993	Respironics Actiheart K052489
Respiration Rate	Hidalgo Equivital EQ-10 K061993	VivoMetrics LifeShirt Real Time K043604

Skin Temperature	Hidalgo Equivital EQ-10 K061993	
Activity/Body Orientation	Hidalgo Equivital EQ-10 K061993	Respironics Actiheart K052489
Bluetooth Telemetry	Hidalgo Equivital EQ-10 K061993	GMP|Wireless Medicine LifeSync K030795

12. Performance data

Performance measurement and review to the applicable sections of the following standards has been conducted and successfully demonstrated as recommended by available guidance from the agency:

ANSI/AAMI ES60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

ANSI/AAMI/IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests.

ANSI/AAMI/ISO 10993-1:2003, Biological evaluation of medical devices – Part 1: Evaluation and testing.

ANSI/AAMI EC13:2002/(R) 2007, Cardiac monitors, heart rate meters, and alarms. The device provides function as a heart rate meter, but is not indicated for use as an ECG monitor.

ASTM E1965 - 98(2009) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.

Reviews and tests have also been carried out for general functionality and performance of the BioHarness.

Software has been developed using a structured software development process which meets the requirements of IEC 60601-1-4:1996/(R)2005, Medical electrical equipment - Part 1: General requirements for safety. 4. Collateral Standard: Programmable electrical medical systems.

14. Conclusion

This pre-market notification has shown the substantial equivalence of the BioHarness to the identified predicates, by comparison to the descriptive material and performance testing of the device.

8/12

5 DESCRIPTION OF DEVICE

The BioHarness is a compact physiological monitor that consists of two components:
1. A chest strap with conductive fabric skin electrodes and a thoracic expansion sensor.
2. A battery-powered electronics module that attaches to the chest strap.

The device provides both storage and real-time transmission of the user's Heart Rate, Respiration Rate, Temperature, Posture and Activity Level. The device uses heart electrical activity signals and respiratory breathing frequency inferred from thoracic movement to derive the Heart Rate and Respiration Rate respectively.

An accessory cradle is provided to recharge the internal battery and transfer internally stored data to a computer.

The transmitted data provided by the device over Bluetooth may be integrated into third party monitoring applications. A simple software utility that displays vital sign data is provided. Users may transmit vital sign data from the BioHarness to the application on a PC via Bluetooth using the Bluetooth adapter.

The figures below show the BioHarness and accessories.

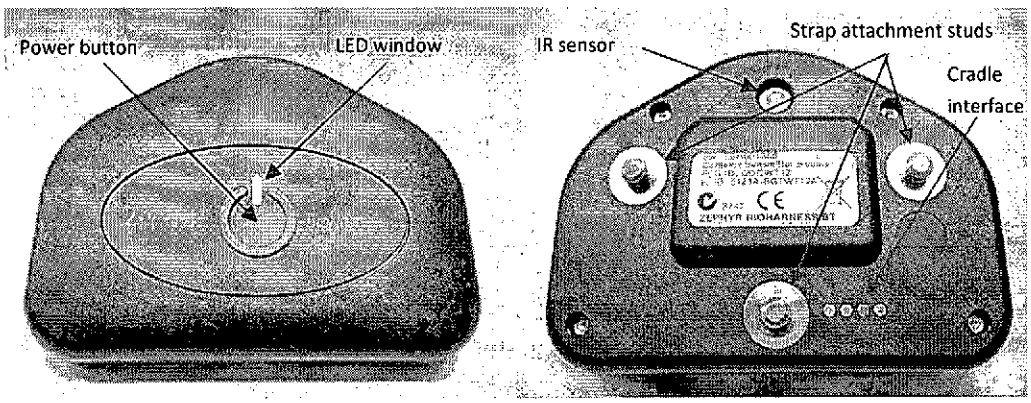


Figure 7.1 – BioHarness, external front and rear views

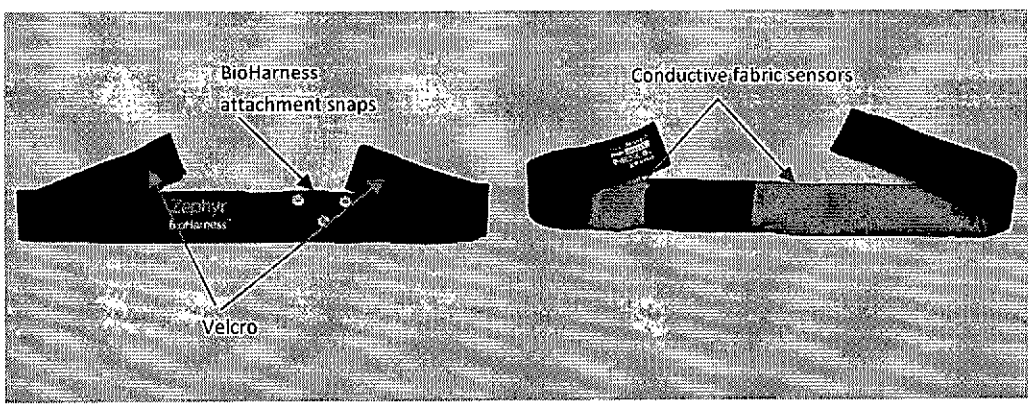


Figure 7.2 – BioHarness strap, front and rear views

9/12

6 TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the BioHarness are described in the following sections.

6.1 General Functionality

The BioHarness stores and transmits physiological data including heart rate, respiration rate, thoracic skin temperature, body orientation and activity level. The digital data are derived from physiological signals acquired from the user through the chest strap for heart rate and respiration rate. An infrared sensor is used to measure skin temperature on the user's chest. The user's activity and body orientation are derived from accelerometry signals from an internal triaxial accelerometer. Data may be transmitted over Bluetooth to a computer. The BioHarness has an internal rechargeable lithium polymer battery.

A. Heart Rate

The BioHarness monitors electrical signals produced by the heart through a chest strap with conductive fabric skin electrodes and derives heart rate based on proprietary analysis of the QRS complex. The BioHarness is not an ECG monitor and provides no analysis capability in cases of abnormal QRS complex. The chest strap uses conductive lycra fabric to form a sensor, measuring electrical activity in the V4 lead position (fifth intercostals space in the midclavicular). A single-ended ECG circuit is used to detect QRS complexes. The circuit incorporates ESD protection, both passive and active filtering and an ADC to convert the signal to a digital representation. Proprietary digital filtering and signal analysis is performed on the signal with a microcontroller circuit to derive heart rate.

B. Respiration Rate

The BioHarness monitors thoracic movement (chest expansion and contraction) through a chest strap containing a proprietary capacitive sensor. The capacitive sensor is composed of layers of conductive fabric, foam and flexible mylar (dielectric). The sensor capacitance is driven with a low-level 500kHz PWM signal. Thoracic expansion and contraction cause changes in capacitance which in turn result in changes in impedance causing the amplitude of the drive signal to vary. The BioHarness respiration circuit detects, filters and amplifies this change in amplitude to produce a varying voltage signal that represents thoracic movement. The signal is passed to an ADC and proprietary digital filtering and signal analysis is performed with a microcontroller circuit to derive respiration rate. Respiration rate is inferred by thoracic movement measured via the capacitive sensor and circuit.

C. Skin Temperature

The BioHarness uses an infrared thermometer to perform non-contact temperature measurements on user's chests. The infrared thermometer is mounted internal to the device, but has a viewing window that faces the user's chest. The Hidalgo uses a thermistor in the sensor module near an ECG electrode to measure skin temperature. Both sensors provide similar accuracy in temperature measurement.

D. Body Orientation

The BioHarness measures body orientation by proprietary analysis of acceleration values output by an internal precision triaxial accelerometer and provides a measure of user posture (upright, supine, prone) in degrees from vertical. The Hidalgo device calculates body orientation using three orthogonal accelerometer channels.

E. Activity

The BioHarness measures activity level by proprietary analysis of acceleration values output by an internal precision triaxial accelerometer (Analog Devices ADXL330 3-axis +/-3 g iMEMS) and provides activity level in Vector Magnitude Units (VMU). The Hidalgo device calculates activity using three orthogonal accelerometer channels.

6.2 Basic Safety and Essential Performance

The BioHarness meets the relevant requirements of ANSI/AAMI ES60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

1. Electrical Safety

A review of ANSI/AAMI ES60601-1:2005 has been conducted with respect to electrical hazards, with specific attention given to the relevant subclauses in clauses 8, 13 and 4. The risks associated with electrical hazards were assessed in accordance with Zephyr's risk management procedure. The subclauses relevant for Zephyr's device are discussed below.

2. Mechanical Safety

A review of ANSI/AAMI ES60601-1:2005 has been conducted with respect to mechanical hazards, with specific attention given to the relevant subclauses in clauses 9, 13 and 4. The risks associated with mechanical hazards were assessed in accordance with Zephyr's risk management procedure. The subclauses relevant for Zephyr's device are discussed below.

3. Radiation Hazards

A review of ANSI/AAMI ES60601-1:2005 has been conducted with respect to radiation hazards, with specific attention given to the relevant subclauses in clauses 10, 13 and 4. The risks associated with these hazards were assessed in accordance with Zephyr's risk management procedure. The subclauses relevant for Zephyr's device are discussed below.

4. Temperature and Other Safety Concerns

A review of ANSI/AAMI ES60601-1:2005 has been conducted with respect to excessive temperatures and other hazards, with specific attention given to the relevant subclauses in clauses 11, 13 and 4. The risks associated with these hazards were assessed in accordance with Zephyr's risk management procedure.

5. Accuracy of Controls and Protection Against Hazardous Outputs

A review of ANSI/AAMI ES60601-1:2005 has been conducted with respect to accuracy of controls and instruments and protection against hazardous outputs, with specific attention given to the relevant subclauses in clauses 12, 13 and 4. The risks associated with these hazards were assessed in accordance with Zephyr's risk management procedure

6. Hazardous Situations and Fault Conditions

A review of ANSI/AAMI ES60601-1:2005 has been conducted with respect to hazardous situations and fault conditions, with specific attention given to the relevant subclauses in clauses 13 and 4. The risks associated with these hazards were assessed in accordance with Zephyr's risk management procedure.

7. Construction of ME Equipment

A review of ANSI/AAMI ES60601-1:2005 has been conducted with respect to construction of ME Equipment, with specific attention given to the relevant subclauses in clauses 15, 13 and 4. The risks associated with these hazards were assessed in accordance with Zephyr's risk management procedure.

8. Electromagnetic Compatibility

The BioHarness has been tested and shown to be compliant with electromagnetic compatibility requirements in the US (FCC) and the EU (R&TTE Directive).

The BioHarness complies with FCC Part 15 Subparts A and B as a Class B Unintentional Radiator (using methods described in ANSI C63.4 – 2003). The BioHarness also complies with the essential requirements of the R&TTE Directive. The BioHarness complies with EN 301 489-17 V1.2.1 (2002-08) when tested in accordance with EN 301-489-1 V1.6.1 (2005-09).

The AC Adapter complies with the requirements of the electrical safety standard AS/NZS 60950.1:2003 + A1 + A2 + A3.

9. Biocompatibility

The BioHarness meets the relevant requirements of ANSI/AAMI/ISO 10993-1:2003, Biological evaluation of medical devices – Part 1: Evaluation and testing.

10. Cardiac monitoring

The BioHarness meets the relevant requirement for heart rate metering in ANSI/AAMI EC13:2002/(R) 2007, Cardiac monitors, heart rate meters, and alarms.

11. Infrared Thermometry

The BioHarness meets the relevant requirements of ASTM E1965 - 98(2009), Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.

12. Software

The BioHarness software has been developed using a structured software lifecycle which meets the requirements of IEC 60601-1-4:1996/(R)2005, Medical electrical equipment - Part 1: General requirements for safety. 4. Collateral Standard: Programmable electrical medical systems.

7 PERFORMANCE DATA

Reviews and tests have been carried out for general functionality and performance of the BioHarness.

Additional performance measurement and review to the applicable sections of the following standards has been undertaken and successfully demonstrated as recommended by available guidance from the agency:

ANSI/AAMI ES60601-1:2005, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

ANSI/AAMI/IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests

ANSI/AAMI/ISO 10993-1:2003, Biological evaluation of medical devices – Part 1: Evaluation and testing

ANSI/AAMI EC13:2002/(R) 2007, Cardiac monitors, heart rate meters, and alarms

ASTM E1965 - 98(2009) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature

The BioHarness software has been developed using a structured software lifecycle which meets the requirements of IEC 60601-1-4:1996/(R)2005, Medical electrical equipment - Part 1: General requirements for safety. 4. Collateral Standard: Programmable electrical medical systems

7.1 General Functionality

General functionality of the BioHarness has been reviewed and tested iteratively throughout the development cycle. Devices and accessories are also tested as part of the production process.

Development testing of BioHarness functionality has occurred at the bench level and under simulated field conditions (i.e. field trials).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Zephyr Technology Corporation
c/o Mr. Code Cubitt
Chief Operating Officer
1 Annapolis Street, Suite 200
Annapolis, MD 21401

DEC - 3 2010

Re: K100040
Trade/Device Name: BioHarness
Regulation Numbe r: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: Undated
Received: December 1, 2010

Dear Mr. Cubitt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEC - 3 2010

ZEPHYR TECHNOLOGY BIOHARNESS

INDICATIONS FOR USE STATEMENT

510(k)Number (If Known): K100040

Device Name: BioHarness

Indications for Use:

The BioHarness is a physiological monitoring telemetry device intended for monitoring of adults in the home, workplace and alternate care settings. The device consists of a chest strap and an electronics module that attaches to the strap. The device stores and transmits vital sign data including heart rate, respiration rate, thoracic skin temperature, body orientation and activity.

The BioHarness collects and transmits measurements captured during both sedentary as well as rigorous activity for Heart Rate, Skin Temperature, Posture and Activity. Breathing rate values are accurately transmitted only during sedentary periods.

The BioHarness is indicated for use as a general patient monitor to provide physiological information as part of an occupational welfare monitoring system, and for general research and performance measurement purposes.

Prescription Use <√> AND/OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence by CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100040

510(k) Summary

General Information:

JUL 15 2010

Date of Summary Preparation:	June 10, 2010
Name and Address of Manufacturer:	WellDoc, Inc. 1501 St Paul Street, Suite 118 Baltimore, MD 21217
Contact Person:	Ryan Sysko Chief Executive Officer Telephone (443) 692-3101 Fax (444) 269-0272
Trade Names:	DiabetesManager® System DiabetesManager®-Rx System
Common Names:	Medical computers and software Infusion pump accessories
Regulation Numbers:	LNX is unclassified and therefore has no regulation number 21 CFR 880.5725 (Infusion Pump)
Classification Names:	Medical computers and software Infusion pump
Regulatory Class:	II
Classification Panel:	General Hospital
Product Codes:	LNX MRZ
Predicate Devices:	K043529 ACCU-CHEK®-Advisor Insulin Guidance Software K080227 ACCU-CHEK®-360° Diabetes Management System

Indications for Use:

DiabetesManager® (OTC Use): The WellDoc DiabetesManager® System is indicated for use by healthcare providers (HCPs) and their adult patients – aged 21 years and older – who have type 2 diabetes. The DiabetesManager® System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager® System analyzes and reports blood glucose test results and supports medication adherence. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.
The DiabetesManager® System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

DiabetesManager®-Rx (Prescription Use): The WellDoc DiabetesManager®-Rx System is indicated for use by healthcare providers (HCPs) and their adult patients – aged 21 years and older – who have type 2 diabetes. The DiabetesManager®-Rx System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager®-Rx System analyzes and reports blood glucose test results and supports medication adherence. In addition, the DiabetesManager®-Rx System provides coaching messages (motivational, behavioral, and educational) based on real-time blood glucose values and trends. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.
The DiabetesManager®-Rx System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

Device Description:

The DiabetesManager System (Version 1.1) is a stand-alone, over-the-counter (OTC) software system that has the capability of providing additional functions, if and when, the functions are prescribed by the prescribing healthcare provider. Once the additional prescription (Rx) functions are activated, the entire software system is called DiabetesManager-Rx® System (Version 1.1).

Both DiabetesManager System and DiabetesManager-Rx System are implemented through an enterprise such as a health plan or large physician group in tandem with healthcare providers (HCPs) and are comprised of a Mobile application (patient only) and Web-based applications for the patient, account director (AD), and healthcare provider(s). The applications are called:

- Account Director Web-Based Application
- Patient Mobile Based Application
- Patient Web-Based Application
- HCP Web-based Application

The Account Director application is used for administrative purposes. The HCP application is used by healthcare providers to review patient entered data and the prescribing healthcare provider can activate the Rx system for the patient.

Patient Applications

The Patient Web-based application and the Patient Mobile application have a similar feature set. Data entered into these applications is stored in the database and can be retrieved for display in either application. Both applications require the initial web-based registration before the patient can access them. Patients are identified by healthcare providers and invitations to register are sent by Account Directors.

On the patient applications (Mobile and Web-based), the basic DiabetesManager System functions as an information repository (logbook and Personal Health Record-PHR), diabetes education resource (learning library and health tips), and secure communication system (Message Center). If and when a prescription is obtained, additional functions become available to the patient as DiabetesManager-Rx System. Prescription functions include additional medication information (dose and schedule), coaching (BG real-time coaching feedback), messaging (Message Center Content), and workflow and decision support for healthcare providers.

Performance Data:

Human factors study results and software verification and validation (documented in accordance with FDA's "Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices") were provided and supported substantial equivalence.

Substantial Equivalence:

The DiabetesManager and DiabetesManager-Rx include indications for use that are similar to and consistent with those of the predicate devices, do not impact safety or effectiveness, and have the same intended uses as the predicate devices. Additionally, the DiabetesManager and DiabetesManager-Rx's technological characteristics are similar to and consistent with those of the predicate devices, e.g., all include software applications that provide data capture, storage, transmission, analysis and reporting of blood glucose (BG) values; all have data analysis and review features that provide BG trends and statistics; the DiabetesManager, DiabetesManager-Rx and ACCU-CHEK® 360° identify, analyze and display in- and out-of- target BG and historical lab values. Additionally, the ACCU-CHEK® Advisor provides directions which are similar to directions that physicians provide to patients as part of routine clinical practice. Likewise, the self management messages in the DiabetesManager and the blood glucose feedback and trend messages in the DiabetesManager-Rx are similar to directions that physicians provide to patients as part of routine clinical practice and are based on evidence-based standards of care. Minor technological differences do not impact safety or effectiveness as compared to the predicate devices. Therefore, DiabetesManager and DiabetesManager-Rx are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Ryan Sysko
Chief Executive Officer
WellDoc, Incorporated
1501 Saint Paul Street, Suite 118
Baltimore, Maryland 21202

JUL 15 2010

Re: K100066
Trade/Device Name: WellDoc DiabetesManager ® System and DiabetesManager ® Rx System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ , LNX
Dated: June 14, 2010
Received: June 15, 2010

Dear Mr. Sysko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment A: Revised Indications for Use

Indications for Use

510(k) Number (if known): _____

Device Name: WellDoc DiabetesManager® System and DiabetesManager® -Rx System

Indications for Use:

DiabetesManager (OTC Use):

The WellDoc DiabetesManager® System is indicated for use by healthcare providers (HCPs) and their adult patients – aged 21 years and older – who have type 2 diabetes. The DiabetesManager System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager System analyzes and reports blood glucose test results and supports medication adherence. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.

The DiabetesManager System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

DiabetesManager-Rx (Prescription Use):

The WellDoc DiabetesManager -Rx System is indicated for use by healthcare providers (HCPs) and their adult patients – aged 21 years and older – who have type 2 diabetes. The DiabetesManager-Rx System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager -Rx System analyzes and reports blood glucose test results and supports medication adherence. In addition, the DiabetesManager -Rx System provides coaching messages (motivational, behavioral, and educational) based on real-time blood glucose values and trends. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information. The DiabetesManager-Rx System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K100066

K100133

510(k) Summary

Date:	May 25, 2010
Submitter:	AirStrip Technologies Inc. 3303 Oakwell Court #120 San Antonio, TX 78218
Contact Person:	Andy Miller Director, QA/RA Phone: 210-805-0444 Fax: 210-805-0446 E-Mail: andymiller@airstriptech.com
Trade Name:	AirStrip RPM
Common/Usual Name:	Doctor's Remote Data Viewing Software
Classification Reference:	Patient monitoring software has been classified as Class II, 870.2300. The classification panel 870: Cardiovascular. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for remote data viewing of cardiovascular data.
Predicate Devices:	GE Pocket Viewer (K061994) Cerner iBus (K093134)

JUL 2 3 2010

Device Description

AirStrip RPM is software that runs on devices capable of running Apple iPhone OS. It interfaces with third-party centralized monitoring systems that in turn gather data from patient monitors and other devices in the hospital. AirStrip RPM gives health care providers the ability to view near-real-time patient physiological data remotely.

Predicate Devices

The AirStrip RPM client is substantially equivalent to two FDA cleared devices. The GE Pocket Viewer (K061994) device provides the ability for the clinician to view real-time waveforms and other physiological patient data via Windows Mobile based PDA Smart Phones. Pocket Viewer works by retrieving patient data from the hospital monitoring system and providing that data to the end user's device via WiFi or cellular modem over the Internet. This is the same approach used for the AirStrip RPM product.

Physiological parameters that will be displayed by AirStrip RPM are collected through the Cerner iBus (K093134), which is listed as a predicate device to AirStrip RPM. These physiological parameters include ECG, invasive blood pressure, non-invasive blood pressure, heart rate, pulse oximetry and carbon dioxide. The complete list of physiological parameters captured is included in the Indications for Use below.

K100133

In addition to physiological data, the iBus provides other patient data such as patient demographics and other non-physiological Electronic Medical Record (EMR) data. This data will also be made available through AirStrip RPM.

Indications for Use

AirStrip RPM is software capable of displaying physiologic and other patient information. This information is generated by other medical devices and patient information system, and not by AirStrip RPM. AirStrip RPM captures this information from these other systems and displays it for clinicians.

AirStrip RPM is intended to be used by clinicians for the following purposes:

- By using a cellular telephone or other device on which AirStrip RPM is installed, to review physiologic data of a patient when the clinician is not at the hospital
- To view the near real-time waveforms remotely
- To remotely review other standard or critical near real-time patient data from the monitored system
- To provide a request for remote consultation regarding a patient's waveform or other data

The AirStrip RPM software can display the following the physiologic data captured by other medical devices:

- ECG Waveform
- Blood Pressure Waveform
- O2 Waveform
- CO2 Waveform
- Heart Rate
- Respiratory Rate
- Oxygen Saturation
- Intracranial Pressure
- Central Venous Pressure
- Pulmonary Capillary Wedge Pressure
- Cardiac Index
- Cardiac Output
- Cerebral Perfusion Pressure
- Urine Output
- Urine/Stool Mix Output
- Systolic Blood Pressure Invasive
- Mean Arterial Pressure Invasive
- Diastolic Blood Pressure Invasive
- Systolic Blood Pressure Cuff
- Mean Arterial Pressure Cuff
- Diastolic Blood Pressure Cuff
- Vasoactive Infusions

K100133

- Antiarrhythmics
- Sedation
- Paralytics
- Laboratory Data including
  - Blood Gas
  - Chemistry
  - Hematology
  - Coagulation
- Allergies
- Medications

Contraindications

AirStrip RPM software is intended for installation on cellular telephones and other wireless devices, and is not intended for use anywhere cellular telephones or wireless devices are prohibited.

Substantial Equivalence

AirStrip Technologies identified GE's Pocket Viewer and Cerner's iBus, formerly known as MDBus, as predicate devices to AirStrip RPM.

Pocket Viewer was originally submitted by Datex-Ohmeda and cleared by the FDA on October 29, 2003 through 510(k) K033078. A subsequent Pocket Viewer 510(k) submission submitted by GE was cleared by the FDA on January 20, 2006 through 510(k) number K052975. A third Pocket Viewer 510(k) submission submitted by GE was cleared by the FDA on August 11, 2006 through 510(k) number K061994. Further, the Pocket Viewer clearance is based on substantial equivalence to the Datex-Ohmeda Network and Central device which was cleared by the FDA on July 13, 2000.

Cerner's iBus was cleared by the FDA on November 27, 2009 through 510(k) K093134.

Device description and Substantial Equivalence Comparison between AirStrip RPM and the predicate devices, Pocket Viewer and iBus, are captured below.

Device Description and Comparison

AirStrip RPM is a software application that interfaces with centralized monitoring systems in hospitals to allow health care professionals the ability to view near real-time patient data remotely. The AirStrip RPM platform is designed around a reusable architecture allowing display of any waveform or other patient data through the creation of an adapter to allow for data exchange with patient monitoring systems.

The AirStrip RPM client is substantially equivalent to the FDA cleared GE Pocket Viewer device which received initial FDA clearance as a Datex-Ohmeda product on October 29, 2003 through 510(k) K033078. The most recent FDA clearance for Pocket Viewer was granted in 510(k) number K061994 on August 11, 2006. GE Pocket Viewer provides the ability for the clinician to view real-time waveforms and other physiological patient data via Windows Mobile based PDA

K100133

Smart Phones. Pocket Viewer works by retrieving patient data from the hospital monitoring system and providing that data to the end user's device via WiFi or cellular modem over the Internet. This is the same approach used for the AirStrip RPM product.

The initial adapter proposed in this submission is the FDA-cleared Cerner CareAware iBus, also known as MDBus, which was cleared through 510(k) K093134 on November 27, 2009. Physiological parameters that will be displayed include those physiological parameters collected through the iBus interface from FDA-cleared patient monitors. These physiological parameters include such parameters as ECG, invasive blood pressure, non-invasive blood pressure, heart rate, temperature, cardiac output, respiration, pulse oximetry and carbon dioxide.

In addition to the physiological data that iBus provides, other patient data such as patient demographics data and Electronic Medical Record (EMR) data are also available within the application and made available to AirStrip RPM.

Substantial Equivalence - Client

GE's Pocket Viewer device provides the ability for clinicians to remotely view patient data on a Windows Mobile handheld PDA. It displays patient physiological data and waveforms based on data that is made available via the Datex-Ohmeda Network or Unity network. Based on the Pocket Viewer brochure, the data that can be displayed includes waveforms and vital signs. Based on the Pocket Viewer User's Guide, the type of waveforms that are available include ECG, EEG, O2, and CO2. These waveforms are captured as selection options on pages 47-48 of the User's Guide. The data that the Pocket Viewer is cleared to display is based on the data that the Web Viewer was cleared to display through 510(k) submission K013387 dated January 8, 2002 as it served as the predicate device. The predicate device for the Web Viewer is the Datex-Ohmeda S/5 Network and Central device which was cleared through 510(k) K000647 dated July 13, 2000. These two clearance letters are included in Appendix B. In the device description section of the 510(k) clearance letter for of the Datex-Ohmeda Network and Central device, one of the monitors listed is the Cardiocap 5 Critical Care monitor. The brochure for the Datex-Ohmeda Cardiocap 5 monitor describes the types of waveforms that are displayed on the monitor including ECG. The table below captures the relationship between the predicate devices and our proposed device regarding the ability to display ECG waveform data. It is clear from this table that the GE Pocket Viewer device is cleared to display ECG waveform data and therefore can serve as a predicate device to the AirStrip RPM client for displaying ECG waveform data.

Datex-Ohmeda Cardiocap 5 Monitor	Datex-Ohmeda S/5 Network and Central	Datex-Ohmeda Web Viewer	GE Pocket Viewer	AirStrip RPM
510(k): K992323	510(k): K000647	510(k): K013387, K023497	510(k): K033078, K061994	Proposed
ECG Waveform display	Includes ability to display waveforms from the Cardiocap 5 monitor.	Provides same ability as S/5 Network and Central to view waveform data which would include ECG.	Provides same ability as Web Viewer to view waveform data which would include ECG.	Provides ability to view ECG waveforms through interface with iBus
	Predicate device for Web Viewer	Predicate device for Pocket Viewer	Predicate device for AirStrip RPM 3.1	

Table 1- ECG Waveform Clearance in Predicate Device

The client portion of the AirStrip RPM software application has the following similarities to GE's Pocket Viewer which previously received 510(k) clearance:

- has the same indicated use,
- has the same target population,
- uses the same operating principle,
- uses the same communication methods and protocols,
- uses the same data source location,
- uses the same data presentation type, and
- incorporates the same basic software design.

Substantial equivalence of operating function is detailed in the table below:

Function Specification	GE Pocket Viewer (FDA Cleared)	AirStrip RPM (Proposed)
Function – Indications for Use	Smart Client application that allows users at remote locations (anywhere there is internet access) to view patient information including physiological data, waveforms and other EMR related data.	Smart Client application that allows users at remote locations (anywhere there is internet access) to view patient information including physiological data, waveforms and other EMR related data.
Target Population	Clinicians	Clinicians
Materials	Software application and configured PDA	Software application and configured PDA
Internet Communication	Secure Sockets Layer (SSL) via HTTPS	Secure Sockets Layer (SSL) via HTTPS
Communication Methods	Cellular Modem, Wi-Fi	Cellular Modem, Wi-Fi
Data Source Location	Hospital	Hospital
Security Administration	Yes	Yes
Where Used	Anywhere the clinician has remote internet access	Anywhere the clinician has remote internet access
Operating Systems	Microsoft Windows CE.NET family of operating systems	iPhone OS
Presentation of Data	Smart Client	Smart Client
Ability to view near Real-time Data	Yes	Yes

Table 2- Substantial Equivalence Operation Functional Comparison

Substantial Equivalence - Adapter

Cerner's CareAware iBus is the adapter through which AirStrip RPM will capture patient data. CareAware iBus was cleared through the FDA on November 27, 2009 through 510(k) K093134.

CareAware iBus provides the ability to gather data from connected medical devices by capturing the data from the connected device and making it available the hospital's healthcare IT system. The proposed AirStrip RPM solution provides the ability to gather data from connected medical devices by capturing the data from the connected device and making it available to the AirStrip RPM server via the CareAware iBus adapter.

The patient monitoring data presented in the AirStrip RPM software application has the following similarities to the Cerner CareAware iBus which previously received 510(k) concurrence through 510(k) K093134 dated November 27, 2009:

- has the same operating principle,
- has the same target population,
- uses the same type of data sources.

Function Specification	Cerner CareAware iBus (FDA Cleared)	AirStrip RPM (Proposed)
Function – Indications for Use	Capture patient data from externally connected devices and make available to networked clinical information systems	Capture patient data from clinical information system and display on remote devices
Target Population	Clinicians	Clinicians
Data Source Location	Hospital	Hospital
Data Types	Patient physiological data including blood pressure, cardiac monitor, breathing frequency, oxygen uptake	Patient physiological data including blood pressure, cardiac monitor, breathing frequency, oxygen uptake
Security Administration	Yes	Yes
Where Used	Anywhere the physician has Clinical Information System access	Anywhere the physician has remote internet access
Presentation of Data	Networked Clinical Information System	Smart Client
Ability to View Near Real-time Data	Yes	Yes

Table 4 - Substantial Equivalence Comparison

The table below lists the data physiological and non-physiological data elements provided by FDA-cleared Cerner iBus, the level of concern of each element, and which of these are displayed by the FDA-cleared Pocket Viewer and proposed AirStrip RPM.

Data Element Provided by Cerner iBus (FDA Cleared)	Level of Concern	GE Pocket Viewer (FDA Cleared)	AirStrip RPM (Proposed)
Logon	High	Displays	Displays
Patient Census	High	Displays	Displays
Automatically Gathered (Monitored) Waveform Physiological Data with Scrolling			
ECG	High	Displays	Displays
Blood Pressure	High	Displays	Displays
O2	High	Displays	Displays
CO2	High	Displays	Displays
Automatically Gathered (Monitored) Near-Real-Time Patient Physiological Data			
Heart Rate	High	Displays	Displays
Respiratory Rate	High	Displays	Displays
Oxygen Saturation	High	Displays	Displays
Intracranial Pressure	High	Displays	Displays
Central Venous Pressure	High	Displays	Displays
Pulmonary Capillary Wedge Pressure	High	Displays	Displays
Cardiac Index	High	Displays	Displays
Cardiac Output	High	Displays	Displays
Cerebral Perfusion Pressure	High	Displays	Displays
Systolic Blood Pressure Cuff	High	Displays	Displays
Mean Blood Pressure Cuff	High	Displays	Displays
Diastolic Blood Pressure Cuff	High	Displays	Displays
Systolic Blood Pressure Invasive	High	Displays	Displays
Mean Blood Pressure Invasive	High	Displays	Displays
Diastolic Blood Pressure Invasive	High	Displays	Displays
Temperature	High	Displays	Displays
Manually Gathered (Non-Monitored) Patient Physiological Data			
Urine Output	Low	Does Not Display	Displays
Urine/Stool Mix Output	Low	Does Not Display	Displays
Vasoactive Infusions	Low	Does Not Display	Displays
Antiarryhthmics	Low	Does Not Display	Displays
Sedation	Low	Does Not Display	Displays
Paralytics	Low	Does Not Display	Displays
Manually Gathered (Non-Monitored) Patient Laboratory Data			
Blood Gas	Low	Does Not Display	Displays
Chemistry	Low	Does Not Display	Displays
Hematology	Low	Does Not Display	Displays
Coagulation	Low	Does Not Display	Displays
Other Manually Gathered (Non-Monitored) Patient Information			
Patient Allergies	Low	Does Not Display	Displays
Patient Medications	Low	Does Not Display	Displays
Patient Demographics	Low	Does Not Display	Displays

Table 3 - Equivalent Data Function Comparison

As the table above illustrates, GE Pocket Viewer does not currently display every data point AirStrip RPM displays. However, GE Pocket Viewer does display every automatically gathered – or monitored – physiologic data point AirStrip RPM proposes to display. These data points are

considered to be of a higher level of concern since they are compiled without human intervention.

AirStrip Technologies conducted verification testing of all data points listed. In this test, known datasets were gathered from Cerner iBus and displayed on AirStrip RPM. These datasets included all data points proposed in AirStrip RPM; all waveforms, all monitored data, all manual data, including patient demographics. In all cases, AirStrip RPM was able to display data points with complete accuracy. The verification test report is provided as Appendix SSSSS.

Testing and Labeling

Since a comparison of the descriptive characteristics of the proposed and predicate devices may not be sufficient to precisely assure safety and effectiveness, AirStrip Technologies used "Radio-Frequency Wireless Technology in Medical Guidance: Draft Guidance for Industry and FDA Staff" as a guide to determine what testing should be done on AirStrip RPM and to determine what additional labeling should be included with the product.

Testing

AirStrip RPM is only intended for installation on Apple iPhone, iPod Touch or iPad. AirStrip Technologies reviewed testing conducted by the Original Equipment Manufacturer (OEM), Apple Computer, on these devices. Additional testing was performed on AirStrip RPM when needed.

Other guidance used:

- ANSI/AAMI/IEC 60601-1-2: Medical electrical equipment – Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- ISO/TR 2130: Health informatics – Use of mobile wireless communication and computing technology in healthcare facilities – Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devices
- ANSI C63.18-1997: American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio-Frequency Transmitters

AirStrip Technologies testing included:

- AirStrip RPM Software Waveform Functional Testing
- AirStrip RPM Software Non-Waveform Functional Testing
- AirStrip RPM In-Band Interference and Wireless Network Coexistence Testing
- AirStrip RPM On-Site Ad Hoc Electromagnetic Immunity Testing

AirStrip RPM was found to have met all testing requirements.

Labeling

AirStrip RPM is intended for use by clinicians when they cannot be at the hospital. It is intended for use by clinicians as a diagnostic aid, and not as a replacement for direct viewing of any of the monitoring devices from which it obtains its data. Further, since AirStrip RPM is installed on a cellular telephone or other wireless device, it is possible that radiated emissions from other medical devices could interfere with its operation. For this reason, AirStrip RPM is not intended for use in hospitals. These contraindications are clearly explained in end-user training and product documentation. Further, a warning message is prominently display to the end user on the AirStrip RPM logon screen.

Manufacturer's guidance is also included in AirStrip RPM documentation. This guidance was developed using IEC 60601-1-2 as a template and instructs the user on how to minimize risk of using AirStrip RPM in areas with medical equipment and other sources of radiated and conducted electromagnetic disturbances. AirStrip Technologies also provides clients with guidance on how to test AirStrip RPM for use in their environment based on recognized testing standards.

Conclusion

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetics Act and various guidance documents issued by the Center for Device and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUL 2 3 2010

AirStrip Technologies, LP
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th St, NW
Buffalo MN 55313

Re: K100133
Trade/Device Name: AirStrip RPM 3.1
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (without arrhythmia detection or alarms)
Regulatory Class: Class II
Product Code: MWI
Dated: July 8, 2010
Received: July 9, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Vickers

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K100133

Device Name AirStrip Remote Patient Monitoring (RPM) Remote Data Viewing software

Indications for Use

AirStrip RPM is software capable of displaying physiologic and other patient information. This information is generated by other medical devices and patient information system, and not by AirStrip RPM. AirStrip RPM captures this information from these other systems and displays it for clinicians.

AirStrip RPM is intended to be used by clinicians for the following purposes:

- By using a cellular telephone or other device on which AirStrip RPM is installed, to review physiologic data of a patient when the clinician is not at the hospital
- To view the near real-time waveforms remotely
- To remotely review other standard or critical near real-time patient data from the monitored system
- To provide a request for remote consultation regarding a patient's waveform or other data

The AirStrip RPM software can display the following the physiologic data captured by other medical devices:

- Heart Rate Monitored
- Respiratory Rate
- Oxygen Saturation
- Intracranial Pressure
- Central Venous Pressure
- Pulmonary Capillary Wedge Pressure

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Ockman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100133

- Cardiac Index
- Cardiac Output
- Cerebral Perfusion Pressure
- Urine Output
- Urine/Stool Mix Output
- Systolic Blood Pressure Invasive
- Mean Arterial Pressure Invasive
- Diastolic Blood Pressure Invasive
- Systolic Blood Pressure Cuff
- Mean Arterial Pressure Cuff
- Diastolic Blood Pressure Cuff
- Vasoactive Infusions
- Antiarrhythmics
- Sedation
- Paralytics
- Laboratory Data including
  - Blood Gas
  - Chemistry
  - Hematology
  - Coagulation
- Allergies
- Medications

Contraindications
AirStrip RPM software is intended for installation on cellular telephones and other wireless devices, and is not intended for use anywhere cellular telephones or wireless devices are prohibited.

AirStrip RPM is intended for use by clinicians when they cannot be at the hospital. AirStrip RPM is intended for use by clinicians as a diagnostic aid, and not as a replacement for direct viewing of any of the monitoring devices from which it obtains its data.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anna R. Kahner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100133

K101178
p1/3

JUN 2 9 2010

510(k) Summary
As required by 21 CFR §807.92(c)

Submitter

510(k) Owner:	Intel Corporation
Address:	1900 Prairie City Road, FM7-197, Folsom, CA 95630
Telephone:	(916) 356-1109
Contact Person:	Maureen Glynn
Date Prepared:	April 23rd, 2010

Device Information

Trade Name:	Modification to Intel® Health Guide PHS6000
Common Name:	Remote Patient Monitoring System
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG)

Substantial Equivalence is claimed to the following device:
Intel Corporation's Intel® Health Guide PHS6000 (**K080798 & K083115**)

Device Description

The Intel® Health Guide PHS6000 is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. It collects measurements captured on commercially available wireless or tethered medical devices designed for home use, stores and displays the collected information on the LCD screen, and transmits the information to a secure host server. Caregivers can review the transmitted information and select education and reminders for patients using a caregiver software interface to the host server. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also optionally engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.

510(k) Notification Submission – Special 510(k)
Modification to Intel® Health Guide PHS6000

The Intel® Health Guide PHS6000 system consists of the:

(1) Intel® Health Guide PHS6000 hardware:

The physical component of the Intel® Health Guide PHS6000 is an electronic device contained in a plastic enclosure with a touch screen, video camera with privacy screen, microphones, speakers and a reminder light which is mounted into the top of the case. On the back of the device is a power socket, a headphone socket, a Broadband (high-speed) internet socket for connection to a broadband network. The device has medical device sockets for connection to specific physiological monitors, and may optionally have a phone socket for modem connection to a standard phone line.

(2) Intel® Health Guide software application:

The software application captures, stores, and transmits information to a secure website via a standard telephone line or a LAN/WAN connection.

(3) Intel® Care Management Suite software application:

The application allows caregivers to review patient vital signs on the secure website. The Intel® Care Management Suite allows for predefining upper and lower limits and, when either limit is exceeded, the system emails and/or pages the caregiver.

(4) Processor software application:

The processor software application manages the interface between the Intel® Health Guide PHS6000 software application and the secure website.

The Intel® Health Guide PHS6000 is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention. The device is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

Indications for Use

The Intel® Health Guide PHS6000 is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. It collects measurements captured on commercially available wireless or tethered medical devices designed for home use, stores and displays the collected information on the LCD screen, and transmits the information to a secure host server. Caregivers can review the transmitted information and select education and reminders for patients using a caregiver software interface to the host server. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also optionally engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.

The Intel® Health Guide PHS6000 is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. It is contraindicated for patients requiring direct medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

Technological Characteristics

The Intel® Health Guide PHS6000 is substantially equivalent to the predicate device in terms of data collection software functionality, operating system for the patient device, communication method of patient device with central server, types of sensors which can be interfaced to the patient device, implementation method of collecting data from sensors, sensor software, connectivity, communication protocol, power source, and display method.

Safety and Efficacy

The Intel® Health Guide PHS6000 does not rely on an assessment of clinical performance data. The device conforms to FDA's recognized consensus standards and relies on its conformity to demonstrate the safety and efficacy. The device introduces no new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 29 2010

Intel Corporation
c/o Ms. Maureen Glynn
Director of Regulatory Affairs
1900 Prairie City Road
Folsom, CA 95630

Re: K101178
Trade/Device Name: Modification to Intel® Health Guide PHS6000
Regulatory Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: II (two)
Product Code: 74 DRG
Dated: May 20, 2010
Received: June 8, 2010

Dear Ms. Glynn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. J. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101178

Indications for Use:

510(k) Number: K101178

Device Name: Modification to Intel® Health Guide PHS6000

Indications for Use:

The Intel® Health Guide PHS6000 is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. It collects measurements captured on commercially available wireless or tethered medical devices designed for home use, stores and displays the collected information on the LCD screen, and transmits the information to a secure host server. Caregivers can review the transmitted information and select education and reminders for patients using a caregiver software interface to the host server. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also optionally engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.

The Intel® Health Guide PHS6000 is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. It is contraindicated for patients requiring direct medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101178

K101597

AgaMatrix

10 Manor Parkway
Salem, NH 03079
Office: +1 (603) 328-6000
Fax: +1 (603) 893-4191

510(k) SAFETY AND EFFECTIVENESS SUMMARY

OCT 18 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter's Name, Address, Telephone Number, Contact Person, and date the summary was prepared.

Submitter's Name:	AgaMatrix, Inc.
Address:	10 Manor Parkway Salem, NH 03079 (603) 328-6000
Contact Person:	Connie Hertel Director Quality & Regulatory Affairs chertel@agamatrix.com
Date the summary prepared:	August 31, 2010

2. Device Name

Trade/Proprietary Name:	AgaMatrix WaveSense Diabetes Manager
Common/Usual Name:	WaveSense Diabetes Manager
Classification Name:	None
Class	unclassified

Trade/Proprietary Name:	AgaMatrix WaveSense BGM meters
Common/Usual Name:	AgaMatrix WaveSense BGM meters
Classification Name:	NBW, JQP
Class	II

3. Predicate Device

Zero-Click Data Management System
510(k) number: k062434

4. Device Description

The WaveSense Diabetes Manager (WDM) application (app) is a digital logbook and diabetes management tool for the iPhone operating system platform. The application can be used alone or with the WaveSense Direct Connect Cable and a WaveSense-enabled Blood Glucose Meter (BGM) with a mini-USB port.

AgaMatrix

10 Manor Parkway
Salem, NH 03079
Office: +1 (603) 328-6000
Fax: +1 (603) 893-4191

5. Intended Use:

The AgaMatrix WaveSense Diabetes Manager (WDM) application (app) is intended for use in the home and professional settings to aid individuals with diabetes and their healthcare professionals: in the review, analysis and evaluation of blood glucose test results to support an effective diabetes management program. It is an optional data management software accessory for use with the WaveSense-enabled blood glucose meter (BGM) with a mini-USB port. The WaveSense Diabetes Manager allows users to download Blood glucose reading automatically from the meter to an iPhone Operating System platform.

6. Assessment of Performance:

An evaluation of the WaveSense Diabetes Manager was studied in house and in a Clinical setting by persons with diabetes. The studies demonstrated the ease of operating the WaveSense Diabetes Manager application as intended.

7. Comparison to Predicate device

	Zero-Click Data Management Software	WaveSense Diabetes Management Application
Intended Use	The AgaMatrix WaveSense Diabetes Manager (WDM) application (app) is intended for use in the home and professional settings to aid individuals with diabetes and their healthcare professionals: in the review, analysis and evaluation of blood glucose test results to support an effective diabetes management program	same
Accessory to	WaveSense Blood Glucose Monitoring Meters	same
Log book for	Blood glucose readings	Blood glucose readings and Insulin and Carbohydrates intake
Use on	PC	iPhone Operating System platform

8. Conclusions

The results of clinical evaluations of the WaveSense Diabetes Manager application demonstrate that the application is equivalent in performance to the predicate device and suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Agamatrix
c/o Connie Hertel
10 Maor Parkway,
Salem, NH 03079

OCT 18 2010

Re: k101597
Trade/Device Name: WaveSense Diabetes Manager application
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: NBW, JQP
Dated: September 22, 2010
Received: September 24, 2010

Dear: Ms. Hertel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

AgaMatrix

10 Manor Parkway
Salem, NH 03079
Office: +1 (603) 328-6000
Fax: +1 (603) 893-4191

Indications for Use

510(k) Number (if known): K101597

Device Name: WaveSense Diabetes Manager application

OCT 18 2010

Indications for Use:

The WaveSense Diabetes Manager (WDM) application (app) is intended for use in the home and professional settings to aid individuals with diabetes and their healthcare professionals; in the review, analysis and evaluation of blood glucose readings to support an effective diabetes management program. The WaveSense Diabetes Manager application is a digital logbook and diabetes management tool designed to operate using the iPhone Operating System platform. The application can be used alone or with the WaveSense Direct Connect Cable and a WaveSense-enabled blood glucose meter (BGM) with a mini-USB port.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _X_ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
K101597

510(k) Summary: Modified CG-6108 ACT-1L Continuous ECG Monitor and Arrhythmia Detector

JUN 25 2010

Introduction

This document contains the 510(k) summary for the modified CG-6108 1L Continuous ECG Monitor and Arrhythmia Detector. The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

Submitter	Card Guard Scientific Survival Ltd.,	
Establishment Registration Number	9681879	
Address	2 Pekeris St., P.O.B. 527, Rehovot, 76100, Israel	
Contact person:	Asher Kassel, Director of RA & QA, Card Guard Scientific Survival Ltd.	
Phone:	972-8-9484010 (direct)	Fax: 972-8-9484044
E-mail:	asherk@cardguard.com	
Date Prepared:	June 8, 2010	
Predicate device	Unmodified version of CG-6108 ACT-1L Continuous ECG Monitor and Arrhythmia Detector, cleared in K071995 on December 18, 2007.	
Trade Name:	CG-6108 ACT-1L Continuous ECG Monitor and Arrhythmia Detector	
Classification:	Detector and alarm, arrhythmia / Transmitters and receivers, electrocardiograph, telephone	
Product Code:	DSI DXH	
Regulation No:	870.1025, 870.2920	
Class:	II	

Device Description

CG-6108 ACT-1L Continuous ECG Monitor and Arrhythmia Detector is designed for self-testing by patients at home and for analysis by medical professionals at a remote Monitoring Center.

The chest-worn sensor is used for the acquisition, recording, and transmission of the ECG signal. The device is equipped with 3 electrodes on a harness and it houses a 3.6V AA battery, a Bluetooth transceiver and a buzzer.

The ECG signals are transmitted via Bluetooth to a handheld device with a proprietary interactive application, configured to process and transmit the ECG recordings. The handheld device is a mobile computing device with a display and a touch input such as a cell-phone. It has sufficient memory and processing capability to run the proprietary application.

When an arrhythmia event is detected the handheld device transmits the recorded ECG information automatically via cellular link, to the Monitoring Center or professional analysis. When cellular service is unavailable the patient has an option to transmit via landline telephone.

Indications for Use:

The CG-6108 Continuous ECG Monitor and Arrhythmia Detector is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors a one lead ECG, automatically generates an alarm triggered by an arrhythmia detection algorithm or generates an alarm manually triggered by the patient, and transmits the recorded data transtelephonically to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.

Summary of the Technological Characteristics / Principles of Operation

The technological characteristics and principles of operation of the modified device are the same as the predicate device. The chest-worn ECG sensor transmits signals via Bluetooth to the handheld device equipped with the Medical Application, which incorporates an algorithm for detection of cardiac events: Atrial Fibrillation, Tachycardia, Bradycardia and Pause. A detected artifact triggers transmission of the signal to the Monitoring Center for analysis.

Non-clinical performance data for the CG-6108 ACT-1L:

The modified version CG-6108 has been subjected to extensive verification / validation testing. Final testing of the system included various performance tests and software validation tests designed to ensure that the device meet all of its functional and performance requirements and is fit for its intended use. The following list summarizes the testing performed on the device;

- Software Verification and Validation
  - Software Functional Unit Verification
  - System Level Software Validation
  - Arrhythmia Detection Algorithm Performance Validation
- Hardware Verification and Validation
- Verification of Conformance with Special Controls Guidance Document

Performance Standards:

This 510(k) submission was written in accordance with the FDA Guidance document "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm, October 28, 2003" and the device conforms to the applicable performance requirements contained in and referenced in this document. In addition, this submission was prepared in accordance with "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11 2005". The design of the CG-6108 ACT-1L conforms to the following voluntary standards:

- ANSI/AAMI/ISO EC57:1998 (R) 2008: Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms
- ANSI/AAMI EC38:1998 Ambulatory Electrocardiograph
- ISO 14971:2007: Medical devices – application of risk management to medical devices;
- IEC 60601-1:1988, 2nd edition, Part 1, plus A1:1991 and A2:1995: Medical electrical equipment; Part 1: General requirements for safety
- IEC 60601-1-2: 2001, plus am. 1:2004, Part 1: Medical electrical equipment, Part 1-2; Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-4:2000, plus Amendment 1:2004: Medical electrical equipment; Part 1: 4. Collateral Std: Programmable electric medical systems
- IEC 62304:2006: Medical device software – Software life cycle processes
- ISO 15223:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Substantial Equivalence:

The modified CG-6108 ACT-1L device is substantially equivalent with respect to the indications for use, technological characteristics and performance characteristics to the identified legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Card Guard Scientific Survival Ltd.,
c/o Clay Anselmo
President and CEO,
Reglera LLC.
555 Zang Street Suite 100
Lakewood, Colorado 80228

JUN 2 5 2010

Re: K101639
Trade/Device Name: CG-6108 ACT-1L Continuous ECG Monitor and Arrhythmia Detector
Regulation Number: 21 CFR 870.1025, 21 CFR 870.2920
Regulation Name: Arrhythmia Detector and Alarm, Telephone Electrocardiograph Transmitter and Receiver.
Regulatory Class: Class II (two)
Product Code: DSI, DXH
Dated: June 8, 2010
Received: June10, 2010

Dear Mr. Anselmo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101639

Device Name: CG-6108 ACT-1L Continuous ECG Monitor and Arrhythmia Detector

Indications for Use:

The CG-6108 ACT-1L Continuous ECG Monitor and Arrhythmia Detector are intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors patient ECG, automatically generates an alarm triggered by an arrhythmia detection algorithm, or generates an alarm manually triggered by the patient, and transmits the recorded data transtelephonically to a monitoring center.

The monitoring center provides the ECG data to the medical practitioner for evaluation.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Dev...
510(k) Number K101639

510(k) Summary: Modified CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector

Introduction

This document contains the 510(k) summary for the modified CG-6108 1L Continuous ECG Monitor and Arrhythmia Detector. The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

Submitter	Card Guard Scientific Survival Ltd.,	
Establishment Registration Number	9681879	
Address	2 Pekeris St., P.O.B. 527, Rehovot, 76100, Israel	
Contact person:	Asher Kassel, Director of RA & QA, Card Guard Scientific Survival Ltd.	
Phone:	972-8-9484010 (direct)	Fax: 972-8-9484044
E-mail:	asherk@cardguard.com	
Date Prepared:	June 8, 2010	
Predicate device	Unmodified version of CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector, cleared in K081257 on May 29, 2008.	
Trade Name:	CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector	
Classification:	Detector and alarm, arrhythmia / Transmitters and receivers, electrocardiograph, telephone	
Product Code:	DSI, DXH	
Regulation No:	870.1025, 870.2920	
Class:	II	

Device Description

CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector is designed for self-testing by patients at home and for analysis by medical professionals at a remote Monitoring Center.

The chest-worn sensor is used for the acquisition, recording, and transmission of the ECG signal. The device is equipped with 4 electrodes on a harness and it houses a 3.6V AA battery, a Bluetooth transceiver and a buzzer.

The ECG signals are transmitted via Bluetooth to a handheld device with a proprietary interactive application, configured to process and transmit the ECG recordings. The handheld device is a mobile computing device with a display and a touch input such as a cell-phone. It has sufficient memory and processing capability to run the proprietary application.

When an arrhythmia event is detected the handheld device transmits the recorded ECG information automatically via cellular link, to the Monitoring Center or professional analysis. When cellular service is unavailable the patient has an option to transmit via a landline telephone.

Indications for Use:

The CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors patient ECG, automatically generates an alarm triggered by an arrhythmia detection algorithm, or generates an alarm manually triggered by the patient, and transmits the recorded data transtelephonically to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.

Summary of the Technological Characteristics / Principles of Operation

The technological characteristics and principles of operation of the modified device are the same as the predicate device. The chest-worn ECG sensor transmits signals via Bluetooth to the handheld device equipped with the Medical Application, which incorporates an algorithm for detection of cardiac events: Atrial Fibrillation, Tachycardia, Bradycardia and Pause. A detected artifact triggers transmission of the signal to the Monitoring Center for analysis.

Non-clinical performance data for the CG-6108 ACT-3L:

The modified version CG-6108 has been subjected to extensive verification / validation testing. Final testing of the system included various performance tests and software validation tests designed to ensure that the device meet all of its functional and performance requirements and is fit for its intended use. The following list summarizes the testing performed on the device;

- Software Verification and Validation
  - Software Functional Unit Verification
  - System Level Software Validation
  - Arrhythmia Detection Algorithm Performance Validation
- Hardware Verification and Validation
- Verification of Conformance with Special Controls Guidance Document

Performance Standards:

This 510(k) submission was written in accordance with the FDA Guidance document "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm, October 28, 2003" and the device conforms to the applicable performance requirements contained in and referenced in this document. In addition, this submission was prepared in accordance with "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11 2005". The design of the CG-6108 ACT-1L conforms to the following voluntary standards:

- ANSI/AAMI/ISO EC57:1998 (R) 2008: Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms
- ANSI/AAMI EC38:1998 Ambulatory Electrocardiograph
- ISO 14971:2007: Medical devices – application of risk management to medical devices;
- IEC 60601-1:1988, 2nd edition, Part 1, plus A1:1991 and A2:1995: Medical electrical equipment; Part 1: General requirements for safety
- IEC 60601-1-2: 2001, plus am. 1:2004, Part 1: Medical electrical equipment, Part 1-2; Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-4:2000, plus Amendment 1:2004: Medical electrical equipment; Part 1: 4. Collateral Std: Programmable electric medical systems
- IEC 62304:2006: Medical device software – Software life cycle processes
- ISO 15223:2007: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Substantial Equivalence:

The modified CG-6108 ACT-3L device is substantially equivalent with respect to the indications for use, technological characteristics and performance characteristics to the identified legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JUL 13 2010

Card Guard Scientific Survival Ltd.,
c/o Clay Anselmo
President and CEO,
Reglera LLC.
555 Zang Street Suite 100
Lakewood, Colorado 80228

Re: K101703
Trade/Device Name: CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm.
Regulatory Class: Class II (two)
Product Code: DSI, DXH
Dated: June 14, 2010
Received: June 17, 2010

Dear Mr. Anselmo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101703

Device Name: CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector

Indications for Use:

The CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors patient ECG, automatically generates an alarm triggered by an arrhythmia detection algorithm, or generates an alarm manually triggered by the patient, and transmits the recorded data transtelephonically to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101703

K101806

SUMMARY AND CERTIFICATION

510(k) SUMMARY

DEC - 7 2010

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Aidera summary for the ***Diasend System.***

SUBMITTER'S NAME:	Aidera
ADDRESS:	Aidera AB Sahlgrenska Science Park Medicinaregatan 8A SE 413 46 Goteborg Sweden
CONTACT PERSON:	Anders Sonesson
TELEPHONE NUMBER:	+46 31 741 17 85
FAX NUMBER:	+46 31 741 17 01
DATE OF SUBMISSION:	June 18, 2010

1. **Identification of device**

Proprietary Name:	Diasend
Common Name:	Accessories, Pump, Infusion System, Test, Blood Glucose, Over The Counter
Classification Status:	Class II according to Sec. 880.2910 and 862.1345
Product Codes:	MRZ, NBW

2. **Equivalent devices**
   K083221, Aidera AB, Aidera Diasend
   K072698, Confidant Inc, Confidant 2.5
   K032164, Medtronic Inc, Medtronic Minimed DDMS

3. **Description of the Device**
   Diasend is a system for transmitting data from patients' home monitoring devices and consists of a transmitter, a server database and a website available for the care provider and the patient.

   The software transmitter is a Diasend software concept developed by Aidera that may run on a computer device, e.g. desktop computer, laptop or mobile phone, designed to transmit data to the Diasend server database. Current implementation is on Windows XP.

4. **Intended use**
   Aidera Diasend is indicated for use by individuals or healthcare professionals in the home or health care facilities for transmitting data from home monitoring devices such as glucose meters and insulin pumps to a server database to support diabetes management. The device is indicated for professional use and over-the-counter sales.

5. **Technological characteristics, comparison to predicate device.**
The Diasend system is intact except for the addition of the software transmitter compared to previously cleared device. See section 5 for a more elaborate comparison.

6. **Discussion of performance testing.**
The Diasend transmitter is tested and found to comply with applicable EMC and FCC requirements and standards.

7. **Conclusion**
Based on comparison with the predicate devices, the Aidera Diasend System is substantially equivalent to the previously cleared devices and presents no new concerns about safety and effectiveness.

8. **Indications for Use Statement**
Aidera Diasend is indicated for use by individuals or healthcare professionals in the home or health care facilities for transmitting data from home monitoring devices such as glucose meters and insulin pumps to a server database to support diabetes management. The device is indicated for professional use and over-the-counter sales.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Anders Sonesson
CEO
AIDERA AB
Medicinaregatan 8A
SE 413 46 Goteborg
Sweden

DEC - 7 2010

Re: K101806
Trade/Device Name: Aidera Diasend System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ, NBW
Dated: November 17, 2010
Received: November 22, 2010

Dear Mr. Sonesson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

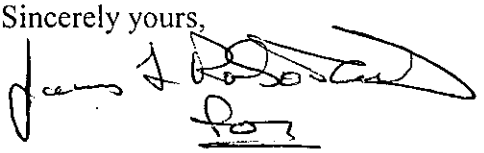
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number K101806

DEC - 7 2010

Device Name:

Aidera Diasend System

Indications for Use:

Aidera Diasend is indicated for use by individuals or healthcare professionals in the home or health care facilities for transmitting data from home monitoring devices such as glucose meters and insulin pumps to a server database to support diabetes management. The device is indicated for professional use and over-the-counter sales.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use X
(Per 21 CFR 801.109)

12/6/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101806

Section 5 - 510(k) Summary

K102153

JAN 20 2011

Submitter: Mobisante, Inc.
14035 NE 85th CT
Redmond, WA 98052

Contact Person: Sailesh Chutani
President and CEO

Telephone: (650) 804-5421

Date Prepared: July 30, 2010

Device Trade Name: MobiUS Ultrasound Imaging System

Device Common Name: Diagnostic Ultrasound System and Accessories
Ultrasound Pulsed Echo Imaging System
Diagnostic Ultrasound Transducer

Classification Number and Product Code: §21CFR 892.1560 90-IYO
§21CFR 892.1570 90-ITX

Device Classification: Class II

Predicate Device(s):

DEVICE NAME	ACCESSION NUMBER(S)
INTERSON USB Ultrasound Probe System	K070907
GE VScan Diagnostic Ultrasound System	K092756
Signos Personal Ultrasound	K090505

Intended Use:

The MobiUS Ultrasound Imaging System is indicated for ultrasound imaging, measurement and analysis of the human body for the following clinical applications: fetal/OB, abdominal, cardiac, pelvic, pediatric, musculoskeletal, and peripheral vessel imaging. Its compact size, portability and user interface enable it for use in primary care and special care areas.

Device Description:

The MobiUS Ultrasound Imaging System is a compact, portable ultrasound imaging system consisting of a handheld ultrasound probe, cable, host computer and user interface. The ultrasound probe and cable is one of the five models of the INTERSON USB Ultrasound Imaging Probe, ranging from 3.5 MHz to 12.0 MHz. The probes consist of a single-element mechanical sector scanner that contains the ultrasound generator and receiver, analog-to-digital converter, microcontroller, control logic, USB 2.0 interface and control within the hand piece. It has a push button control to activate scanning. The probe is connected via a USB cable to a host computer. The host computer comes preloaded with the MobiUS software which utilizes an icon touch-based user interface. The software enables ultrasound image capture and review, image controls for near, mid, and far gain, as well as image intensity and contrast, linear measurement, storage and transmission of images and videos. The MobiUS Ultrasound Imaging System allows the user to image in real-time and review cine or freeze-frame images on the screen in B-Mode scan format.

Technological Characteristics:

The Mobisante MobiUS Ultrasound Imaging System operates in the same manner as the identified predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D images of anatomic structures within the body. All systems allow for the measurement of structures to aid in diagnosis.

Basis for Substantial Equivalence:

The MobiUS Ultrasound Imaging System is substantially equivalent to the identified predicate devices currently cleared for market with respect to intended use, principles of operation, technological characteristics and safety features. The system has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Sailesh Chutani
President and CEO
MOBISANTE, INC.
14035 NE 85th CT
REDMOND WA 98052

JAN 20 2011

Re: K102153
Trade/Device Name: MobiUS Ultrasound Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: January 12, 2011
Received: January 12, 2011

Dear Mr. Chutani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the MobiUS Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

MV 12.0 MHz Mechanical Sector Probe
EC 7.5 MHz Mechanical Sector Probe
SR 7.5 MHz Mechanical Sector Probe
GP 5.0 MHz Mechanical Sector Probe
GP 3.5 MHz Mechanical Sector Probe

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Section 4 - Indications for Use Statement

510(k) Number (if known): K102153

Device Name: MobiUS Ultrasound Imaging System

Indications for Use:

The MobiUS Ultrasound Imaging System is indicated for ultrasound imaging, measurement and analysis of the human body for the following clinical applications: fetal/OB, abdominal, cardiac, pelvic, pediatric, musculoskeletal, and peripheral vessel imaging. Its compact size, portability and user interface enable it for use in primary care and special care areas.

Please refer to the following diagnostic ultrasound indications for use forms for specific imaging modes and applications.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102153

Diagnostic Ultrasound Indications for Use

510(k) Number:

System: MobiUS Ultrasound Imaging System with INTERSON USB Ultrasound Probe System

Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N						Note 3
	Abdominal	N						Note 1 Note 3
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N						Note 3
	Small Organ (Specify)	N						Note 3 Note 2
	Neonatal Cephalic	N						
	Adult Cephalic							
	Trans-rectal	N						Note 3
	Trans-vaginal	N						Note 3
	Trans-urethral							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**	N						
	Musculo-skeletal **(Superficial)**	N						
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	N						
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N						
	Other (Specify)							

N=New Indication

Note 1: Abdominal, Solid organs, aneurysms

Note 2: Small organ, breast, thyroid, testes

Note 3: Includes imaging for guidance of biopsy

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

~~concurrence of CDRH, Office of Device Evaluation~~ (Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Prescription Use: YES

Per 21 CFR 801. 109

510K_____ 510(k) Number_____

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102153

Diagnostic Ultrasound Indications for Use

510(k) Number:

System: MobiUS Ultrasound Imaging System

Transducer: **INTERSON USB Ultrasound Probe System**
MV 12.0 MHz Mechanical Sector Probe

Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)	P						Note 2 Note 3
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P						Note 3
	Other (Specify)							

P=Previously Cleared by INTERSON Corporation: K070907

Note 2: Small organ, breast, thyroid, testes

Note 3: Includes imaging for guidance of biopsy

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

concurrence of CDRH, Office of Device Evaluation

Prescription Use: YES
Per 21 CFR 801. 109

510(k) Number_____

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102153

Diagnostic Ultrasound Indications for Use

510(k) Number:

System: MobiUS Ultrasound Imaging System

Transducer: INTERSON USB Ultrasound Probe System
EC 7.5 MHz Mechanical Sector Probe

Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P						Note 3
	Trans-vaginal	P						Note 3
	Trans-urethral							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

P=Previously Cleared by INTERSON Corporation: K070907

Note 3: Includes imaging for guidance of biopsy

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

concurrence of CDRH, Office of Device Evaluation

Prescription Use: YES
Per 21 CFR 801. 109

510(k) Number_____

Diagnostic Ultrasound Indications for Use

510(k) Number:

System: MobiUS Ultrasound Imaging System

Transducer: **INTERSON USB Ultrasound Probe System**
SR 7.5 MHz Mechanical Sector Probe

Intended Use: **Diagnostic ultrasound imaging of the human body as follows:**

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P						Note 3
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)	P						
	Neonatal Cephalic	P						
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	P						
	Other (Specify)							

P=Previously Cleared by INTERSON Corporation: K070907

Note 3: Includes imaging for guidance of biopsy

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)
concurrence of CDRH, Office of Device Evaluation

Prescription Use: YES
Per 21 CFR 801. 109

510(k) Number_____

Mary S. Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102153

Diagnostic Ultrasound Indications for Use

510(k) Number:

System: MobiUS Ultrasound Imaging System

Transducer: **INTERSON USB Ultrasound Probe System**
GP 5.0 MHz Mechanical Sector Probe

Intended Use: **Diagnostic ultrasound imaging of the human body as follows:**

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P						
	Abdominal	P						Note 3
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)	P						Note 2
	Neonatal Cephalic	P						
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult	P						
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

P=Previously Cleared by INTERSON Corporation: K070907

Note 2: Small organ, breast, thyroid, testes

Note 3: Includes imaging for guidance of biopsy

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

concurrence of CDRH, Office of Device Evaluation

Prescription Use: YES
Per 21 CFR 801. 109

510(k) Number_____

Diagnostic Ultrasound Indications for Use

510(k) Number:

System: MobiUS Ultrasound Imaging System

Transducer: INTERSON USB Ultrasound Probe System
GP 3.5 MHz Mechanical Sector Probe

Intended Use: Diagnostic ultrasound imaging of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P						
	Abdominal	P						Note 3
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)	P						Note 2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

P= Previously Cleared by INTERSON Corporation: K070907

Note 2: Small organ, breast, thyroid, testes

Note 3: Includes imaging for guidance of biopsy

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

concurrence of CDRH, Office of Device Evaluation

Prescription Use: YES
Per 21 CFR 801. 109

510(k) Number_____

Mary S Pastel
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102153

MAY 17 2011

K102251

510 (k) Summary of Safety and Effectiveness for DASH knee

Manufacturer:

Address:	BrainLAB AG Kapellenstrasse 12 85622 Feldkirchen Germany
Phone:	+49 89 99 15 68 0
Fax:	+49 89 99 15 68 33
Contact Person:	Mr. Alexander Schwiersch

Summary Date: July 12, 2010

Device Name:

Trade name:	DASH knee
Common/Classification Name:	BrainLAB DASH, BrainLAB Image Guided Surgery System / Instrument, Stereotaxic

Predicate Device:
BrainLAB Knee (K073615)
Kolibri Image Guided Surgery System (K014256)

Device Classification Name: Instrument, Stereotaxic
Regulatory Class: Class II
Regulation Number: 21 CFR 882.4560
Product Code: OLO

Device Description:
Dash is an image guided surgery system for total knee replacement surgery based on landmark based visualization of the femur and tibia. It is intended to enable operational navigation in orthopedic surgery. It links a surgical instrument, tracked by passive markers to virtual computer image space on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. DASH knee uses the registered landmarks to navigate the femoral and tibial cutting guides to the optimally position.

DASH knee software registers the patient data needed for navigating the surgery intraoperatively. No preoperative CT-scanning is necessary.

Intended Use:
DASH knee is intended to be an intraoperative image guided localization system to enable minimally invasive surgery. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical

structure, such as the skull, a long bone, or vertebra, can be identified relative to the anatomy. The system aids the surgeon to accurately navigate a knee prosthesis to the intraoperatively planned position. Ligament balancing and measurements of bone alignment are provided by DASH knee.

Changes made to the predicate device:

Reduced SW complexity: The spectrum of possible workflows has been reduced to one already contained universal express workflow. Within that express workflow registration steps have been combined with the help of an additional instrument.

Additional instrument: Device for multiple point acquisition on femur condyles. Compared to the predicate device, where femoral landmarks have been calculated out of two surface acquisition steps, regarding landmarks are here acquired directly in one step. In combination with a regarding femoral acquisition page the amount of registration steps has been reduced for the user.

Reduced Platform: Compared to predicate device, the main calculation unit is part of the camera stand. A smaller separated display, represented by an iPod touch, acts an embedded display in the instrumentation for navigation.

Wireless communication between embedded display (iPod touch) and main calculation unit (integrated in camera stand).

Completed verification activities:

Following design verification activities have been per formed to ensure correct system functionality as it has been specified:

The first part of the verification covered the instrument and system accuracy during registration and navigation. The registration values have been compared to external measured reference values.
After the verification of the instruments in combination with the software the verification of the software algorithms itself has been performed.
Part three of the verification includes the testing of all possible workflows to ensure the correct behavior of the system for all possible procedures.
With the knowledge of the above named points the current device has been compared to the predicate device.
The next step was the detailed verification of the signed specifications covering the detailed functionality of buttons for example.
At last the measures against the defined risks of the risk analysis have been tested.

This strategy ensures the verification of basic software algorithms up to specific detailed functionality, the comparison to the predicate device and the safety of the defined measures of the risk analysis. All tests have been successfully completed.

Completed validation activities
Following design validation activities have been performed:

A literature search has been performed to prove safety and effectiveness of BrainLAB computer assisted total knee replacement software. This applies directly to DASH knee, since DASH knee is derived from the previous marketed device BrainLAB knee (K073615).

Non-clinical Validation has been performed to prove the system targets and supplement requirement specifications if necessary. With the help of usability workshops (use labs) OR setups and surgery proceedings have been simulated with plastic bones (sawbones).

Pre-clinical Validation has been performed to confirm/ complete detailed specification for each requirement. Here OR setups and surgery proceedings have been simulated in a cadaver lab. Testing persons went through same procedure like for the non clinical use lab sessions.

To prove that all validation issues are addressed, a final validation has been performed under non clinical conditions.

Substantial equivalence:
Dash knee has been verified and validated according to BrainLAB's procedures for product design and development. The information provided by BrainLAB in this 510 (k) application was found to be substantially equivalent with the predicate device BrainLAB Knee (K073615) and Kolibri Image Guided Surgery System (K014256).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

BrainLAB AG
% Mr. Alexander Schwiersch
Kapellenstrasse 12
85622 Feldkirchen, Germany

MAY 17 2011

Re: K102251
Trade/Device Name: DASH Knee
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 29, 2011
Received: May 06, 2011

Dear Mr. Schwiersch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Peter D. Pfendler DEPDP

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K102251

Device Name: DASH knee

Indications For Use:

DASH knee is intended to be an intraoperative image guided localization system to enable minimally invasive surgery. It links a freehand probe, tracked by a passive marker sensor system to virtual computer image space on an individual 3D-model of the patient's bone, which is generated through acquiring multiple landmarks on the bone surface. The system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate and where a reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to the anatomy. The system aids the surgeon to accurately navigate a knee prosthesis to the intraoperatively planned position. Ligament balancing and measurements of bone alignment are provided by **DASH knee**.

Example orthopedic surgical procedures include but are not limited to:
- Total Knee Replacement
- Ligament Balancing

Prescription Use ____X____ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

(Division Sign-Off)

Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102251

510(k) Summary

FEB 2 3 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1.0 submitter's information

Name: Andon Health Co., Ltd.
Address: No 3, Jinping Street Ya An Road, Nankai District, Tianjin, P.R. China
Phone number: 86-22-6052 6161
Fax number: 86-22-6052 6162
Contact: Liu Yi
Date of Application: 09/27/2010

2.0 Device information

Trade name: iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock

Classification name: Noninvasive blood pressure measurement system

3.0 Classification

Production code: DXN- Noninvasive blood pressure measurement system.
Regulation number: 870.1130
Classification: II
Panel: Cardiovascular

4.0 Predicate device information

Manufacturer: Andon Health Co., Ltd.
Device: KD-930 Fully Automatic Electronic Blood Pressure Monitor
510(k) number: K101950

5.0 Device description

iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.
iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock is designed and manufactured according to ANSI/AAMI SP10--manual, electronic or automated sphygmanometers.

The operational principle is based on oscillometric and silicon integrates pressure sensor technology. it can calculate the systolic and diastolic blood pressure, the measurements results can also be classified by the function of blood pressure classification indicator. If any irregular heartbeat is detected, it can be shown to the user. More over, it also obtains the function of averaging the measurement results.

iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock achieves its function by integrate the device with an iPhone, ipod or ipad. For it does not contain an LCD or other display components, so It's necessary for the new device to connect to an iPhone, ipod or ipad containing a support software to constitute a complete blood pressure measurement system.

6.0 Intended use

iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

The intended use and the indication for use of the iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock, as described in its labeling are the same as the predicate device KD-930.

7.0 Summary comparing technological characteristics with predicate device

Technological Characteristics	Comparison result
Design principle	Identical
Appearance	Similar
Patients contact Materials	Identical
Performance	Similar
Biocompatibility	Identical
Mechanical safety	Identical
Energy source	Identical
Standards met	Identical
Electrical safety	Identical
EMC	Identical
Function	Similar

8.0 Discussion of non-clinical and clinical test performed

Non-clinical Tests have been done as follows:

a. Electromagnetic compatibility test according to IEC 60601-1-2;
b. Electrical safety according test to IEC 60601-1 and IEC 60601-1-1
c. FCC test according to FCC part 15 (2009)
d. Safety and performance characteristics of the test according to SP10

None of the test demonstrates that iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock brings new questions of safety and effectiveness.

Clinical Test Concerning the Compliance of ANSI/AAMI SP10

Compared to deflation detection of its predicate device KD-930, iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock is an inflation detection device, so the arithmetic is changed. As a result, a new clinical test is done in accordance with ANSI/AAMI SP10, and the device met all applicable requirements of the standard.

9.0 Performance summary

iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock conforms to the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- UL 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 2003.
- IEC 60601-1-1, Medical Electrical Equipment - Part 1: General Requirements for Safety – 1. Collateral standard: Safety Requirements for Medical Electrical Systems, 2000.
- EN 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests, 2007.
- AAMI SP10:2002, Manual, electronic or automated sphygmomanometers.
- AAMI / ANSI SP10:2002/A1:2003 --, Amendment 1 to ANSI/AAMI SP10:2002 Manual, electronic, or automated sphygmomanometers.
- AAMI / ANSI SP10:2002/A2:2006 --, Amendment 2 to ANSI/AAMI SP10:2002 Manual, electronic, or automated sphygmomanometers.

10.0 Comparison to the predicate device and the conclusion

Our device iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock is substantially equivalent to the Fully Automatic Electronic Blood Pressure Monitor KD-930 whose 510(k) number is K101950.

The two devices are very similar in the intended use, the design principle, the material, the performance and the applicable standards. Only their appearance, the memory time, and the user interface are different. The measure process is also changed, that is the new device will get the measurement results when the device is inflating, while KD-930 gets the result during the deflating period. What's more, iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock can achieve its function with an iphone, ipod or ipad, while KD-930 can only connect an iphone to achieve its function.

However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Andon Health Co., Ltd.
C/O Mr. Liu Yi, President
No. 3 Jinping Street Ya'an Road
Nankai District, Tianjin 300190
China

FEB 2 3 2011

Re: K102939
Trade Name: iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: Not Dated
Received: February 15, 2011

Dear Mr. Yi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number : K102939

Device name: iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock

Indications for use:

iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

Prescription use _____ AND/OR Over-The-Counter Use YES

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-COUNTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102939

K103276

FEB - 8 2011

510(k) Summary
As required by 21 CFR §807.92(c)

Submitter

510(k) Owner:	Intel Corporation
Address:	1900 Prairie City Road, FM7-197, Folsom, CA 95630
Telephone:	916 847-7794
Contact Person:	Maureen Glynn
Date Prepared:	01/06/2011

Device Information

Trade Name:	Intel® Health Guide Express
Common Name:	Remote Patient Monitoring System
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG)

Substantial Equivalence is claimed to the following device:
1. Intel's Intel® Health Guide PHS6000 **(K080798, K083115 and K101178)**

Device Description

The Intel® Health Guide Express is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. The Intel® Health Guide Express is a software application running on a Commercial Off The Shelf (COTS) Personal Computer (PC). It collects measurements captured on commercially available wireless or tethered medical devices which are designed for home use and connection to a COTS PC. It displays the collected measurement on the PC, and securely stores the collected information locally on a memory device installed in the PC. The Intel® Health Guide Express also stores the information remotely on a host server, where the caregiver can view the measurement via the host server once synchronization between the host server and Intel® Health Guide Express has been completed. The Intel® Health Guide Express can be used to display educational and motivational content from the caregiver and can facilitate communication between the caregiver and patient via health wellness surveys and optional video conferencing.

The Intel® Health Guide Express is not interpretive, nor is it intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. It is contraindicated for patients requiring direct medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

The Intel® Health Guide PHS Express system consists of the:

(1) Intel® Health Guide Express software application:

The software application captures, stores, displays and transmits information to a secure database on a host server running the Intel® Health Care Management Suite software via a standard telephone line or internet connection. The Intel® Health Guide Express software runs on a Commercial Off The Shelf (COTS) Personal Computer (PC).

(2) Intel® Health Care Management Suite software application:

The software application runs on a host server and allows caregivers to review patient vital signs on the secure website. The Intel® Health Care Management Suite allows for predefining upper and lower limits and, when either limit is exceeded, the system emails and/or pages the caregiver.

Indications for Use

The Intel® Health Guide Express is intended to collect vital sign measurements from physiological measurement devices intended for use in the home. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.

The Intel® Health Care Management Suite allows the caregiver to review patient data and initiate video conferencing with patients, or select and send educational and motivational content to patients.

The Intel® Health Guide Express is not interpretive, nor is it intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required.

The Intel® Health Guide Express is contraindicated for patients requiring direct medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

Technological Characteristics

The Intel® Health Guide Express is substantially equivalent to the predicate device Intel® Health Guide PHS 6000 (**K080798, K083115 and K101178**) in terms of data collection software functionality, operating system for the patient device, communication method of patient device with central server, types of sensors which can be interfaced to the patient

device, implementation method of collecting data from sensors, sensor software, connectivity, communication protocol, power source, and display method.

Table 1: Peripherals Comparison between the predicate device and the **Intel® Health Guide Express**

Physiological Parameter	**Intel® Health Guide PHS6000 (K080798, K083115 and K101178)**	**Intel® Health Guide Express**
Blood Pressure	A&D UA-767PC (K982481)	
Weight	A&D UC-321PBT (exempt)	
	A&D UC-321PL (exempt)	
Blood Glucose Level	Bayer Diagnostics Ascensia Breeze2 (K062347)	
	Bayer Diagnostics Ascensia Contour Blood Glucose Monitoring System (K062058)	
	LifeScan OneTouch Ultra Family of Blood Glucose Monitoring Systems (K043197)	
	LifeScan OneTouch Ultra 2 of Blood Glucose Monitoring Systems (K053529)	
Oxygen Saturation	Nonin 4100 Pulse Oximeter (K043359)	
	N/A	Onyx® II 9560 (K081285)
FEV/PEF	Microlife PF100 (K031024)	

Table 2: Hardware Comparison between the COTS PC meeting minimum specifications and the predicate device[1]

Hardware Parameter	**Intel® Health Guide PHS6000 (K080798, K083115 and K101178)**	**COTS PC**
Operating System	Microsoft Windows XP embedded	Microsoft Windows 7 (32-bit versions)
CPU Core Frequency	1.5 GHz	Minimum: 1.6 GHz (Single Core)
System Memory Size	512MB	Minimum: 1 Gbyte
Pointing Device	HID compliant pointing device	HID compliant pointing device
Available Storage Capacity	40GB	Minimum: 10 Gbytes
LAN Connection	Externally accessible RJ45 jack for 802.3 10/100 LAN interface.	Externally accessible RJ45 jack for 802.3 10/100 LAN interface.
Ports	4 USB Ports	Minimum: 2 USB Ports
SD Card Slot	N/A	Minimum: 1 memory card SDHC compliant with the SD Card Association 2.00 card specification, Class 4 or faster.
Wireless Peripheral Connection	Bluetooth 2.0 Interface	Bluetooth 2.0 Interface
Display	600 x 800 18 bit color	Minimum: 1024 x 600 24 bit color
Speakers	1 Mono	Minimum: 1 (mono)
Microphone	1 Mono	Minimum: 1 (mono)

[1]Differences are to accommodate the Microsoft Windows 7 operating system

K103276

Table 3: Main difference between the COTS PC meeting minimum specifications and the predicate device

Parameter	Intel® Health Guide PHS6000 (K080798, K083115 and K101178)	COTS PC
Safety Standard	ES60601-1:2005 Medical electrical equipment – Part 1: General requirements for basic and essential performance	UL 60950-1:2007 Information Technology Equipment – Safety – Part 1: General Requirements
Patient Leakage Current – From Patient connection to earth[1]	100µA	3.5mA

[1]This is not meant to be an exhaustive list of differences between ES60601-1 and UL 60950-1 but highlights the differences covered in the risk analysis for a COTS PC used with the Intel® Health Guide Express.

Safety and Efficacy

The Intel® Health Guide Express does not rely on an assessment of clinical performance data. The device will conform to FDA's recognized consensus standards and relies on its conformity to demonstrate the safety and efficacy. The device introduces no new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Intel Corporation
c/o Ms. Maureen Glynn
1900 Prairie City Rd.
MS FM7-197
Folsom, CA 95630

FEB - 8 2011

Re: K103276
Trade Name: Intel Health Guide Express
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: January 10, 2011
Received: January 11, 2011

Dear Ms. Glynn:

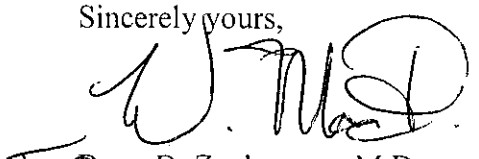
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103276

510(k) Notification Submission – Abbreviated
Intel Corporation, Inc.
Intel® Health Guide Express

Indications for Use:

510(k) Number: _____

Device Name: Intel® Health Guide Express

Indications for Use:

The Intel® Health Guide Express is intended to collect vital sign measurements from physiological measurement devices intended for use in the home. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.

The Intel® Health Care Management Suite allows the caregiver to review patient data and initiate video conferencing with patients, or select and send educational and motivational content to patients.

The Intel® Health Guide Express is not interpretive, nor is it intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required.

The Intel® Health Guide Express is contraindicated for patients requiring direct medical supervision or emergency intervention. It is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103276

K103544

DEC - 7 2011

AgaMatrix

AgaMatrix, Inc. • 7C Raymond Avenue • Salem, NH 03079 USA

510(k) Summary

This summary of 510k) safety and effectiveness information is being submitted in accordance with the requirements of SMFA 1990 and CFR 807.92.

510(k) Number: K103544

Prepared: December 5, 2011

Submitter: AgaMatrix, Inc.

Address: 7C Raymond Ave.
Salem, NH 03079
Phone: (603) 328-6000
Fax: (617) 588-0430

Contact: William H. McGrail
Executive Director, Regulatory & Clinical Affairs

Device Name: Trade/Proprietary Name: iBGStar Blood Glucose Monitoring System
Common Name: Glucose Test System

Product Name: iBGStar Diabetes Manager Application
Common Name: Diabetes Management Software

Device Classification:

Product Code	Classification	Regulation Section	Panel
CGA – glucose Oxidase	Class II	21 CFR 862.1345	75, Clinical Chemistry
NBW – system, test, blood glucose, over the counter	Class II	21 CFR 862.1345	75, Clinical Chemistry
JJX- Quality Control Material	Class 1	21 CFR 862.1660	75, Clinical Chemistry
JQP - Calculator/data processing module for clinical use.	Class 1	21 CFR 862.2100	75, Clinical Chemistry

Predicate Device: 1) Jazz Blood Glucose Monitoring System, 510(k) # k071393
2) WaveSense Diabetes Manager, 510(k) # 5101597

Device Description: The iBGStar Blood Glucose Monitoring System consists of:

- iBGStar Blood Glucose Meter
- BGStar Test Strips
- BGStar Control Solution

AgaMatrix, Inc. 7C Raymond Avenue Salem, New Hampshire 03079 USA | TEL +1 (603) 328 6000 | FAX +1 (617) 588 0430 | WEB www.agamatrix.com

Intended Use:

The iBGStar™ Blood Glucose Monitoring System is intended for the quantitative measurement of blood glucose levels in fresh capillary whole blood samples drawn from the fingertip, palms (at the base of the thumb), or forearms. It is intended to be used by a single patient and should not be used for testing multiple patients. The iBGStar™ Blood Glucose Monitoring System is intended for self testing outside the body (In vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The iBGstar Blood Glucose Monitoring System is not for the diagnosis of, or screening for diabetes, and is not intended for use with neonates.

The iBGStar Diabetes Manager Application is intended for use in the home with the capability of sending glucose readings through email to an individual's healthcare professional in the review, analysis and evaluation of glucose test results to support an effective diabetes management program. It is an optional data management software accessory for use with the iBGStar Blood Glucose Monitoring System.

Technological Characteristics:

There were no changes to the fundamental scientific technology.

Comparison to Predicate:

1) The iBGStar BGMS has the following similarities to the predicate device:

Item	Jazz BGMS	iBGStar BGMS
Indications for Use	Blood glucose monitoring	Same
Intended Use	Home Use	Same
Calibration	No coding required	Same
Test Principle/Enzyme	Glucose Oxidase	Same
System Characteristics	Operating Temp, Test Time, Test Range, Sample Size, Test strips	Same

The iBGStar BGMS has the following differences from the predicate device:

Item	Jazz BGMS	iBGStar BGMS
Backlight	Yes	No
Number of results stored	1865	300
Power Source	Two (2) CR-2032, 3 volt,	Polymer lithium-ion
Size	L-84 mm, W-46 mm, H-19.5	L-56 mm, W-24 mm, H-10
Weight	48g	8.5g

AgaMatrix, Inc. 7C Raymond Avenue
Salem, New Hampshire 03079 USA
TEL +1 (603) 328 6000
FAX +1 (617) 588 0430
WEB www.agamatrix.com

2) The iBGStar Diabetes Manager app has the following similarities to the predicate device:

Item	WaveSense Diabetes Manager app (predicate device)	iBGStar Diabetes Manager app
Indications for Use	Download glucose readings to a data management system to aid in the effective management of diabetes.	Same
Intended Use	Home Use	Same
Management Tools	Logbook and Trend Charts	Same

The iBGStar Diabetes Manager app has the following differences from the predicate device:

Item	WaveSense Diabetes	iBGStar Diabetes Manager app
Upload To	PC (computer)	Device compatible with the iPhone Operating System platform
Transfer of Glucose Readings	Cable Download	The iBGStar meter directly connects to idevice

Assessment of Performance:

An evaluation of the iBGStar BGMS and iBGStar Diabetes Manager Application were studied in house and in a clinical setting by person with diabetes. The studies demonstrated the ease of operating the iBGStar BGMS and iBGStar Diabetes Manager Application as intended.

Conclusion:

The results of clinical evaluations of the iBGStar BGMS and the iBGStar Diabetes Manager app demonstrate the meter and application are equivalent in performance to the predicate devices and suitable for its intended use.

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WEB www.agamatrix.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

AgaMatrix, Inc.
c/o William McGrail
7C Raymond Ave
Salem, NH 03079

JAN 11 2012

Re: k103544
Trade Name: iBGStar Blood Glucose Monitoring System, iBGStar Diabetes Manager Application, BGStar Control Solutions
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: CGA, JQP, NBW, JJX
Dated: November 23, 2011
Received: November 25, 2011

Dear Mr. McGrail:

This letter corrects our letter of December 7, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

AgaMatrix, Inc.
7C Raymond Ave
Salem, NH 03079 USA

Indications for Use

510(k) Number (if known): K103544

Device Name: iBGStar Blood Glucose Monitoring System, iBGStar Diabetes Manager Application

Indications for Use:

The iBGStar™ Blood Glucose Monitoring
The iBGStar™ Blood Glucose Monitoring System is Intended for the quantitative measurement of blood glucose levels in fresh capillary whole blood samples drawn from the fingertip, palms (at the base of the thumb), or forearms. It is intended to be used by a single patient and should not be used for testing multiple patients. The iBGStar™ Blood Glucose Monitoring System is intended for self testing outside the body (*In vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The iBGstar Blood Glucose Monitoring System is not for the diagnosis of, or screening for diabetes, and is not intended for use with neonates.

BGStar™ Test Strips
BGStar™ Test Strips are for use with the iBGStar™ Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertip, palms (at the base of the thumb), or forearms. Palm and forearm testing (Alternative Site Testing) should be done only during steady-state times (when glucose is not changing rapidly).

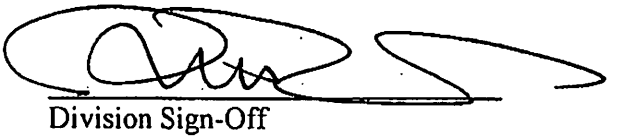
BGStar Control Solutions
BGStar Control Solutions are for use with the iBGStar™ Blood Glucose Meter and BGStar Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

The iBGStar Diabetes Manager Application – Home Use
The iBGStar Diabetes Manager Application is intended for use in the home with the capability of sending glucose readings through email to an individual's healthcare professional in the review, analysis and evaluation of glucose test results to support an effective diabetes management program. It is an optional data management software accessory for use with the iBGStar Blood Glucose Monitoring System.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k): K103544

510(k) Summary of Safety and Effectiveness

(The following information is in conformance with 21 CFR 807.92)

Submitter:

MIM Software Inc.
25200 Chagrin Blvd. Suite 200
Cleveland, OH 44122

Phone: 216-455-0600
Fax: 216-455-0601

Contact Person: Lynn Hanigan

Date Summary Prepared: Jan 26, 2011

Device Name

Trade Name: Mobile MIM
Common Name: Medical Imaging Software
Classification Name: System, Imaging Processing, Radiological

Predicate Device

K062163	MIMviewer 1.0	MIM Software Inc. (formerly MIMvista Corp.)

Intended Use / Indications for Use

The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.

Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography.

Device Description

The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.

Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

The software is not to be used for mammography.

It includes the capability to measure distance and image intensity values such as Standardized Uptake Value, displays measurement lines, annotations and regions of interest, and provides window/level, zoom/pan, and fusion blending control functionality.

Mobile MIM retrieves patient image data securely via a network connection with a MIM workstation or server. Processed DICOM images from the workstation or server are losslessly compressed for network transfer and downloaded by Mobile MIM for display.

Mobile MIM operates on "off-the-shelf" portable hardware devices and is therefore subject to factors not typical for reading room workstations (e.g. screen size, environmental variability, network dependencies, etc.). It is therefore required that the user follows the operating instructions properly and utilizes the risk mitigation features in order to make decisions safely and effectively.

Device Comparison Table between new device and predicate:

ITEM	Mobile MIM	MIMviewer
Intended Use / Indications For Use	The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI. Mobile MIM provides wireless and portable access	MIMviewer is a software package that aids the physician in the diagnosis of patients by means of medical images. MIMviewer is used to display, register and fuse medical images from multiple modalities. The MIMviewer software

ITEM	Mobile MIM	MIMviewer
	to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. This device is not to be used for mammography.	program is used for the registration, fusion and display of medical images from multi-modalities, such as SPECT, PET, CT, and MRI. MIMviewer provides tools for image review, manipulation, and analysis that assist physicians both inside and outside the medical environment.
Receive, Store, Retrieve, Display, and Process Digital Medical Images	Yes	Yes
Display of Clinical Patient Data When No Access to a Workstation	Yes	Yes
Image Fusion	Yes	Yes
Multi-Planar Reconstruction (MPR)	Yes	Yes
Maximum Intensity Projection (MIP)	Yes	Yes
Standardized Uptake Value (SUV)	Yes	Yes
Distance Measurements	Yes	Yes

ITEM	Mobile MIM	MIMviewer
Window/Level	Yes	Yes
Zoom/Pan	Yes	Yes
User Authentication	Yes	Yes
Modalities	SPECT, PET, CT, MRI	SPECT, PET, CT, MRI
Remote Handheld Viewing Device	Yes	No
Operating Platform	Apple® iOS	Windows® 2000/XP MacOS X® 10.4+ Linux®
Hardware Requirements	Apple® iOS handheld devices	Pentium® 4+ G4+

Substantial Equivalence

The comparison chart above provides evidence to facilitate the substantial equivalence determination between Mobile MIM and our chosen predicate device, MIMviewer (K062163)

The differences in the Indication Statements between Mobile MIM and MIMviewer describe specific restrictions on how Mobile MIM is to be used, given the hardware and portability differences between these two devices. Mobile MIM adds the explicate requirement that it should only be used when there is no access to a workstation, and that it is not to be used for mammography.

The technological characteristics between Mobile MIM and MIMviewer are different, as the software operates on different hardware. These differences are addressed through the labeling and additional software features of Mobile MIM.

Performance Data

MIM Software Inc. has conducted display performance testing using Mobile MIM software on various portable devices, both prior to and after utilizing the application's calibration procedure. Testing measured contrast response and evaluated test patterns for luminosity, resolution, and noise according to IEC 62563-1 and TG18 guidelines. All testing passed requirements following the Mobile MIM's calibration procedure.

MIM Software Inc. also performed multiple studies with qualified radiologists using a variety of modalities, specifically MRI, CT, SPECT, and PET, under different environmental conditions. Results of these studies affirm the diagnostic image viewing capabilities of Mobile MIM when used as indicated.

Furthermore, MIM Software Inc. has conducted verification, validation, and functional testing on the Mobile MIM software. In all cases, the software passed its performance requirements and met specifications.

Conclusion

Therefore, from all evidence gathered, it is our belief that Mobile MIM provides a diagnostic viewer of medical images substantially equivalent to the MIMviewer software, with portable device characteristics and functionality.

25200 Chagrin Blvd. Suite 200
Cleveland, OH 44122

www.mimsoftware.com

Tel: 866-421-2536
Fax: 216-455-0601

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Lynn Hanigan
Quality Manager
MIM Software
25200 Chargrin Blvd., Suite 200
CLEVELAND OH 44122

FEB - 4 2011

Re: K103785
Trade/Device Name: Mobile MIM
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 22, 2010
Received: December 27, 2010

Dear Ms. Hanigan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD K103785

Device Name: Mobile MIM

Indications for Use:

The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MRI.

Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K103785

APR - 6 2011

510(k) Summary: Modified CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector

Introduction

This document contains the 510(k) summary for the modified CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector. The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

Submitter	Card Guard Scientific Survival Ltd.,	
Establishment Registration Number	9681879	
Address	2 Pekeris St., P.O.B. 527, Rehovot, 76100, Israel	
Contact person:	Asher Kassel, Director of RA & QA, Card Guard Scientific Survival Ltd.	
Phone:	972-8-9484010 (direct)	Fax: 972-8-9484044
E-mail:	asherk@cardguard.com	
Date Prepared:	February 18, 2011	
Predicate device	Unmodified version of CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector, cleared in K101703 on July 13, 2010.	
Trade Name:	CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector	
Classification:	Detector and alarm, arrhythmia /Transmitters and receivers, electrocardiograph, telephone	
Product Code:	DSI, DXH	
Regulation No:	870.1025, 870.2920	
Class:	II	

Device Description

The CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector is designed for self-testing by patients at home and for analysis by medical professionals at a remote Monitoring Center.

The chest-worn sensor is used for the acquisition, recording, and transmission of the ECG signal. The device is equipped with 4 electrodes on a harness and it houses a 3.6V AA battery, a Bluetooth transceiver and a buzzer.

The ECG signals are transmitted via Bluetooth to a handheld device with a proprietary interactive application, configured to process and transmit the ECG recordings. The handheld device is a mobile computing device with a display and a touch input such as a cell phone. It has sufficient memory and processing capability to run the proprietary application.

When an arrhythmia event is detected, the handheld device transmits the recorded ECG information automatically via cellular link, to the Monitoring Center for professional analysis. When cellular service is unavailable the patient has an option to transmit via a landline telephone.

The Patient and Physician manuals are being modified to change a warning to allow the use of the ACT-3L on patients with an Implanted Cardioverter Defibrillator (ICD) if specific precautions are observed.

Indications for Use

The CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors patient ECG, automatically generates an alarm triggered by an arrhythmia detection algorithm, or generates an alarm manually triggered by the patient, and transmits the

recorded data transtelephonically to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.

Summary of the Technological Characteristics / Principles of Operation

The technological characteristics and principles of operation of the modified device are the same as the predicate device. The chest-worn ECG sensor transmits signals via Bluetooth to the handheld device equipped with the Medical Application, which incorporates an algorithm for detection of cardiac events: Atrial Fibrillation, Tachycardia, Bradycardia and Pause. A detected artifact triggers transmission of the signal to the Monitoring Center for analysis.

Non-clinical performance data for the CG-6108 ACT-3L

In order to support the labeling change the following testing has been performed:

- ACT-3L High Voltage Pulse Test, Card Guard document # ENTR-0112
- ACT-3L EMC Dipole Antenna Test, Card Guard document # ENTR-0113

Performance Standards:

This 510(k) submission was written in accordance with the FDA Guidance document "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm, October 28, 2003" and the device conforms to the applicable performance requirements contained in and referenced in this document. In addition, this submission was prepared in accordance with "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11 2005". The design of the CG-6108 ACT-3L conforms to the following voluntary standards:

- ANSI/AAMI EC57:1998 (R) 2008: Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms (Cardiovascular)
- ANSI/AAMI EC38:1998 Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems (Cardiovascular)
- ISO 14971:2007: Medical devices – application of risk management to medical devices (General)
- IEC 60601-1:1988, 2nd edition, Part 1, plus A1:1991 and A2:1995: Medical electrical equipment; Part 1: General requirements for safety
- IEC 60601-1-2: 2001, plus A1:2004, Part 1: Medical electrical equipment, Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-4:2000, Medical electrical equipment - Part 1:General requirements for safety; Part 1-4: Collateral standard: Programmable electrical medical systems
- IEC 62304:2006: Medical device software – Software life cycle processes
- ISO 15223:2000: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

Substantial Equivalence:

The modified CG-6108 ACT-3L device is substantially equivalent with respect to the indications for use, technological characteristics and performance characteristics to the identified legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Card Guard Scientific Survival Ltd
c/o Mr. Asher Kassel
Vice President of Operations
2 Pekeris St.
Rehovot, 76100 Israel

APR - 6 2011

Re: K110499
Trade/Device Name: CG-6108-3L Continuous ECG Monitor and Arrhythmia Detector
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detection or alarms (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: DSI and DXH
Dated: February 18, 2011
Received: February 22, 2011

Dear Mr. Kassel:

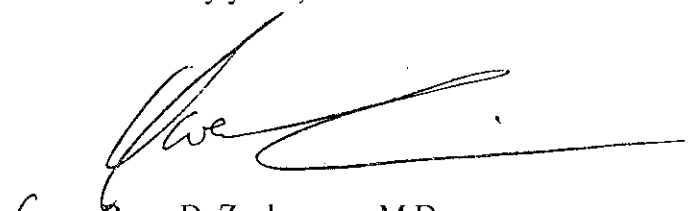
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110499

Indications for Use

510(k) Number (if known): K110499

Device Name: CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector

Indications for Use:

The CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors patient ECG, automatically generates an alarm triggered by an arrhythmia detection algorithm, or generates an alarm manually triggered by the patient, and transmits the recorded data transtelephonically to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110499

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AirStrip Technologies, LP
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

MAR 10 2011

Re: K110503
Trade/Device Name: AirStrip RPM I2 Support
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: February 18, 2011
Received: February 22, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use
510(k) Number (if known): ~~K100133~~ K110503

Device Name: AirStrip Remote Patient Monitoring (RPM) Remote Data Viewing software

Indications for Use:
AirStrip RPM is software capable of displaying physiologic and other patient information. This information is generated by other medical devices and patient information system, and not by AirStrip RPM. AirStrip RPM captures this information from these other systems and displays it for clinicians.

AirStrip RPM is intended to be used by clinicians for the following purposes:
• By using a cellular telephone or other device on which AirStrip RPM is installed, to review physiologic data of a patient when the clinician is not at the hospital
• To view the near real-time waveforms remotely
• To remotely review other standard or critical near real-time patient data from the monitored system
• To provide a request for remote consultation regarding a patient's waveform or other data

The AirStrip RPM software can display the following the physiologic data captured by other medical devices:
• ECG Waveform
• Heart Rate Monitored
• Respiratory Rate
• Oxygen Saturation
• Intracranial Pressure
• Central Venous Pressure
• Pulmonary Capillary Wedge Pressure
• Cardiac Index
• Cardiac Output
• Cerebral Perfusion Pressure
• Urine Output
• Urine/Stool Mix Output
• Systolic Blood Pressure Invasive
• Mean Arterial Pressure Invasive
• Diastolic Blood Pressure Invasive
• Systolic Blood Pressure Cuff
• Mean Arterial Pressure Cuff
• Diastolic Blood Pressure Cuff
• Vasoactive Infusions
• Antiarrhythmics
• Sedation
• Paralytics
• Laboratory Data including
- Blood Gas
- Chemistry
- Hematology
- Coagulation
• Allergies
• Medications

Counter-Indications
AirStrip RPM software is intended for installation on cellular telephones and other wireless devices, and is not intended for use anywhere cellular telephones or wireless devices are prohibited. AirStrip RPM is intended for use by clinicians when they cannot be at the hospital. AirStrip RPM is intended for use by clinicians as a diagnostic aid, and not as a replacement for direct viewing of any of the monitoring devices from which it obtains its data.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED) Donna R Lechner

(Division Sign-Off)

Division of Cardiovascular Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K110503

JUL 28 2011

510(k) Summary

K110571

Submitter:	Jonathan Javitt, M.D., M.P.H., Chief Executive Officer Telcare, Inc. 2 Bethesda Metro Center, Suite 1350 Bethesda, MD, 20814
Contact Person:	Jonathan Javitt, M.D., M.P.H., Chief Executive Officer Telcare, Inc. 2 Bethesda Metro Center, Suite 1350 Bethesda, MD, 20814 Telephone: (240) 396-6003, Fax: 877-777-4710 Email: JJavitt@telcare.com
Date Prepared:	July 27, 2011
Trade Names:	Telcare Blood Glucose Monitoring System, Telserve Data Management System, Telcare Blood Glucose Test Strips, Telcare Glucose Control Solutions
Classification Names:	Glucose test system, 21 CFR 862.1345, Class II Quality control material (assayed and unassayed), 21 CFR 862.1600, Class I Calculator/data processing module for clinical use, 21 CFR 862.2100, Class I Exempt (non exempt is associated with blood glucose monitoring system)
Product Codes:	NBW, CGA, JJX, JQP
Predicate Devices:	AutoSure Voice II Blood Glucose Monitoring System (BGM) - k102037, MCT-Diabetes (Data Management Software) – k073699, Gluco Track Blood Glucose Monitoring System (control solutions) – k062799
Device Description:	The Telcare Blood Glucose Monitoring System consists of the Telcare Blood Glucose Meter (BGM), Telcare Blood Glucose Test Strips, and Telcare Glucose Control Solutions. The Telcare BGM, when used with the Telcare Test Strips, quantitatively measures glucose in capillary whole blood. The Telcare Control Solutions verify the performance of the Telcare Test Strips. An embedded cellular module within the Telcare BGM enables wireless communication between the meter and Telcare's remote database, called the Telserve Data Management System (Telserve). The Telserve Data Management System serves as an accessory to blood glucose meters to assist in the review and evaluation of blood glucose test results and related information to aid in diabetes management. The software system consists of two different levels of functionality: 1) Telserve Data Management System – Home Use and 2) Telserve Data Management System – Professional Use

510(k) Summary (Cont'd)

Intended Use:	**Telcare Blood Glucose Monitoring System** The Telcare Blood Glucose Monitoring system is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. It is intended for lay use by persons with diabetes to aid in diabetes management. It is indicated for use at home (over the counter [OTC]) and should be used only by a single patient and should not be shared. Testing is done outside the body (*in vitro* diagnostic use). The Telcare Blood Glucose Monitoring System consists of the Telcare Blood Glucose Meter, Telcare Blood Glucose Test Strips, and Telcare Glucose Control Solutions. The Telcare Blood Glucose Monitoring system is not indicated for the diagnosis or screening of diabetes or for neonatal use. Palm and forearm testing should be done only during steady-state times when glucose is not changing rapidly. The Telcare Blood Glucose Meter uses cellular data transmission to send test results to Telcare's remote database, Telserve, and to receive messages from Telserve. The Telcare Blood Glucose Monitoring System is not intended to provide automated treatment guidance or decisions, nor is it to be used as a substitute for professional healthcare judgment. **Telcare Blood Glucose Test Strips** The Telcare Blood Glucose Test Strips are to be used with the Telcare Blood Glucose Meter for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, palm, or forearm. These test strips are intended for lay use by persons with diabetes and should only be used by a single patient. They are not indicated for the diagnosis or screening of diabetes or for neonatal use. Palm and forearm testing should be done only during steady-state times when glucose is not changing rapidly. **Telcare Glucose Control Solutions** The purpose of the control solution test is to validate the performance of the Telcare Blood Glucose Monitoring System by using a test solution with a known amount of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.

510(k) Summary (Cont'd)

Intended Use (Cont'd)	The **Telserve Data Management System – Home Use (Telserve – Home)** is an accessory to blood glucose monitoring systems for the review and evaluation of blood glucose test results to aid in diabetes management. Telserve collects data from blood glucose meters such as the Telcare BGM. Telserve – Home is not intended to provide automated treatment guidance or decisions, nor is it to be used as a substitute for professional healthcare judgment. The **Telserve Data Management System – Professional Use (Telserve – Pro)** is an accessory to blood glucose monitoring systems for the review and evaluation of blood glucose test results to aid in diabetes management. Telserve collects data from blood glucose meters such as the Telcare BGM.
Technological Characteristics	The Telcare Blood Glucose Monitoring System consists of a glucose meter that can wirelessly transmit data to a remote database using standard cellular technology embedded within the glucose meter. The meter uses biosensor test strips. Telserve Data Management System consists entirely of software run on a central server.
Non-Clinical Testing	Telcare BGM: Minimum Sample Volume, Linearity, Detection Limit, Precision, Hematocrit, Altitude, Humidity/Temperature, and Interfering Substances testing were done. Control Solution Qualification was conducted. EMC, Electrical Safety and FCC testing were conducted. Software verification and validation were done. All testing demonstrated safety and effectiveness of the Telcare Blood Glucose Monitoring system and substantial equivalence to the predicate. Telserve Data Management System: Software verification and validation demonstrated safety and effectiveness of the Telserve remote database and substantial equivalence to the predicate.

510(k) Summary (Cont'd)

Clinical Testing:	Telcare Blood Glucose Monitoring (BGM) System: A User Performance Study was conducted to evaluate the ease of use of the Telcare BGM and ease of understanding of the Telcare BGM user manual. An Accuracy and User Performance Study was conducted with professional and self-testing with fresh fingertip, palm and forearm testing. User control solution testing was conducted. A User Performance Study was conducted to evaluate the ease of use of the Telcare BGM Test Strip Insertion Process and ease of understanding of the Telcare BGM Test Strip Insertion instructions in the user manual. Telserve Data Management System (Telserve): A User Performance Study was conducted to evaluate the ease of use of Telserve-Home and ease of understanding of the Telserve – Home user manual. A User Performance Study was conducted to evaluate the ease of use obtaining login credentials to Telserve and ease of understanding of the Telserve – Home user manual. A User Performance Study was conducted to evaluate the ease of use of Telserve-Pro, the ease of use of obtaining login credentials, and ease of understanding of the Telserve – Pro user manual. The results show Telcare BGM System and Telserve showed substantial equivalence to the predicate devices.
Conclusion:	The Telcare Blood Glucose Monitoring System and its accessory Telserve Data Management System are substantially equivalent to their predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUL 28 2011

Telcare, Incorporated
c/o Dr. Jonathan C. Javitt
Chief Executive Officer
3 Bethesda Metro Center Suite 430
Bethesda, MD 20814

Re: k110571
Trade Name: Telcare Blood Glucose Monitoring System, Telserve Data Management System – Home Use, Telserve Data Management System – Professional Use
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA, JJX, JQP
Dated: July 8, 2011
Received: July 11, 2011

Dear Dr. Javitt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110571

Device Name: Telcare Blood Glucose Monitoring System
Telserve Data Management System – Home Use
Telserve Data Management System – Professional Use

Indications for Use:

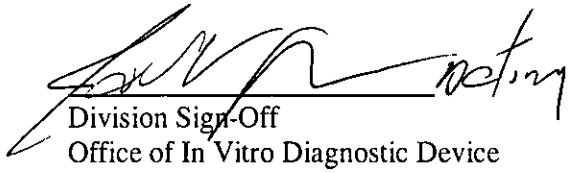
Telcare Blood Glucose Monitoring System
The Telcare Blood Glucose Monitoring system is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. It is intended for lay use by persons with diabetes to aid in diabetes management. It is indicated for use at home (over the counter [OTC]) and should be used only by a single patient and should not be shared. Testing is done outside the body (*in vitro* diagnostic use). The Telcare Blood Glucose Monitoring System consists of the Telcare Blood Glucose Meter, Telcare Blood Glucose Test Strips, and Telcare Glucose Control Solutions. The Telcare Blood Glucose Monitoring system is not indicated for the diagnosis or screening of diabetes or for neonatal use. Palm and forearm testing should be done only during steady-state times when glucose is not changing rapidly. The Telcare Blood Glucose Meter uses cellular data transmission to send test results to Telcare's remote database,Telserve, and to receive messages from Telserve. The Telcare Blood Glucose Monitoring System is not intended to provide automated treatment guidance or decisions, nor is it to be used as a substitute for professional healthcare judgment.

Telcare Blood Glucose Test Strips
The Telcare Blood Glucose Test Strips are to be used with the Telcare Blood Glucose Meter for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, palm, or forearm. These test strips are intended for lay use by persons with diabetes and should only be used by a single patient. They are not indicated for the diagnosis or screening of diabetes or for neonatal use. Palm and forearm testing should be done only during steady-state times when glucose is not changing rapidly.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use __X___ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110571

510(k) Number (if known): K110571

Telcare Glucose Control Solutions
The purpose of the control solution is to validate the performance of the Telcare Blood Glucose Monitoring System by using a test solution with a known amount of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.

Telserve Data Management System - Home Use
The Telserve Data Management System - Home Use (Telserve - Home) is an accessory to blood glucose monitoring systems for the review and evaluation of blood glucose test results to aid in diabetes management. Telserve collects data from blood glucose meters such as the Telcare BGM. Telserve - Home is not intended to provide automated treatment guidance or decisions, nor is it to be used as a substitute for professional healthcare judgment.

Telserve Data Management System – Professional Use
The Telserve Data Management System – Professional Use (Telserve – Pro) is an accessory to blood glucose monitoring systems for the review and evaluation of blood glucose test results to aid in diabetes management. Telserve collects data from blood glucose meters such as the Telcare BGM.

Prescription Use ___X___ And/Or Over the Counter Use __X___
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

for Acting

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110571

Withings

Withings, 37 bis, rue du General Leclerc 92130 ISSY LES MOULINEAUX, FRANCE

www.withings.com

Tél: +33 1 41 46 04 60 Fax: +33 9 56 83 90 32

K110872
P1/3

" 510(k) Summary for_____" MAY 2 0 2011

Submitter's Name:	***Withings***
Address:	*37 bis, rue du General Leclerc, Issy Les Moulineaux Cedex, 92442, FRANCE*
Telephone:	33-1 41 46 04 60
FAX:	33-9 56 83 90 32
Manufacturer's Name:	**YA HORNG Electronic Co., Ltd.**
Address:	*No. 35, Zsha Lun, Jon Zsha Village, Antin Shiang, Tainan, 74555, Taiwan, ROC*
Contact Person:	Dr. Jen, Ke-Min
Date Summary Prepared:	March 20, 2011
Proprietary Name:	*Withings Blood Pressure Monitor, Upper Arm Type: BP-800*
Common Name:	BLOOD PRESSURE MONITOR
Classification Name:	NON-INVASIVE BLOOD-PRESSURE MEASUREMENT SYSTEM (per 21CFR section 870.1130)
Device Class:	Class II (performance standards)
Specialty:	CARDIOVASCULAR
Product code:	DXN
Legally Marketed (Predicate) Device :	• YA HORNG Digital Upper Arm Blood Pressure Monitor BP-700, BP-700T, BP-700U, BP-700B, BP-700TB, BP-700UB, and BP-700TUB (K090058) • KD-931D Fully Automatic Electronic Blood Pressure Monitor (K102631)

Withings

Withings. 37 bis. rue du General Leclerc 92130 ISSY LES MOULINEAUX. FRANCE

www.withings.com

Tél : +33 1 41 46 04 60 Fax : +33 9 56 83 90 32

Description of the new device: (Same as the predicate devices)

Withings Blood Pressure Monitor, Upper Arm Type:BP-800 uses the Oscillometric method to measure the blood pressure. The Oscillometric method is adopted clinically to measure the blood pressure recently. It is not needed to use the stethoscope, as in the traditional measuring method, to monitor the Korotkov sound when deciding the systolic or diastolic pressure. The Oscillometric method senses the vibrating signal via the closed air pipe system and utilizes the microcomputer to automatically sense the characteristics of the pulse signal. Through simple calculation, the reading can reflect the accurate real blood pressure, and the systolic pressure is defined as the pressure when the cuff pressure oscillating amplitude begins to increase and the diastolic pressure as the pressure when the cuff pressure oscillating amplitude stops decreasing.

Technological Characteristics of our new device compared to the predicate device:

The technological characteristics of Withings Blood Pressure Monitor, Upper Arm Type:BP-800 is substantially equivalent to YA HORNG Digital Upper Arm Blood Pressure Monitor BP-700, BP-700T, BP-700U, BP-700B, BP-700TB, BP-700UB, and BP-700TUB (K090058); and KD-931D Fully Automatic Electronic Blood Pressure Monitor (K102631). There is the same manufacturer, YA HORNG Electronic Co., Ltd., which FDA owner number is 9040892 for the new device BP-800 and predicate BP-700 series. Especially, there are the same design specifications, the same form and intended to be used in the same manner that means the new devices are same as the predicate devices.

The mainly different are:

1. The new devices are different vision appearance and specifications for the predicate devices.
2. There are different storage temperature, operating temperature, and humidity for the new device and predicate devices.
3. The new device and the predicate devices have the different sizes of the cuff for upper arm.

Withings

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K110872
p3/3

4. The new device BP-800 and the predicate device KD-931D can connect to **iPhone;** and the predicate devices BP-700 series are the identical device with the optional functions for the BP-700U, BP-700UB, and BP-700TUB which can connect to the PC, backlight, and the voice function for the general upper arm use.

Thus there are substantially equivalent.

Test Summary:

1. **ELECTRIC SAFETY, EMC and FCC test reports,**

General safety	*IEC/EN 60601-1:2007*	***PASS***
	EN 1060-1:2009, EN 1060-3:2009	***PASS***
EMC conformity	*EN 60601-1-2: 2007*	***PASS***
FCC conformity	*ANSI C63.4: 2008*	***PASS***

2. **WOVEN COTTON SHEETING:**

(Same as the predicate devices: K090058, BP-700 series)

Uses the 510K Blood-Pressure Cuff: YA HORNG Blood-Pressure Cuff (K051539).

3. **PERFORMANCE & CLINICAL TEST**

AAMI / ANSI SP10

***Withings** believes this information and referred document to be sufficient for the FDA to find our proposed device substantially equivalent to the predicate product and other products currently in distribution.*

Dr. Jen, Ke-Min
official correspondent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 18 2011

Withings
c/o Dr. Jen Ke-Min
Official Correspondent
ROC Chinese-European Industry Research Society
No. 58 Fu Chiun Street
Hsin Chu City
CHINA (TAIWAN) 30067

Re: K110872
Trade/Device Name: Withings Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: 74 DXN
Dated (Date on orig SE ltr): March 20, 2011
Received (Date on orig SE ltr): March 29, 2011

Dear Dr. Ke-Min:

This letter corrects our substantially equivalent letter of May 20, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K110872

Indications for Use

510(k) Number: K

Device Name: Withings Blood Pressure Monitor, Upper Arm Type: BP-800

- *Indications for use:*

The Withings Blood Pressure Monitor, Upper Arm Type: BP-800 is noninvasive blood pressure measurement systems intended to measure the systolic and diastolic blood pressures and pulse rate of an adult individual, over age 18, at home by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.
The cuff circumference is limited to be 9'~17' (22cm~42cm) for Upper Arm type.

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110872

C1

K110919

Carestream

OCT 20 2011

Carestream Health Inc.
150 Verona Street
Rochester, NY 14608

"510(k) Summary"

510(k) Owner Name:	Carestream Health, Inc.
510(k) Owner Address:	150 Verona Street Rochester, New York 14608
510(k) Owner Phone:	585 627-6543
510(k) Owner Fax:	585 454-1894
Contact Name & Info:	John Pardo Director, Regulatory Affairs and Quality Systems John.pardo@carestreamhealth.com 585-627-6543
Date Summary Prepared:	7/15/2011
Device Trade Name:	Carestream PACS
Device Common Name:	PACS
Classification Name:	System, Image Processing, Radiological
Regulation Name:	Picture Archiving and Communication System
Device Class:	Class II
Device Code:	LLZ
Regulation Number:	21 CFR 892.2050
Predicate Device:	Carestream PACS Manufactured by Carestream Health, Inc. 510(k) No. – K083673 (December 30, 2008)

Carestream

Carestream Health Inc.
150 Verona Street
Rochester, NY 14608

Device Description:
CARESTREAM PACS is an image management system whose intended use is to provide completely scalable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve and display images and data from all hospital modalities and information systems.

It is a software only solution that contains interactive tools in order to ease the process of analyzing and comparing three dimensional (3D) images. It is a single system that integrates the review, dictation and reporting tools that creates a productive work environment for the radiologists and physicians. It offers an intuitive user interface which includes a tab concept, grouping features, and functions with the same context together such as Image display, Monitor layout, Comparison, Wide area user tab, etc.

The device provides functionality to allow remote site access to image and patient data enabling diagnostic reading through industry standard interfaces. It is designed using an open architecture that allows for various proprietary and off the shelf software components to be integrated with off the shelf hardware components and configured meeting the user's specific needs in a single-site or multi-site environment.

Carestream PACS provides support for 3D registration of studies taken at different times or by different modalities for reading of CT/MRI or PET-CT images. The volumetric data sets are synchronized allowing the user to view reformatted series side by side and superimposed images. In all methods the algorithm is only using a rigid space transformation. Automatic vessel segmentation suggests a segmentation that that can either be accepted, ignored or fine tuned by the user.

The CARESTREAM PACS LightWeight Viewer feature addresses the need for a fast and simple web based tool to access patient records and images. It allows for high speed distribution of image data to users in a wide area setup. The software technology uses HTML5 which allows browser enabled devices to run the application without local software installation. The LightViewer has a simple GUI for viewing including zoom, pan, windowing, basic measurements, cine, etc.

The CARESTREAM PACS Lightweight Viewer provides wireless and portable access to medical images for referral purposes. It provides a diagnostic viewer of medical images substantially equivalent to the CARESTREAM PACS software, with portable device characteristics and functionality. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. The CARESTREAM PACS LightWeight Viewer software is not to be used for mammography in the US.

Carestream

Carestream Health Inc.
150 Verona Street
Rochester, NY 14608

The CARESTREAM PACS LightWeight Viewer operates on "off-the-shelf 'portable hardware devices and is therefore subject to factors not typical for reading room workstations (e.g. screen size, environmental variability, network dependencies, etc.). It is therefore required that the user follows the operating instructions and adhere to the risk mitigation guidelines.

CARESTREAM PACS does not drive or influence the use of the source device. It does not directly drive a decision regarding treatment or therapy without the intervention of subsidiary means. Images must be evaluated and the decision regarding treatment or therapy is determined by the user based on their standard procedures. CARESTREAM PACS is a complement to these standard procedures.

Intended Use:
The CARESTREAM PACS is an image management system whose intended use is to provide completely scaleable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve and display images and data from all hospital modalities and information systems.

The system contains interactive tools in order to ease the process of analyzing and comparing three dimensional (3D) images. It is a single system that integrates the review, dictation and reporting tools that creates a productive work environment for the radiologists and physicians.

The CARESTREAM PACS Lightweight Viewer software program is used for patient management by the referral community in order to access and display patient data, medical reports, and medical images from different modalities including CR, DR, CT, MR, NM and US after the primary reading has been completed on dedicated diagnostic workstations.

The CARESTREAM PACS Lightweight Viewer provides wireless and portable access to medical images for referral purposes. It is not intended to be used as, or to replace, a full diagnostic workstation or system and should be used only when there is no access to a workstation. This device is not to be used for mammography.

Carestream

Carestream Health Inc.
150 Verona Street
Rochester, NY 14608

Comparison of Technological Characteristics:
The modifications to the CARESTREAM PACS do not alter the fundamental scientific technology of the device. The only device modification was to the software. No new image manipulation tools are implemented that do not currently exist in the Carestream PACS device.

The differences in the Indication Statements between Carestream PACS and CARESTREAM PACS LightWeight Viewer describe specific restrictions on how CARESTREAM PACS LightWeight Viewer is to be used, given the hardware and portability differences between these two devices. CARESTREAM PACS LightWeight Viewer adds the explicate requirement that it should only be used when there is no access to a workstation, and that it is not to be used for mammography in the US.

Discussion of Testing
Performance testing was conducted to verify the design output met the design input requirements and to validate the device conformed to the defined user needs and intended uses. Testing was conducted under simulated use conditions. Predefined acceptance criteria was met and demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device.

Carestream Health conducted display performance testing using the CARESTREAM PACS Lightweight Viewer software on the iPad device. Testing measured contrast response and evaluated test patterns for luminosity, resolution, and noise according to IEC 62563-1 and AA PM TGI8 guidelines. Carestream Health also performed multiple studies with qualified radiologists using a variety of modalities, specifically CR, DR, CT, MR, NM and US under different environmental conditions. Results of these studies affirm the diagnostic image viewing capabilities of CARESTREAM PACS LightWeight Viewer when used as indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT 20 2011

Mr. John Pardo
Senior Director, Regulatory Affairs and Quality Systems
Carestream Health, Inc.
150 Vernon Street
ROCHESTER NY 14608

Re: K110919
Trade/Device Name: CARESTREAM PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 29, 2011
Received: September 30, 2011

Dear Mr. Pardo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K110919

Device Name: CARESTREAM PACS

Indications for Use:
The CARESTREAM PACS is an image management system whose intended use is to provide completely scaleable local and wide area PACS solutions for hospital and related institutions/sites, which will archive, distribute, retrieve and display images and data from all hospital modalities and information systems.

The system contains interactive tools in order to ease the process of analyzing and comparing three dimensional (3D) images. It is a single system that integrates the review, dictation and reporting tools that creates a productive work environment for the radiologists and physicians.

The CARESTREAM PACS Lightweight Viewer software program is used for patient management by the referral community in order to access and display patient data, medical reports, and medical images from different modalities including CR, DR, CT, MR, NM and US after the primary reading has been completed on dedicated diagnostic workstations.

The CARESTREAM PACS Lightweight Viewer provides wireless and portable access to medical images for referral purposes. It is not intended to be used as, or to replace, a full diagnostic workstation or system and should be used only when there is no access to a workstation. This device is not to be used for mammography.

Prescription Use____X____ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110919

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Kyle Peterson
Director, Regulatory & Corporate Affairs
Calgary Scientific, Inc.
1210 20th Avenue SE, Suite 208
Calgery, AB T2G 1MB
CANADA

SEP - 9 2011

Re: K111346
Trade/Device Name: ResolutionMD™ Mobile
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 29, 2011
Received: August 1, 2011

Dear Mr. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Applicant: Calgary Scientific, Inc., Suite 208 – 1210 20th Ave. SE, Calgary, Alberta, CANADA T2G 1M8

510(k) Number: ~~K093682~~ K111346

Device Name: ResolutionMD™ Mobile

Indications for Use:

The ResolutionMD™ Mobile software is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and specific mobile devices. It provides for communication, storage, reformatting, rendering on the server component and communication and display of DICOM 3.0-compliant CT and MR medical images as well as reports on the mobile device.

The ResolutionMD Mobile provides wireless and portable access to medical images. The device is intended for use as a diagnostic, review, and analysis tool by trained professionals such as radiologists, physicians and technologists. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

The ResolutionMD Mobile is not to be used for mammography.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111346

REKA

510 (k) Summary SEP 12 2011

K 111438

In accordance with 21 CFR 807.87(h), the following 510 (k) summary has been prepared per 21 CFR 807.92.

Electrocardiograph Recorder / ECG Monitor

Submitter: REKA Pte. Ltd
21 Science Park Road
#03-10/11 The Aquarius
Singapore Science Park
Singapore 117 628

Tax I.D. # CRN 200202641G

Tel: +65 6777 1588
Fax: +65 6779 5677
Email: Kaeyuan.tan@rekapd.com
Website: www.rekapd.com

Contact person: Larry Petersen
Regulatory Affairs Specialist
Phone: 303-489-2500 USA
Email: Larrypetersen7@gmail.com
Date summary prepared: July 29, 2011
Device trade name: REKA E100
Device common name: ECG Event Recorder (Cardiac Rhythm Monitor)
Device classification: Handheld ECG Recorder /Monitor; Product Code: DPS
21 CFR 870-2340, Class II

Legally marketed Predicate devices to which this device is Substantially Equivalent:

Predicate Device #1 **Daily Care Biomedical, Inc.** Model: **ReadMyHeart**
FDA 510(k): **K052303** (2005)

Predicate Device #2 **Omron Corp.** Model: **HCG- 801**
FDA 510(k): **K060766** (2006)

Predicate Device #3 **Card Guard Scientific Survival, Ltd.** Model: **CG-6106**
FDA 510(k): **K963811** (1996)

Predicate Device #4 **Beijing Choice Electronics** Model: **MD100**
FDA 510(k): **K093872** (2010)

REKA

Description of the Device: Section 5

The REKA E100 device has the following characteristics:

Device Description

The REKA E100 ECG Event Recorder (Cardiac Rhythm Monitor) is designed for on-demand, self-recording of a single channel ECG by patients at almost any place and any time. The recording takes 30 seconds and is transmitted to backend website for analysis and interpretation by medical professionals of the remote Monitoring Center. ECG signals are acquired by the two (2) built-in finger electrode sensors on the device. As an alternative, a better quality ECG can be recorded using the 2-leadwire cable with 2 electrodes pasted on body. The acquired signals are recorded in a build-in NAND flash memory and E100 can store up to 4000 ECG records.

The recorded EGG data can be transferred to mobile phone using micro USB cable/ 30-pin cable provided. The ECG then can be transmitted via cellular link or WiFi to an Internet depository when the patient ECG records are filed. The Internet depositories compatible with E100 can be accessed via www.reka.net and www.rekahealth.com. The compatible smart cell/mobile phones that can upload ECG records from E100 include iPhone®, Blackberry®, Symbian® and smart phones running on Android™. These mobile phones will require to install E100 Uploader (Apps) developed by REKA, the user can easily download the Apps from App World, Android Market etc. and install it.

Alternatively, the EGG signals stored in E100 can be transmitted to backend website through PC or Laptop with Internet connection by plugging E100 to computer using USB cable. For computer with Windows® & Mac®, user can easily access to the corresponding Uploader apps pre-stored in the device to run it for installation at 1st time use. After then the Uploader runs automatically once E100 is plugged in. For computer with Linux®, user can directly upload ECG data by clicking the apps, no installation required.

Indications for Use:

The REKA E100 ECG Event Recorder (Cardiac Rhythm Monitor) is intended for use by patients who may experience transient symptoms that could suggest cardiac arrhythmia. The device records the patients EGG on demand at any time the patient feels any physical symptom indicative of a potential heart event. A 30 second single channel ECG is recorded and transmitted to a monitoring center. The monitoring center provides the EGG data to the medical practitioner for evaluation. The Indications for Use are the same as the predicate devices.

The REKA E100 is designed for self-recording an ECG by out-hospital patients and for analysis by medical professionals at a remote monitoring center or a cardiologist or a physician. The E100 EGG is intended for use by patients who may experience transient symptoms that could suggest cardiac arrhythmia. The device is intended for non-lethal long term monitoring. The intended use is the same as the predicate devices.

It is suitable for adult users, who suffer from cardio-vascular diseases, are considered at high risk for potential cardiovascular events or other adult people who are concerned about their heart function and rhythm as they more about during their daily life. This device is not intended for use as a conventional diagnostic tool, but is to be used as a healthcare patient evaluation

REKA

tool which can provide a doctor with the recorded ECG data as a reference to help detect and analyze heart events that a patient may experience at any time or any place.

Summary of Technological Characteristics & Principals of Operation

The technological characteristics and principles of operation of REKA E100 are the same as the predicate device. The two finger electrode sensors built in the REKA E100 are used for the ECG signal acquisition and the acquired signal is recorded in a build-in memory. Alternatively, patient can use the 2-leadwire cable provided and 2 electrodes pasted on body to capture better quality ECG signal. The ECG data stored in E100 will be transmitted to backend website through smart mobile phone or computer using cables provided. The ECG data uploaded on website will be as reference for analysis by medical professionals at a remote monitoring center or a cardiologist or a physician.

Non-Clinical Performance Tests and Data for the REKA E100:

REKA E100 has been subjected to extensive verification & validation testing.
Final testing of the system included various performance tests and software validation tests designed to ensure that the device meet all of its functional and performance requirements and is fit for its intended use. The following list summarizes the testing performed on the device;

- Product Specification Verification
- Software Verification and Validation according to IEC 60601-1-4 and IEC 62304, including Firmware, Uploader, Backend, and the system level
- IEC 60601-1 Safety Test
- IEC 60601-1-2 EMC Test
- ISO 10993 Biocompatibility Test
- Functionality Test, including accuracy test, compatibility test
- Reliability Test, including drop test, environment test, connector test, button test, packaging test
- Risk Management according to ISO 14971
- Bench Test against predicate device
- Performance Test voluntarily against AAMI EC38

Performance Standards:

This 510(k) submission was written in accordance with the FDA Guidance document "Class II Special Controls Guidance Document: Arrhythmia Detector, October 28, 2003" and the device conforms to the applicable performance requirements contained in and referenced in this document. In addition, this submission was prepared in accordance with "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11 2005".

Reka

Below is the list of the specific recognized standards that Reka E100 conforms to.

1. **IEC 60601-1:1988/A1:1991/A2:1995** Medical electrical equipment – Part 1: General requirements for safety
2. **IEC 60601-1-2:2007** Medical electrical equipment, Part 1-2 General requirements for safety – Collateral Standard: Electromagnetic compatibility -Requirements and tests
3. **ISO 10993-1:2009** Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
4. **ISO 10993-5:2009** Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
5. **ISO 10993-10:2010** Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
6. **IEC 60601-1-4:1996/A1:1999** Medical electrical equipment; Part 1-4 General requirements for safety – Collateral Standard: Programmable electric medical systems
7. **IEC 62304:2006** Medical device software - Software life cycle processes
8. **ISO 15223-1:2007** Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements
9. **ISO 14971:2009** Medical devices -- Application of risk management to medical devices

E100 is also tested voluntarily against the applicable clauses of:

- **AAMI/ANSI EC38:2007** Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

Substantial Equivalence:
The REKA E100 device is substantially equivalent with respect to the indications for use, technological characteristics and performance characteristics to the identified legally marketed predicate devices.

Assessment of non-clinical performance data:
The results of the bench tests (Please refer to Section 18) demonstrate that the REKA E100 is as safe and effective as compared to the currently marketed predicate device.

Summary:
The REKA E100 ECG Monitor has the same intended use as the predicate devices. Based on the assessment of non-clinical performance data to verify the intended use, and the technological characteristic comparison, the REKA E100 is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

REKA Pte, Ltd.
c/o Mr. Larry Petersen
Regulatory Affairs Consultant
1001 Bear Island Road, Suite 136
Summerville, SC 29483

SEP 12 2011

Re: K111438
Trade/Device Name: REKA E100
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: August 9, 2011
Received: August 11, 2011

Dear Mr. Petersen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111438

Reka

Indications for Use

Section 4

510(k) Number: K111438

Device Name: Reka E100

Indications for Use

The REKA E100 EGG Event Recorder (Cardiac Rhythm Monitor) is intended for use by patients who may be at risk for experiencing transient cardiac symptoms that could suggest cardiac arrhythmia. The device records the patients EGG on demand at any time the patient feels any physical symptoms indicative of a potential heart event. A 30 second single channel ECG is recorded and transmitted to a monitoring center. The monitoring center provides the EGG data to the medical practitioner for evaluation. The Indications for Use are the same as the predicate devices.

The device is a handheld, personal electrocardiograph unit, which can measure electrical activities of the heart easily and conveniently. It is immediately available at any time to manually record transient cardiac events, suitable for home health care use, and which can record and store an ECG signal, and then transmit the ECG recording to a hospital or cardiology center for interpretation and review.

It is suitable for adult users, who suffer from cardio-vascular diseases, are considered at high risk for potential cardiovascular events or other adult people who are concerned about their heart function and rhythm as they move about during their daily life.

This device is not intended for use as a conventional diagnostic tool, but is to be used as a healthcare patient evaluation tool which can provide a doctor with the recorded ECG data as a reference to help detect and analyze heart events that a patient may experience at any time or any place.

Prescription Use: X AND/OR Over-The Counter Use: _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

Please do not write below this line

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K111438

NOV 10 2011 K111932

510(K) Notification	510 (k) SUMMARY	positive ID
Section: 5		
Doc # NA		
Confidential		

Section 5 510(k) SUMMARY

Date Prepared: June 30, 2011

Company Name and Address:

PositiveID Corporation
1690 South Congress Avenue, Suite 200
Delray Beach, FL 33445
Telephone: 561.805.8015
Contact person: Triana Dorland

Device Name:

The iglucose™ System collects and transmits stored data from a variety of FDA cleared blood glucose meters such as the LifeScan® OneTouch® and Home Diagnostics™ True™ monitoring systems to a secure database via wireless cellular technology. Subsequently, blood glucose data can then be reviewed through a web portal as an aid in supporting diabetes management.

Classification Name:

Classification:

Glucose Test System 21 CFR 862.1345 Product code: NBW

Class II

Predicate Devices:

1) MedApps Remote Patient Monitoring System, K062377, Product Code: NBW

2) IDEAL LIFE Pod, K080538, Product Code: NBW, JQP

Indications for Use:

The iglucose™ System collects and transmits stored data from a variety of FDA cleared blood glucose meters such as the LifeScan® OneTouch® and Home Diagnostics™ True™ monitoring systems to a secure database via wireless cellular technology. Subsequently, blood glucose data can then be reviewed through a web portal as an aid in supporting diabetes management. It is intended to be used in a home or health care facility settings.

The iglucose™ System does not measure, interpret or make decisions on the data that it conveys, nor is it intended to provide automated treatment decisions, or to be used as a substitute for professional healthcare judgment. All medical diagnosis and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

Device Description:

The iglucose™ System is designed to assist individuals with diabetes with their record keeping management, by automatically tracking and storing historical blood glucose readings. It has been developed for home or health care facility settings as an aid in supporting diabetes management. iglucose™ is designed to connect to glucose meters and automatically transmit blood glucose reading(s) to a secure database. Users can then utilize the iglucoe™ diabetes management portal (web-based application) to view their blood glucose readings as well as to generate and display reports. At the user's discretion, authorized individuals can also view blood glucose readings and reports.

More specifically, the iglucose™ System is comprised of the following:

- iglucose™ Device
- Secure Database
- iglucose™ Diabetes Management Portal (web-based application)

The iglucose™ device is approximately the size of a cell phone and has a rechargeable battery. It connects to compatible FDA cleared glucose meters via a data cable and extracts data from a glucose meter. It then wirelessly (via the cellular network) transmits data (blood glucose readings, date and time) from a glucose meter to a secure database. Software used for the database enables the data to be viewable in an organized manner via the iglucose™ diabetes management portal (web-based application). At the user's discretion, the data can be communicated via email, SMS text message and/or fax.

Data can be displayed in a logbook form. In addition, data can be displayed and trended in reports that are in tabular and graphical formats such as line graphs, pie charts and histograms.

Summary of Characteristics Compared to Predicate Devices:

The Intended Use and Indications for Use of the predicate devices and the iglucose™ System are virtually the same and all are intended for over the counter use. Intended users are home users and health care providers.

The operation of the subject device is similar to the predicate devices in that the user connects the device to a compatible glucose meters and then initiates the transmission of glucose readings from the glucose meters to a central database. The user or healthcare provider can then access and view glucose readings using a web-based application. The features of the method of operation are described in the table below.

Attribute	**MedApps Remote Patient Monitoring System** **K062377**	**IDEAL LIFE Pod** **K080538**	**Subject Device (iglucose™ System)**
Connection to glucose meters	Wirelessly Bluetooth	Wirelessly	Data cable
Compatible glucose meters	510(k) cleared	Same	Same
Data Collection Software Functionality	Transmit data from sensor device to Central Database	Same	Same
Transmission to database	Cellular technology	Telephone Line	Same (as MedApps Predicate device)

The underlying technology of the iglucose™ System is similar to that of the predicate devices in that they all connect to compatible glucose meters and transmit the glucose readings to a secure central database. They each transmit data using wired or wireless telecommunication. The transmitted data can then be accessed and reviewed by users and healthcare providers. All devices supply historical readings, reports and graphs to the user.

Minor Differences:

There are four minor differences between the iglucose™ and the two predicate devices: 1. Connection to the glucose meters, 2. Power source, 3. Type of telecommunications technology used to communication method with central server and 4. Method of outbound communication of information. These are described in the table below.

Attribute	**MedApps Remote Patient Monitoring System** **K062377**	**IDEAL LIFE Pod** **K080538**	**Subject Device (iglucose™ Solution)**
Connection to glucose meters	Bluetooth and Cellular Technology	Short Range Radio System using Bluetooth and wired SmartCable	Data cable
Power source	Wall power plug for hub (120 VAC/50-60)	Wall power plug for Pod.	Wall power plug (100 to 240 VAC/ 50-60) and rechargeable battery in iglucose™
Type of Telecommunications Technology used; Communication method with central server.	Cellular Technology (Cell phone with embedded cellular module).	Telephone line (Pod with embedded modem)	Cellular Technology (iglucose™ device with embedded cellular module)
Method of Outbound communication of information	Stored in repository database for access by the healthcare provider and Interactive Voice Response System	Data is viewed in a web-based application, sent via email. SMS text and fax.	Data is viewed in a web-based application, sent via email, SMS text and fax. No voice Response System.

Summary of Testing:

Software:

Validation was performed as an output requirement from the analysis that led to the software being established as a Moderate Level of Concern. Some examples of testing performed: Home Page, Registration, Log-in Procedure, Administrative Area, device interfacing and data transmission. All tests passed.

Firmware:

Validation was performed as an output requirement from the analysis that led to the device being established as a Moderate Level of Concern. Some examples of testing performed: Power and initialization, network communication, glucose meters connection, battery testing. Also, integration testing was performed in order to test the interoperability and function of the device. All tests passed.

Mechanical:

Durability testing was performed on the power cord and data cable, and all tests passed.

Usability Study:

A usability validation was conducted in May, 2011. Eighteen users with Type 1 or Type 2 diabetes participated in the study. The test goals for the iglucose™ System usability study were to validate: the effectiveness of the user manual, creating accounts, logging in, connections, viewing the readings, and to verify that the validation success criteria were met.

Overall the usability test was successful, and demonstrated that the iglucose™ System is easy to use and safe for the purpose for which it is intended.

Conclusion:

Results of software, firmware and mechanical testing indicate the device performs as expected, and meets all its specification requirements. Usability testing demonstrates the device is easy to use and safe for its intended purpose.

PositiveID Corporation believes that based on the indications for use, descriptive information, and test results provided in this submission, the iglucose™ System has been shown to be

equivalent in technology, method of operation, functional performance and indications for use to its predicate devices, and is safe for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

PositiveID Corporation
c/o Edward Valdez
Quality Systems Manager
1690 S. Congress Avenue, Suite 200
Delray Beach, FL 33445

NOV 10 2011

Re: k111932
Trade/Device Name: iglucose System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: NBW, JQP
Dated: October 11, 2011
Received: October 17, 2011

Dear: Mr. Valdez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 4 INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: iglucose™ System

Indications for Use:

The iglucose™ System collects and transmits stored data from a variety of FDA cleared blood glucose meters such as the LifeScan® OneTouch® and Home Diagnostics™ True™ monitoring systems to a secure database via wireless cellular technology. Subsequently, blood glucose data can then be reviewed through a web portal as an aid in supporting diabetes management. It is intended to be used in a home or health care facility settings.

The iglucose™ System does not measure, interpret or make decisions on the data that it conveys, nor is it intended to provide automated treatment decisions, or to be used as a substitute for professional healthcare judgment. All medical diagnosis and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

Prescription Use _____ AND/OR Over-The-Counter Use __X__

21 CFR Part 801 Subpart D 21 CFR 801 Subpart C

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K111932

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 26 2011

Airstrip Technologies, LP
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K112235
Trade Name: Airstrip Remote Patient Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (no alarms)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: August 3, 2011
Received: August 4, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use
510(k) Number (if known):

Device Name: AirStrip Remote Patient Monitoring (RPM) Remote Data Viewing software

Indications for Use:
AirStrip RPM is software capable of displaying physiologic and other patient information. This information is generated by other medical devices and patient information system, and not by AirStrip RPM. AirStrip RPM captures this information from these other systems and displays it for clinicians.

AirStrip RPM is intended to be used by clinicians for the following purposes:
• By using a cellular telephone or other device on which AirStrip RPM is installed, to review physiologic data of a patient when the clinician is not at the hospital
• To view the near real-time waveforms remotely
• To remotely review other standard or critical near real-time patient data from the monitored system
• To provide a request for remote consultation regarding a patient's waveform or other data

The AirStrip RPM software can display the following the physiologic data captured by other medical devices:
• ECG Waveform
• Heart Rate Monitored
• Respiratory Rate
• Oxygen Saturation
• Intracranial Pressure
• Central Venous Pressure
• Pulmonary Capillary Wedge Pressure
• Cardiac Index
• Cardiac Output
• Cerebral Perfusion Pressure
• Urine Output
• Urine/Stool Mix Output
• Systolic Blood Pressure Invasive
• Mean Arterial Pressure Invasive
• Diastolic Blood Pressure Invasive
• Systolic Blood Pressure Cuff
• Mean Arterial Pressure Cuff
• Diastolic Blood Pressure Cuff
• Vasoactive Infusions
• Antiarrhythmics
• Sedation
• Paralytics
• Laboratory Data including
 - Blood Gas
 - Chemistry
 - Hematology
 - Coagulation
• Allergies
• Medications

Contraindications
AirStrip RPM software is intended for installation on cellular telephones and other wireless devices, and is not intended for use anywhere cellular telephones or wireless devices are prohibited. AirStrip RPM is intended for use by clinicians when they cannot be at the hospital. AirStrip RPM is intended for use by clinicians as a diagnostic aid, and not as a replacement for direct viewing of any of the monitoring devices from which it obtains its data.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112235

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Lauren Bronich-Hall
Director, Quality System
WellDoc Incorporated
1501 Saint Paul Street, Suite 118
Baltimore, Maryland 21202

OCT 14 2011

Re: K112370
Trade/Device Name: WellDoc DiabetesManager® System and DiabetesManager®-Rx System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ, LNX
Dated: September 19, 2011
Received: September 21, 2011

Dear Ms. Bronich-Hall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112370

Device Name: WellDoc DiabetesManager® System and DiabetesManager®-Rx

Indications for Use:
DiabetesManager® ***(OTC Use):*** The WellDoc DiabetesManager® System is indicated for use by healthcare providers (HCPs) and their adult patients - aged 21 years and older -who have type 2 diabetes. The DiabetesManager® System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager® System analyzes and reports blood glucose test results and supports medication adherence. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.

The DiabetesManager® System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 10/3/4

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112370

DiabetesManager®-Rx ***(Prescription Use):*** The WellDoc DiabetesManager®-Rx System is indicated for use by healthcare providers (HCPs) and their adult patients - aged 21 years and older - who have type 2 diabetes. The DiabetesManager®)-Rx System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager®-Rx System analyzes and reports blood glucose test results and supports medication adherence. In addition, the DiabetesManager®-Rx System provides coaching messages (motivational, behavioral, and educational) based on real-time blood glucose values and trends. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.

The DiabetesManager®-Rx System is not intended to replace the care provided by a Licensed healthcare professional, including prescriptions, diagnosis, or treatment.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

10/13/6

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K112370

DEC - 2 2011

EXHIBIT 02

K112559

PREMARKET NOTIFICATION 510(k) SUMMARY
As required by 21 CFR §807.92(c)

Submitter

510(k) Owner:	MedApps, Inc.
Owner / Operator:	10027842
Registration:	3005916763
Address:	7975 North Hayden Road, Suite A-203, Scottsdale, AZ 85258
Telephone:	480-305-6323
Fax Number:	480-393-1892
Contact Person:	Kent Dicks
Contact Person Title:	Founder / CEO
Date Prepared:	August 31, 2011

Device Information

Trade Name:	MedApps 2.0 - Remote Patient Monitoring System
Common Name:	Remote Patient Monitoring System
Classification Status:	Class II per regulations 870.2910
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG)

A. LEGALLY MARKETED PREDICATE DEVICE

Legally marketed predicate devices are:

K080798	Intel Health Guide PHS6000
K072698	Confidant 2.5
K062377	MedApps Remote Patient Monitoring System (D-PAL)
K083862	MedApps 2.0 - Remote Patient Monitoring System

B. INDICATIONS FOR USE

The MedApps 2.0 - Remote Patient Monitoring System consists of a patient device, MedApps HealthPAL, a mobile over-the-counter wireless communication hub, or MedApps HealthAIR, a portable over-the-counter wireless communication hub, which connects to commercially available glucose meters, scales, blood pressure monitors and pulse oximeters and HealthCOM, MedApps' secure host server system.

MedApps Remote Patient Monitoring devices receive and store measurements collected from the described monitors, either wirelessly (HealthPAL) or tethered (HealthPAL or HealthAIR). MedApps devices do not alter the indicated use of the peripheral monitors that they integrate with. MedApps devices indicate successful or failed reception and transmission of data with visual and audio cues (HealthPAL via OLED display screen, verbal message and audio tones; HealthAIR via LED lights and audio tones). MedApps devices store collected data and transmit to

HealthCOM using commercially available, FCC compliant, wireless telecommunication protocols (including but not limited to cellular GSM, CDMA and WiMax).

Healthcare professionals can review the transmitted information within the MedApps HealthCOM system, set thresholds to flag readings based on specific thresholds being exceeded. In addition, the MedApps Interactive Voice Response (IVR) has the ability to contact the patient remotely and use pre-approved ("canned") educational or reminder messages. ("Your nurse would like to talk to you, can I connect you now", "We haven't received a reading from you today, please send us your readings").

The MedApps 2.0 - Remote Patient Monitoring System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention.

C. MedApps 2.0 SYSTEM DESCRITPION

The MedApps 2.0 - Remote Patient Monitoring System consists of:

(1) MedApps HealthPAL hardware:

The physical component of the MedApps HealthPAL is an electronic device contained in a plastic enclosure with an OLED screen, built-in M2M cellular chip, speaker, smart cable connection, smart cables, wireless module, LED lights to indicate activity, timer button to assist patients with their reading schedule (i.e. remind them to take their reading in X minutes), last reading button, volume up and down buttons.

(2) MedApps HealthPAL firmware / software:

The firmware captures data from commercially available health monitors, and stores and transmits the information to the MedApps HealthCOM server, via the embedded communication chip / platform.

The firmware allows HealthPAL to receive information via wire or via embedded wireless module from accessory medical devices that are compatibly wireless enabled, which have been paired to the MedApps HealthPAL.

The firmware has many additional functions including:

- Download of user profiles from the server to configure HealthPAL remotely.

- HealthPAL has audio capability to deliver verbal announcement of readings and acknowledgment of data transmission from all connected accessory medical devices, time settings, volume control, educational content and reminders, in any language that is loaded to the device.

- Timer capability, activated by the user to provide assistance with adhering to a reading schedule (reminders to take readings within a set timeframe).

- OLED screen displays information regarding the HealthPAL's status including battery level, volume level, data transmission status, transmission pending indicator, activity icons / messages and other information to provide ease of use and promote patient adherence; as well as information received from accessory medical devices, such as the type of device, measurement, date and time of the last reading collected.

- Battery charging, isolation circuits, and interfaces to individual accessory medical devices / protocols via the smart cable.

(3) MedApps HealthAIR hardware / software:

MA020 HealthAIR is a modified MA105 HealthPAL device. The physical component of the MedApps HealthAIR is an electronic device contained in a plastic enclosure with built-in M2M cellular chip, speaker, standard USB cable and USB Smart Cable connection, and LED lights to indicate activity regarding the receiving and transmitting of collected data.

Like the HealthPAL, HealthAIR's firmware / software captures, data from commercially available retail health monitors, and stores and transmits information to the MedApps HealthCOM server, via the embedded communication chip / platform.

The firmware allows HealthAIR to receive information via wire, either standard USB or with a MedApps USB Smart Cable, from accessory medical devices.

The firmware has many additional functions including:

- Download of user profiles from the server to configure HealthAIR remotely.

- HealthAIR's Audio feature uses audio tones to indicate acknowledgment of collected readings from all connected accessory medical devices as well as reading transmission via the cellular network.

- HealthAIR's visual user interface utilizes LED lights of collected readings from all attached medical devices as well as reading transmission acknowledgements (via).

(5) MedApps HealthCOM software application:

The HealthCOM software application allows caregivers access to review patient data collected from accessory medical devices using MedApps hardware on the secure HealthCOM website. HealthCOM software allows professional caregivers to set patient readings.

HealthCOM software also allows the patient to establish an account and to direct / authorize their data to be directed to an outside, validated Personal Health Record (PHR), Electronic Health Record or Medical Record (EHR or EMR).

(6) MedApps IVR software application:

The IVR (Interactive Voice Response) software application provides the ability to contact the patient remotely, by phone (designated in the user profile), and executes an pre-approved ("canned") scripts to deliver pre-approved ("canned") reminder messages ("Your nurse would like to talk to you, can I connect you now", "We haven't received a reading from you today, please send us your readings"), educational content and gather survey information.

In addition, the MedApps IVR application will send out Email, SMS / Text Messages, Paging, IM and other forms of communications in order to contact patients or caregivers. This will include reminders and alerts, based on clinically defined parameters / thresholds established in HealthCOM by the professional care provider.

The MedApps 2.0 - Remote Patient Monitoring System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention.

D. TECHNOLOGICAL CHARACTERISTICS SUMMARY – as required by 807.92(a)(6)

Feature	**Intel Health Guide PHS6000** **K080798**	**Confidant 2.5** **K072698**	**MedApps Submission** ***(HealthPAL & HealthCOM)*** **K083862**	**MedApps Submission** ***(HealthAIR & HealthCOM)*** **K112559**
Indications of Use	Enables healthcare providers to monitor and manage chronic conditions of patients remotely	Same	Same	Same
Intended Use	Telemedicine System	Same	Same	Same
Intended Users	Home users and Healthcare providers	Same	Same	Same
Site of Use	Home, Clinic	Same	Same	Same
Data Collection Software	Intel Care Management Suite Software	The Hermes Proprietary Software	MedApps Proprietary Software	MedApps Proprietary Software
Data Collection Software Functionality	Transmit data from Sensor devices to Central Database	Same	Same	Same
Communication method of hub with Central Server	Via DSL or Phone Line Connection	Via Cellular Phone	Via Embedded Cellular Technology	Via Embedded Cellular Technology

Feature	Intel Health Guide PHS6000 K080798	Confidant 2.5 K072698	MedApps Submission *(HealthPAL & HealthCOM)* K083862	MedApps Submission *(HealthAIR & HealthCOM)* K112559
Types of sensors which can be interfaced (wired or wirelessly) to receiver hub	Medical Devices designed for Home use: Glucose Scale Blood Pressure Pulse Ox Peak Flow	Medical Devices designed for Home use: Glucose Scale Blood Pressure	Medical Devices designed for Home use: Glucose Scale Blood Pressure Pulse Ox	Medical Devices designed for Home use: Glucose Scale Blood Pressure Pulse Ox
Implementation method of collecting data from sensors	Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables.	Short range radio system using Bluetooth	Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables.	Currently using Wired (tethered) cables (USB), Smart Cables.
Sensor Software	Sensor Software unchanged	Same	Same	Same
Connectivity	Short range radio system using Bluetooth and Wired (tethered) cables.	Short range radio system using Bluetooth	Short range radio system using Bluetooth and Wired (tethered) cables.	Currently using Wired (tethered) cables Future capability to use Bluetooth dongles.
Communication method of hub with devices	Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables.	Short range radio system using Wireless (Bluetooth)	Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables.	Currently using Wired (tethered) cables.
Communications Protocol	Wireless (Bluetooth) V2.0 & Wired (Tethered)	Wireless (Bluetooth) V2.0	Wireless (Bluetooth) V2.0 and Wired (Tethered)	Wired (Tethered)
Communication Frequency	Bluetooth : 2.402 to 2.480 GHz	Bluetooth : 2.402 to 2.480 GHz GSM: 850/ 900 / 1800 / 1950 Mhz	Bluetooth : 2.402 to 2.480 GHz GSM: 850 / 900 / 1800 / 1950 Mhz	GSM: 850 / 900 / 1800 / 1950
Power Source	Wall power plug (120 VAC/50-60)	Wall power plug (120 VAC/50-60) and Rechargeable Batteries in Device	Wall power plug (120 VAC/50-60) or Rechargeable Batteries in HealthPAL	Wall power plug (120 VAC/50-60)
Visual Feedback / Display	On devices and hub, and monitors connected to central server	Same	OLED for HealthPAL	HealthAIR uses LED light indicators
Communication with Patients	On screen display	Same	Audio/visual reading feedback on screen and by speaker; and Interactive Voice Response (IVR) System for patient contact	Audio/visual reading feedback from LED light indicators & audio tones; Interactive Voice Response (IVR) system for patient contact

Data Collection:
The 2 predicate devices and the MedApps solution connect to medical devices (designed for home use) by either wired (cable) connection or wireless (HealthPAL- Bluetooth). The data is collected from the devices and sent to a secure central server using various communication methods.

Telecommunication Platform to Central Server:
Intel Health uses DSL connectivity (wired point of care), Confidant uses an off-the-shelf Cellular Phone; MedApps uses embedded Machine to Machine (M2M) module to transmit data via cellular connectivity.

Patient Feedback Technology:
The 2 predicate devices and the MedApps solution allow data and messages to be displayed on a screen (for the HealthPAL) for the patient to read and acknowledge. HealthAIR uses audio and visual acknowledgement / feedback. The MedApps solution also uses an Interactive Voice Response (IVR) system in order to call the patient and ask questions, gather survey information, or issue reminders.

Backend Data Storage:
All systems (both 2 predicate devices and the MedApps solution), provide a backend system that allows data to be stored, and healthcare professionals to access and monitor collected patient data.

E. NON-CLINICAL PERFORMANCE DATA TESTING AND REVIEW – as required by 807.92(b)(1)

Non-Clinical Testing
The submitted 2.0 System has undergone MedApps' design control verification and validation testing. MedApps 2.0 validation testing include testing of all executable code and functionality and confirmation that all identified risks have been adequately addressed by software functionality, the user interface, documentation or user SOP.

MedApps 2.0 System verification and validation activities as part of the design control process include testing of all Design Specifications (Design Control Inputs) based on risk analysis, certification standards, and Verification plans. MedApps Product Verification and Release Plan execution on both HealthPAL and HealthAIR ensures both medical devices work with each type of user accessory medical device (glucose, blood pressure monitor, scale, and pulse oximeter) as part of the MedApps 2.0 System including integration to HealthCOM backend software application. The output of these design control verification analysis documents **MedApps 2.0 - Remote Patient Monitoring System** shall meet its requirements and design specifications as intended.

Lastly, MedApps has used its Risk Management Plan to perform risk analysis comparing the current MA105 HealthPAL device to the modified MA020 HealthAIR device regarding residual risks, control analysis risks, and human management factors for usability to determine that no significant risks were added by allowing either the MA105 HealthPAL or the MA020 HealthAIR to be functionally used as part of the MedApps 2.0 System.

Lastly, all relevant certification testing such as EMC (60601-1-2) and Safety (60601-1) are described in MedApps' Declaration of Conformity.

F. SUBSTANTIAL EQUIVALENT

The MedApps 2.0 Remote Patient Monitoring System is substantially equivalent to the predicate devices in terms of data collection software functionality, operating system for the patient device, communication method of patient device with central server, types of sensors which can be integrated to the patient medical device, implementation methods of collecting data from sensors, sensor software, connectivity, communication protocol, power source and general display method.

The HealthAIR communication hub device is substantially equivalent to the HealthPAL (described in 510k K083862) as both devices, as part of the MedApps 2.0 System, connect to commercially available Glucose Meters, Scales, Blood Pressure Monitors and Pulse Oximeters; data is collected, stored and transmitted using off-the-shelf FCC approved wireless / cellular connectivity. Both provide audio and visual feedback / acknowledgement that readings have been collected and transmitted to MedApps' secure host server called "HealthCOM".

Below is a Technological Characteristics Summary between the HealthPAL and the HealthAIR medical devices:

Feature	**MA105 HealthPAL**	**MA020 HealthAIR**
Indications of Use	Enables healthcare providers to monitor and manage biometirc patient data collected remotely	Same
Intended Use	Telemedicine System	Same
Intended Users	Home users and patients outside of the clinical setting, as well as Healthcare providers	Same
Site of Use	Remote setting (e.g. Home / Work), Clinic	Same
Data Collection Software & firmware	MedApps Proprietary Software	Same
Data Collection Software Functionality	Transmit data from Sensor devices to Central Database	Same
Communication method of device hub with Central Server	Via Embedded Cellular Technology (GSM or CDMA)	Same
Types of sensors which can be interfaced (wired or wirelessly) to receiver hub	Medical Devices designed for Home use: Glucose, Scale, Blood Pressure Pulse Ox	Same
Transmission	Transmits information to the MedApps secure host server called "HealthCOM"	Same
Implementation method of collecting data from sensors and general Connectivity	Short range radio system using Wireless (Bluetooth) and Wired / tethered (Smart Cables).	HealthAIR uses wired / tethered connection (USB, Smart Cables)

Communication method of hub with devices	Short range radio system using Wireless (Bluetooth) and Wired / tethered (Smart Cables).	HealthAIR uses wired / tethered connection (USB, Smart Cables)
Communication Frequency	Bluetooth : 2.402 to 2.480 GHz GSM: 850 / 900 / 1800 / 1950 Mhz	GSM: 850 / 900 / 1800 / 1950 Mhz
Power Source	Wall power plug (120 VAC/50-60) and Rechargeable Batteries in Device	Same Wall power plug but HealthAIR does not have a rechargeable battery
Device Communication with Patients	On screen display and audio voice feedback	LEDs lights for visual feedback and audio tones (beeps).
Certification Testing	Safety 60601-1, EMC/EMI/FCC (60601-1-2), ESD & Radiated Immunity, FCC Bluetooth, (PTCRB), CTIA (battery), ETSI	Safety 60601-1, EMC/EMI/FCC (60601-1-2), ESD & Radiated Immunity, (PTCRB), ETSI *(See Declaration of Conformity)*

G. SAFETY AND EFFICACY

The MedApps 2.0 Remote Patient Monitoring System does not rely on an assessment of clinical performance data. The device conforms to FDA's recognized consensus standards and relies on its conformity to demonstrate its safety and efficacy. The device does not introduce any new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 2 2011

MedApps, Inc.
c/o Mr. Kent Dicks
Founder / CEO
7975 North Hayden Road, Suite A-203
Scottsdale, AZ 85258

Re: K112559
Trade/Device Name: Modification to MedApps 2.0 – Remote Patient Monitoring System
Regulation Number: 21 CFR 870.2910
Regulation Name: Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulatory Class: Class II (two)
Product Code: DRG
Dated: October 25, 2011
Received: November 3, 2011

Dear Mr. Dicks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MedApps, Inc. (FDA-IU-8014 Rev C) **EXHIBIT 01**
STATEMENT OF INDICATIONS FOR USE

510(k) Number: K112559

Preparation Date: August 31, 2011

Device Name: **Modification to MedApps 2.0 - Remote Patient Monitoring System**

Indications For Use:

The MedApps 2.0 - Remote Patient Monitoring System consists of a patient device, MedApps HealthPAL, a mobile over-the-counter wireless communication hub, or MedApps HealthAIR, a portable over-the-counter wireless communication hub, which connects to commercially available glucose meters, scales, blood pressure monitors and pulse oximeters and HealthCOM, MedApps' secure host server system.

MedApps Remote Patient Monitoring devices receive and store measurements collected from the described monitors, either wirelessly (HealthPAL) or tethered (HealthPAL or HealthAIR). MedApps devices do not alter the indicated use of the peripheral monitors that they integrate with. MedApps devices indicate successful or failed reception and transmission of data with visual and audio cues (HealthPAL via OLED display screen, verbal message and audio tones; HealthAIR via LED lights and audio tones). MedApps devices store collected data and transmit to HealthCOM using commercially available, FCC compliant, wireless telecommunication protocols (including but not limited to cellular GSM, CDMA and WiMax).

Healthcare professionals can review the transmitted information within the MedApps HealthCOM system, set thresholds to flag readings based on specific thresholds being exceeded. In addition, the MedApps Interactive Voice Response (IVR) has the ability to contact the patient remotely and use pre-approved ("canned") educational or reminder messages. ("Your nurse would like to talk to you, can I connect you now", "We haven't received a reading from you today, please send us your readings").

The MedApps 2.0 - Remote Patient Monitoring System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use__X__
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112559

DEC - 2 2011

510(k) Summary of Safety and Effectiveness

(The following information is in conformance with 21 CFR 807.92)

Submitter:

MIM Software Inc.
25200 Chagrin Blvd. Suite 200
Cleveland, OH 44122

Phone: 216-455-0600
Fax: 216-455-0601

Contact Person: Lynn Hanigan

Date Summary Prepared: Sept 30, 2011

Device Name

Trade Name: Mobile MIM (RT)
Common Name: Medical Imaging Software
Classification Name: System, Imaging Processing, Radiological

Predicate Device

K103785	Mobile MIM	MIM Software Inc.
K042956	Vision	Varian Medical System

Intended Use / Indications for Use

The Mobile MIM software program is used for the viewing, registration, fusion, and/or display for diagnosis of medical images from the following modalities: SPECT, PET, CT, MRI, X-ray and Ultrasound.

Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans. Mobile MIM can be used to approve these plans.

Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography.

Device Description

Mobile MIM (RT) extends the Mobile MIM software application previous cleared under K103785. In addition to SPECT, PET, CT, MRI modalities, Mobile MIM can be used for the viewing and/or display for diagnosis of X-ray and Ultrasound medical images.

It also provides functionality for the review of medical images, contours, DVH, and isodose curves from radiation treatment plans. In addition, Mobile MIM (RT) will allow permitted users the ability to approve reviewed radiation treatment plans.

Substantial Equivalence

Mobile MIM is substantially equivalent to Mobile MIM software (K103785) and portions of the Vision product (K042956). It extends Mobile MIM functionality by adding 2 additional image modalities to its indication and having the capability to serve as a mobile reviewing device for radiation treatment plans.

Performance Data

MIM Software Inc. has performed multiple studies with qualified radiologists, dosimetrists and radiation oncologists. Radiologists tested Mobile MIM by evaluating the image quality of the two additional modalities of X-ray and Ultrasound under different environmental conditions. Results of these studies affirm the diagnostic image viewing capabilities of Mobile MIM when used as indicated.

MIM Software also orchestrated radiation therapy plan review tests evaluating multiple areas of treatments by trained medical professionals using plan data from 3 major vendors, and using both smaller format (iPhone and/or iPod touch) and larger format (iPad) devices. The results indicated the display quality for of isodose curves, DVH graphs, and contours was of acceptable quality for review and approval of radiation therapy plans, and were equivalent to those viewed on a full workstation.

Furthermore, MIM Software Inc. has conducted verification, validation, and functional testing on the Mobile MIM software. In all cases, the software passed its performance requirements and met specifications.

25200 Chagrin Blvd. Suite 200
Cleveland, OH 44122
www.mimsoftware.com
Tel: 866-421-2536
Fax: 216-455-0601

Conclusion

Therefore, from all evidence gathered, it is our belief that Mobile MIM (RT) provides a safe and effective diagnostic viewer of the following medical imaging modalities: SPECT, PET, CT, MRI, X-ray and Ultrasound. It also is safe and effective in that it is substantially equivalent to the radiation treatment plan review functionality of Vision (K042956), allowing for portable device characteristics and accessibility when there is no access to a full workstation.

25200 Chagrin Blvd. Suite 200
Cleveland, OH 44122

www.mimsoftware.com

Tel: 866-421-2536
Fax: 216-455-0601

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Lynn Hanigan
Quality Manager
MIM Software, Inc.
25200 Chagrin Blvd, Suite 200
CLEVELAND OH 44122

DEC - 2 2011

Re: K112930
Trade/Device Name: Mobile MIM
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ & MUJ
Dated: September 30, 2011
Received: October 3, 2011

Dear Ms. Hanigan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD K112930

Device Name: Mobile MIM

Indications for Use:

The Mobile MIM software program is used for the viewing, registration, fusion, and/or display for diagnosis of medical images from the following modalities: SPECT, PET, CT, MRI, X-ray and Ultrasound.

Mobile MIM can be used to review images, contours, DVH, and isodose curves from radiation treatment plans. Mobile MIM can be used to approve these plans.

Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112930

K113045

510(k) Summary

(per 21 CFR 807.92)

AUG 14 2012

31 July 2012

Sponsor
Mr. Sailor Mohler
Quality Manager
Zephyr Technology Corporation
1 Annapolis Street, Suite 200
Annapolis MD 21401 USA
Office: 443-569-3603
sailor.mohler@zephyranywhere.com

Consultant
Mr. Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, CT 06907-1659
203 329 2700 F 203 329 2345
rkeen@fda-complianceconsultants.com

Proprietary Name:	BioHarness 3.0
Common Name	BioHarness 3.0
Device Classification Name	(1) Electrocardiograph Electrode (2) Arrhythmia Detector and Alarm
Classification Number:	(1) 21CFR870.2360 (2) 21CFR870.1025
Product Code	(1) DRX (2) MHX
Reviewing Group	Cardiovascular
Device Classification	Class II
Establishment registration No.	# 233836
Predicate Device	(1) Monebo, ***CardioBelt*** [tm], K063044, is a reusable electrode system consisting of an electrode assembly, an elastic chest, and an electronic package to transmit ECG information to a compatible Bluetooth enabled device. (2) Zephyr Technology, ***BioHarness 2.0***, K100040, is an ambulatory patient monitor consisting of a chest strap and an electronics module that attaches to the strap to acquire, store and transmit physiologic data.

Device Description

The BioHarness 3.0, a cardiographic electrode transmitter is composed of:

- proprietary hardware and firmware, enclosed in
- a user case (puck) with a re-chargeable battery,
- various sensors embedded in a reusable chest harness, and
- ECG detection and transmission and
- A cradle (to recharge battery and transfer internally stored date to an ancillary computer).

K113045

510(k) Summary

(per 21 CFR 807.92)

The BioHarness 3.0 is a physiological / cardiographic electrode transmitter manufactured by Zephyr Technology Corporation with reusable electrodes in a chest harness consisting of an electrode assembly, an elastic chest belt, and an electronics package containing a Bluetooth transmitter. The BioHarness 3.0 electrodes are positioned against the patient's skin with light pressure, using the elastic chest belt. The BioHarness 3.0 is designed to be used without electrolytic gels and without adhesives on unprepared skin; that is without the requirements for shaving, abrading, or other skin preparation. This device transmits ECG information to a compatible Bluetooth - enabled device. This transmitter is a class I Bluetooth radio with a range of approximately 100 meters (spherical range).

Indications for Use

The BioHarness 3.0 is a physiological monitoring telemetry device intended for monitoring of adults in the home, workplace and alternate care settings. The device consists of a chest strap and an electronics module that attaches to the strap. The device stores and transmits vital sign data including ECG, heart rate, respiration rate, body orientation and activity. The BioHarness 3.0 provides a facility to detect and transmit single lead ECG signals to be received by Bluetooth / USB qualified ECG instruments.

The BioHarness 3.0 collects and transmits measurements captured during both sedentary as well as rigorous activity for Heart Rate, Posture and Activity. Breathing rate values are accurately transmitted only during sedentary periods.

The BioHarness 3.0 is indicated for use as a general patient monitor to provide physiological information as part of an occupational welfare monitoring system, for general research and performance measurement purposes, or where prescribed by a healthcare professional.

Intended Use

The **intended use** of the BioHarness 3.0 is to provide a facility in the home, workplace and alternate care settings for detecting, storing and transmitting Adult - single lead ECG data to third party ECG instruments for interpretation by qualified persons. The BioHarness 3.0 stores over 140 hours of ECG signals for transmission via USB or real time Bluetooth. The **scientific concept** on which this device is based is the principle that low level electrical pulses from the heart are measurable of the surface of the skin. This device **functions** by capturing these electrical pulses via electrodes and delivering these signals to sophisticated electronics for signal processing. The calibration is established by the factory and yields accurate and calibrated signals that can maintain calibration over its useful life.

Substantial Equivalence

Zephyr Technology Corporation has determined that the BioHarness 3.0 is substantially equivalent to the performance of a predicate Device. The differences between these systems are incidental and not significant. Both devices use a similar technological characteristics and principles.

- Both devices use electrodes to capture signals from the skin,
- both devices convert analog cardiological signals to digital signals,
- both devices use micro-processors, firmware and signal processing,
- both devices transmit the signals to receivers that detect and present the information as ECG waveforms.

K113045

510(k) Summary

(per 21 CFR 807.92)

Safety and Effectiveness

There are no substantial differences between the BioHarness 3.0 defined in this 510(k) submission and the stated predicate device. They are similar to the technologies that are currently used in other similar medical devices.

This device is safe and effective for the application for which it is intended and has been tested to confirm safety and efficacy. A series of factory tests are conducted to verify the intended signals are accurate and can maintain a calibrated energy pattern over its useful life. The BioHarness 3.0 has benefited from design, development, testing and production procedures that conform to Quality Systems.

Zephyr Technology Corporation continues to search all appropriate sources for information relating to safety and effectiveness and maintains an *in-house* reporting device to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 14 2012

Zephyr Technology Corporation
c/o Mr. Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, CT 06907

Re: K113045
Trade/Device Name: BioHarness 3.0
Regulation Number: 21 CFR 870.1025
Regulation Name: Monitor, Physiological, Patient (With Arrhythmia Detection or Alarms)
Regulatory Class: Class II (two)
Product Code: MHX, DRX
Dated: July 31, 2012
Received: August 9, 2012

Dear Mr. Keen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113045

510(K) Number Assigned k113045
Name: *BioHarness 3.0*

INDICATIONS FOR USE

The BioHarness 3.0 is a physiological monitoring telemetry device intended for monitoring of adults in the home, workplace and alternate care settings. The device consists of a chest strap and an electronics module that attaches to the strap. The device stores and transmits vital sign data including ECG, heart rate, respiration rate, body orientation and activity. The BioHarness 3.0 provides a facility to detect and transmit single lead ECG signals to be received by Bluetooth / USB qualified ECG instruments.

The BioHarness 3.0 collects and transmits measurements captured during both sedentary as well as rigorous activity for Heart Rate, Posture and Activity. Breathing rate values are accurately transmitted only during sedentary periods.

The BioHarness 3.0 is indicated for use as a general patient monitor to provide physiological information as part of an occupational welfare monitoring system, for general research and performance measurement purposes, or where prescribed by a healthcare professional.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)		
Prescription Use **___XXX___**	**or**	**Over - The - Counter Use** _____ **(Per 21 CFR 801.109)**
		(Optional Format 1-2-96

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of ~~Device Evaluation (ODE)~~
(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K113045

EVALUATION OF AUTOMATIC CLASS III DESIGNATION (DE NOVO) FOR PROTEUS PERSONAL MONITOR INCLUDING INGESTION EVENT MARKER

REGULATORY INFORMATION

FDA identifies this generic type of device as:

> Ingestible Event Marker - An ingestible event marker is a prescription device used to record time-stamped, patient-logged events. The ingestible component links wirelessly through intra-body communication to an external recorder which records the date and time of ingestion as well as the unique serial number of the ingestible device.

NEW REGULATION NUMBER: ***880.6305***

CLASSIFICATION: ***II***

PRODUCT CODE: ***OZW***

BACKGROUND

DEVICE NAME: ***PROTEUS PERSONAL MONITOR INCLUDING INGESTION EVENT MARKER***

510(K): ***K113070***

DATE OF 510(K) NSE DECISION: ***MAY 7, 2012***

DATE OF DE NOVO PETITION: ***MAY 14, 2012***

PETITIONER CONTACT:
PROTEUS BIOMEDICAL, INC.
2600 BRIDGE PARKWAY, SUITE 101
REDWOOD CITY, CA 94065
Phone: 650-632-4031
Fax: 650-362-1860

PETITIONER'S RECOMMENDED CLASSIFICATION: ***II***

INDICATIONS FOR USE

The Proteus Personal Monitor is a miniaturized, wearable data-logger for ambulatory recording of heart rate, activity, body angle relative to gravity, and time-stamped, patient-logged events, including events signaled by swallowing the Ingestion Event Marker (IEM) accessory. The Proteus Personal Monitor enables unattended data collection for clinical and research applications. The Proteus Personal Monitor may be used in any instance where quantifiable analysis of event-associated heart rate, activity, and body position is desirable.

LIMITATIONS

Prescription-use only

Caution: Do not wear (the Patch) during magnetic resonance imaging (MRI), cautery, and external defibrillation procedures.

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

DEVICE DESCRIPTION

The Proteus Personal Monitor, also called the "Patch", is a body-worn sensor that collects physiological and behavioral metrics including heart rate, activity, body angle and time-stamped user-logged events generated when a user marks an event by swallowing an Ingestion Event Marker (IEM) or by manually pressing an event marker button on the Patch. The Patch stores and wirelessly sends the IEM data to a general computing device.

The Proteus Personal Monitor Including Ingestion Event Marker system is comprised of three main subsystems; (1) the ingestion event marker (IEM), (2) the data recorder (Patch), and (3) the Proteus software.

1. Ingestion Event Marker (IEM)

The grain-of-sand sized IEM is designed to communicate the time-stamped confirmation of IEM device ingestion as a unique identifier to the Proteus Personal Monitor worn on the skin. The ingestion signal is communicated via volume conduction communication also known as intra-body communication. The IEM is attached to an inert pharmaceutical excipient tablet for ease of handling and swallowability.

2. Proteus Personal Monitor (Patch)

The Proteus Personal Monitor (Patch) receives, stores, and wirelessly sends ingestion confirmation data to a general computing device.

3. Software

The Proteus software is used to pair the Patch with a mobile computing device. The software organizes and displays ingestion events.

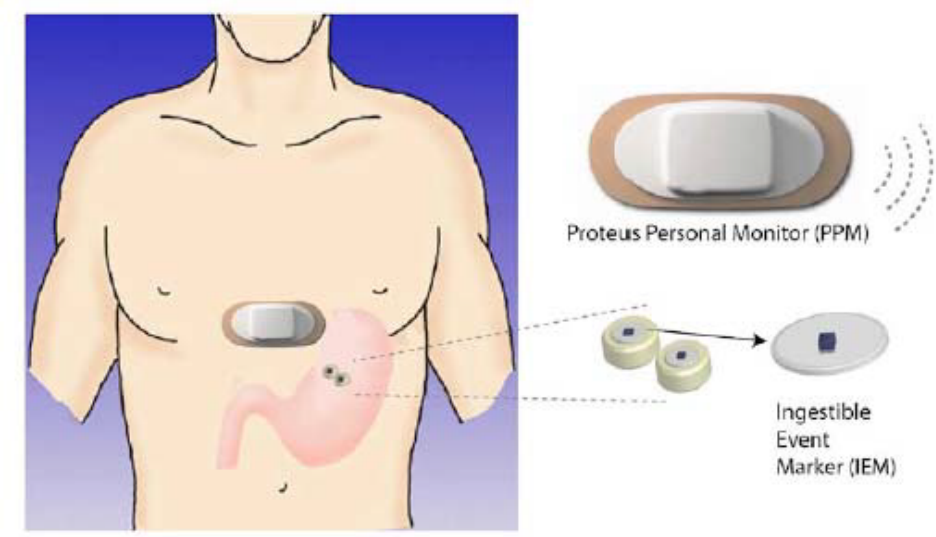

Figure 1: An overview of the Proteus Personal Monitor System – IEM (attached to an inert tablet carrier) and Patch, plus a display screen on a paired computing device (not pictured). Magnified view of IEM with attached excipient skirt is also displayed in graphic.

SUMMARY OF NONCLINICAL/BENCH STUDIES

BIOCOMPATIBILITY/MATERIALS (IEM)

The petitioner conducted a series of tests to demonstrate that the patient-contacting components of the Proteus Personal Monitor demonstrated acceptable performance for its intended purpose, which included the tests indicated below.

ISO 10993-5 CYTOTOXICITY TESTING
ISO 10993-10 IRRITATION TESTING
ISO 10993-11 SYSTEMIC TOXICITY TESTING

Given the results of the biocompatibility testing, the petitioner conducted additional animal testing to assess materials toxicity, which included the following tests summarized in Table 1 below.

TABLE 1. PRE-CLINICAL SAFETY TESTING

	Testing Performed	Results
Chemical Characterization	HPLC And Spectroscopic Analysis Of Concentrated Device Extracts	No Unintended Compounds Detected Above Stringent ICH Reporting Threshold For Drug Impurities
Copper (Cu) Toxicity	Risk Assessment By Gradient Corp (Metal Toxicology Experts)	No Risk Of Cu Toxicity With Realistic Exposure
Cytotoxicity	Quantitative Studies With Physiologic Device Extracts	Realistic Exposure Levels Are Non-Cytotoxic

IN VIVO STUDIES

The petitioner also performed forty-two (42) in-vivo studies, including rodent, canine and porcine models, to characterize device performance and safety. Porcine and canine animal models are frequently used in gastrointestinal (GI) device testing, and were chosen because of the similarities of their GI anatomy to that of a human. Efforts were made to include a wide range of body size in the non-clinical experiments, with body weight ranging from 25 to 95 kg. The purpose of this inclusion criterion is to provide an opportunity to investigate the potential effects of body size on the performance of the system. Canine testing was also performed to validate that device egestion occurred as well as additional rodent testing and literature review to assess toxicology of materials. A summary of the studies conducted are provided in Table 2.

TABLE 2. PERFORMANCE AND SAFETY TESTING

	Testing Performed	Results
Mechanical safety	Excretion and GI injury studies in canines	Ingested IEMs reliably excreted Supra-normal doses of IEMs do not inflict any clinically significant injuries
Electrical safety	Tissue stimulation in canines	No abnormal ECG morphology or arrhythmia
In vivo toxicity	14-day rat oral gavage study with physiologic device extracts	No evidence of toxicity in any dosing groups, including max dose group (equivalent to 30,000 IEMs/day), based upon clinical observations, hematology, serum chemistries and histopathology.
	Canine oral toxicology study	No evidence of IEM toxicity, based upon clinical observations and GI tract histopathology. No changes in blood levels of IEM inorganic materials following exposure.
	Rodent oral toxicology study	No evidence of IEM toxicity—even in highest dosing group, which received the weight-adjusted equivalent of 30,000 IEMs/day—based upon clinical observations, hematology, coagulation tests, blood chemistries, necropsy, and comprehensive histopathology.
	IEM copper (Cu) human health assessment, general use	Practical-use scenario (15 IEMs ingested simultaneously, daily or twice-daily) poses no risk of copper toxicity. Extreme-use scenario (30 IEMs ingested simultaneously, daily) poses no risk of systemic toxicity, but transient, non-systemic gastric upset could result at this dose. This concentration dependent effect

		would be mitigated by intake with a meal.
	IEM copper human health assessment, chronic use in a compromised population (renal transplant patients)	Post-operative renal transplant patients are not at greater risk than the normal population from Cu toxicity associated with chronic ingestion of four IEMs/day. There is no scientific basis to believe that the physiological response to Cu in IEM-enabled medicines will differ from the physiological response to Cu in food.
	Quantitative cytotoxicity	Corroborates conclusion of IEM Cu human health assessment.
	Additional chemical characterizations	No unintended compounds detected above reporting threshold for new drug substances, a stringent standard that was adapted for analysis of the IEM device.

ELECTROMAGNETIC COMPATIBILITY (EMC) AND ELECTRICAL SAFETY

Electromagnetic compatibility and electrical safety testing were performed to FDA recognized standards. All applicable tests passed.

TABLE 3. EMC AND ELECTRICAL SAFETY TESTING

Testing Category	Test Descriptions	Reference	Results
Electrical safety testing	Power input	IEC 60601-1, Sub-clause 7.1	Not applicable, because the unit is internally powered
	Limitation of voltage and/or energy	IEC 60601-1, Sub-clause 15 b	Not applicable, because the unit is internally powered
	Protective earthing, functional earthing and potential equalization	IEC 60601-1, Sub-clause 18 f	Not applicable, because the unit is internally powered and has a non-conductive enclosure
	Earth leakage current	IEC 60601-1, Sub-clause 19.4 f	Not applicable, because the unit is internally powered
	Enclosure leakage current	IEC 60601-1, Sub-clause 19.4 g	Not applicable, because the unit is internally powered and has a non-conductive enclosure
	Patient leakage current	IEC 60601-1, Sub-clause 19.4 h.6	Passed, 0 µA measured

	Patient leakage with mains voltage on F-type isolated applied parts	IEC 60601-1, Sub-clause 19.4 h.6	Passed, 0 µA r.m.s measured
	Patient auxiliary current	IEC 60601-1, Sub-clause 19.4 j	Passed, maximum of <1 µA r.m.s measured
	Dielectric voltage withstand	IEC 60601-1, Sub-clause 20.4	Passed
	Reversed battery connection	IEC 60601-1, Sub-clause 56.7	Not applicable; battery is not user-accessible
	Overflow, spillage, leakage, cleaning	IEC 60601-1, Sub-clause 44	Passed
	Creepage distances and air clearances	IEC 60601-1, Sub-clause 57.10	Passed
EMC testing	Group 1 Class B – Radiated emissions	per EN 60601-1-2, EN 55011 (CISPR 11)	Passed
IEM EMC testing	Electromagnetic compatibility (EMC)	IEC 60601-1-2:2007 6.2.3 Radiated RF electromagnetic fields Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test	Passed

ADDITIONAL DEVICE CHARACTERIZATION AND PERFORMANCE TESTING

The sponsor performed testing to characterize the performance of the ingestible disc antenna used in the IEM (Table 4) and simulation testing signal reception performance of the Patch data recorder (Table 5).

TABLE 4. INGESTIBLE DISC ANTENNA TESTING

Test Description	Result
Mechanical strength – immersion in SGF for 10 minutes at 37°C	(b) (4)
Residual solvent of the disc material	
Friability – immersion in SGF (10 mins) then SIF at 37°C	
Electrical properties of disc	

TABLE 5. DATA RECORDER TESTING

Test	Test Description	Result
High Frequency (HF) Signal Chain Performance Test	A "body simulation" network was interposed between the signal source and the Data Recorder	The passband is substantially flat between 10Hz and 80Hz
Low Frequency (LF) Signal Chain Performance Test	A patient simulator was attached to the inputs and the amplitude of the output was measured by an oscilloscope	The passband is substantially flat between 2Hz and 100Hz
Accelerometer Performance Tests	Rotating the accelerometer with respect to gravity -- Acceleration measurement from a subject during a steady walk	Measured values agreed well with the applied values R^2 =.99 -- The acceleration traces appear to be of a subject walking.
ECG Performance Testing	The algorithm was tested against all 48 test files from the MIT-BIH arrhythmia database. -- The PROMITTER substudy was conducted on the Proteus campus and enrolled 5 healthy volunteer subjects	The Median was 99.7% detection with a 5.9% standard deviation -- ECG results and accuracy was 99.4% for chest location and 99.2% for xyphoid location
Respiratory Rate Performance Testing	R-wave amplitude is modulated by the respiratory cycle, a stationary subject was instructed to breath regularly at a rate of 6 breaths/min	Device measurement result of 6 breaths/minute

MAGNETIC RESONANCE (MR) COMPATIBILITY

No testing has been conducted to demonstrate whether the device is MR compatible. The labeling has included a Caution that the user should not wear the Patch during magnetic resonance imaging (MRI).

SOFTWARE

The petitioner provided a description of software development processes, software hazard analysis and device system performance testing. The Patch software was reviewed in K093976 in conformance with FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005.

SUMMARY OF CLINICAL INFORMATION

The Proteus system has been used by > 250 patients who participated in >3,800 cumulative days of system use involving >11,500 cumulative IEM ingestions as summarized in Tables 6 and 7 below. The studies characterized the safety and performance of the Proteus system. The safety of the system was characterized by recording all patient adverse events (AEs) noted during the study whether device related or not. The key measures of system performance (positive detection accuracy (PDA) and negative detection accuracy (NDA)) characterize the ability of the system to properly detect and register IEM ingestions.

The cumulative average of PDA across all conducted studies is 97.2% (95% CI). The cumulative average of NDA across all conducted studies is 100% (95% CI).

TABLE 6. RESULTS OF HUMAN CLINICAL TESTING

Cumulative Clinical Experience	N		
Number of subjects wearing the Proteus Personal Monitor (Patch)	254		
Number of subjects ingesting IEM	219		
Number of subject/days	3,811		
Number of IEM ingestions	11,655		
No unanticipated adverse device effects, no severe adverse events related to or possibly related to Proteus Personal Monitor System			
Non-serious AEs--92% mild, 8% moderate			
Adverse Event (AE) – Ingestible Sensor		Rate as % of subjects	Rate as % of ingestions
At least one AE	0	0	0
At least one severe AE	0	0	0
Discontinued due to AE	0	0	0
Adverse Events			
Nausea/vomiting	4	1.8%	0.0%
Related	1	0.5%	0.0%
Constipation	2	0.9%	0.0%
Anxiety	1	0.5%	0.0%
Asthma attack	1	0.5%	0.0%
Abdominal cramping	1	0.5%	0.0%
Non-cardiac chest pain	1	0.5%	0.0%
Bitter taste in mouth	1	0.5%	0.0%
Adverse Event – PPM (510(k) cleared component)			
Localized skin irritation and inflammation	45	17.7%	NA
Discontinued due to skin irritation	7	2.8%	NA

TABLE 7. SUMMARY OF HUMAN CLINICAL TESTING

Overall System Performance	
219 subjects of 254 subjects, inclusive of PPM-only users (IEM ingestion) 11,655 ingestions 3810 subject-days of system utilization Maximum daily ingestion: 34 IEMs Maximum system utilization: 42 days	99.3% Detection accuracy 100% Correct identification No SAEs / UADEs related to system

LABELING

Labeling includes all information required for the safe and effective use of the device as outlined in 801.109, including a detailed summary of the non-clinical and clinical testing pertinent to use of the device and the maximum number of daily device ingestions.

RISKS TO HEALTH

Table 8 below identifies the risks to health that may be associated with use of Ingestible Event Markers and the measures recommended to mitigate these risks.

TABLE 8. RISK/MITIGATION MEASURES

Identified Risks	**Recommended Mitigation Measures**
Adverse tissue reaction	Biocompatibility Testing Labeling (dose limits)
Systemic toxicity	Toxicology Testing Labeling (dose limits)
Electromagnetic incompatibility	Electromagnetic Compatibility Testing Wireless testing Labeling
Electrical safety issues	Electrical Safety Testing Labeling
Electrical/Mechanical failure	Non-clinical Performance Testing
Failure to mark event	Non-clinical Performance Testing Clinical Evaluation
Failure to excrete	Animal Testing
Usability	Human Factors Testing Labeling

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the Proteus Personal Monitor including Ingestion Event Marker is subject to the following special controls:

1. The device must be demonstrated to be biocompatible and non-toxic;

2. Non-clinical, animal and clinical testing must provide a reasonable assurance of safety and effectiveness, including device performance, durability, compatibility, usability (human factors testing), event recording, and proper excretion of the device;

3. Appropriate analysis and non-clinical testing must validate electromagnetic compatibility (EMC) performance, wireless performance, and electrical safety; and

4. Labeling must include a detailed summary of the non-clinical and clinical testing pertinent to use of the device and the maximum number of daily device ingestions.

BENEFIT/RISK DETERMINATION

The Benefit/Risk Determination for the Proteus Personal Monitor finds that although the benefits realized by the use of the device system are small, the risks posed by the device system are also small and pose little to no risk to the patient when Special Controls are met and are outweighed by the benefits of the device system.

CONCLUSION

The de novo petition for the Proteus Personal Monitor including Ingestion Event Marker is granted and the device is classified under the following:

Product Code: OZW
Device Type: Proteus Personal Monitor including Ingestion Event Marker
Class: II
Regulation: 21 CFR 880.6305

K113514 P1/2

FEB 2 2 2012

SHL
Telemedicine

510(K) SUMMARY

Smartheart

510(k) Number K_____

Applicant's Name: SHL Telemedicine International Ltd.
90 Yigal Alon Street
Tel Aviv 67891
ISRAEL
Tel (972)3-561-2212
Fax (972)3-624-2414

Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837
Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: Smartheart

Preparation Date November 20, 2011

Classification: **Name**: Telephone electrocardiograph transmitter and receiver
Product Code: DXH
Regulation No: 21 CFR 870.2920
Class: II
Panel: Cardiovascular

Device Description: The ***Smartheart*** is a personal, hand-held battery powered, 12 lead ECG and rhythm strip device with Bluetooth connection. The ***Smartheart*** acquires ECG data via attached electrodes. The ***Smartheart*** transmits the data in real-time to a suitable Bluetooth communication device for forwarding it to a remote location and a certified medical professional capable of interpreting the results.

Intended Use Statement:

The ***Smartheart*** device is intended to condition an electrocardiographic signal so that it can be transmitted digitally via Bluetooth technology and cell-phone or communication device to a remote location. The ***Smartheart*** device is designed to be used by a patient to transmit a 12 lead ECG and rhythm strip in real-time to enable review at a physician's office, hospital or other medical receiving center.

SHL
Telemedicine

Predicate Devices:

The ***Smartheart*** is substantially equivalent to the following predicate device:

Device Name	510k No	Date of Clearance
CardioSen'C™	**K080047**	Jul 11, 2008

Performance Standards:

The ***Smartheart*** device has been tested according to various standards and guidance documents, such as IEC 60601-2-51:2005 (Essential performance, of recording and analyzing single channel and multichannel electrocardiographs), IEC 60601-2-25 (1993) +A1:1999 (requirements for the safety of electrocardiographs), etc.

Usability study:

SHL Telemedicine has conducted a usability study designed to test the effectiveness of the ***Smartheart*** device as a 12 lead ECG transmitter. The results of the study clearly confirmed the efficacy of the ***Smartheart*** as a 12 lead ECG transmitter.

Conclusions:

The ***Smartheart*** device has similar intended use and technological concepts as the market-cleared CardioSen'C™. The ***Smartheart*** is capable of transmitting the electrocardiographic signal digitally so it can be forwarded to a remote location as the market-cleared CardioSen'C™. The results of tests, analyses, and studies performed with the ***Smartheart*** device clearly demonstrate that the ***Smartheart*** device is as safe and effective as its predicate device without raising any new safety and\or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 22 2012

SHL Telemedicine International, Ltd.
c/o Mr. Yoram Levy
Qsite
31 Haavoda St.
Binyamina, Israel 30500

Re: K113514
Trade/Device Name: Smartheart
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: Class II (two)
Product Codes: DXH
Dated: November 20, 2011
Received: November 28, 2011

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SHL
Telemedicine

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K113514

Device Name: Smartheart

Indications for Use: The ***Smartheart*** device is intended to condition an electrocardiographic signal so that it can be transmitted digitally via Bluetooth technology and cell-phone or communication device to a remote location. The ***Smartheart*** device is designed to be used by a patient to transmit a 12 lead ECG and rhythm strip in real-time to enable review at a physician's office, hospital or other medical receiving center.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of Cardiovascular, Respiratory and Neurological Devices
510(k) Number

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113514

APR 2 7 2012

510(k) Summary

Submitter information

Company name	Materialise N.V.
Establishment registration number	3003998208
Street Address	Technologielaan 15
City	Leuven
Zip code	3001
Country	Belgium
Phone number	+32 16 39 62 80
Fax number	+32 16 39 66 06
Principal contact person	Alexandra Razzhivina
Contact title	Regulatory officer
Contact e-mail address	regulatory.affairs@materialise.be
Additional contact person	Mieke Janssen
Contact title	Director, Quality and Regulatory affairs
Contact e-mail address	mieke.janssen@materialise.be
Additional contact person	Toon Lenaerts
Contact title	Product Manager, SurgiCase
Contact e-mail address	toon.lenaerts@materialise.be

Submission information

Trade Name	SurgiCase, SurgiCase Connect
Common Name	Image processing system
Classification Name	Radiological image processing system
Product code	LLZ (21 CFR 892.2050)
Classification panel	Radiology
Device classification	Class II

Device information

Description and functioning of the device

The Materialise **SurgiCase** system is a software medical device to transfer and to segment imaging information from a medical scanner such as a CT or MRI scanner. It allows for pre-surgical simulation and evaluation of implant placement and surgical treatment options.

SurgiCase Connect is a medical device for pre-surgical simulation and evaluation of surgical treatment options. This includes transferring, visualizing and editing medical data.

Based on a pre-surgical software plan the patient specific templates - SurgiCase Guides can be manufactured to fit a specific patient. SurgiCase Guides are not a part of this premarket notification submission.

Indications for Use

The **SurgiCase** system is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging scanner. It is also intended as pre-operative software for simulating / evaluating implant placement and surgical treatment options.

SurgiCase Connect for iPad is a component of the SurgiCase system and intended to be used as a software interface to assist in pre-operative planning by simulation / evaluation of surgical treatment options.

Predicate device

Trade or proprietary or model name	SurgiCase
510(k) number	K073449
Decision date	16/APR/2008
Product code	LLZ
Manufacturer	Materialise

Summary of technological characteristics

The **SurgiCase Connect** for iPad is considered to be substantially equivalent in intended use, performance characteristics, design and function to the predicate SurgiCase system.

Performance data

Non-clinical testing

The **SurgiCase Connect** for iPad has been validated for its intended use to determine substantial equivalence to the predicate device.

Clinical testing

Not applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Ms. Alexandra Razzhivina
Regulatory Officer
Materialise NV
Technologielaan 15
LEUVEN 3001
BELGIUM

APR 2 7 2012

Re: K113599
Trade/Device Name: SurgiCase system (SurgiCase, SurgiCase Connect)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 6, 2012
Received: March 8, 2012

Dear Ms. Razzhivina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K113599

Device Name: **SurgiCase system (SurgiCase, SurgiCase Connect)**

Indications for Use:

The **SurgiCase** system is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging scanner. It is also intended as pre-operative software for simulating / evaluating implant placement and surgical treatment options.

SurgiCase Connect for iPad is a component of the SurgiCase system and is intended to be used as a software interface to assist in pre-operative planning by simulation / evaluation of surgical treatment options.

Prescription Use _ X ____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __ _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety
510(k) K113599

K113656

JUL 26 2012

SECTION 5

510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS FOR CareGuide™ Oximeter

Submitter Information

Name:	Reflectance Medical, Inc. (RMI)
Address:	116 Flanders Road, Suite 1000 Westborough, MA 01581 USA
Telephone Number:	508.366.4700
Registration Number:	NA (RMI will apply for registration number following 510(k) clearance, prior to commencement of commercial shipment.)
Contact Person:	Dr. Babs Soller
Telephone Number:	508.366.4700, Ext 223
Fax Number:	508.366.4770
Email:	Babs.Soller@reflectancemedical.com
Date Prepared:	July 26, 2012

Device Name

Device Trade Name:	CareGuide™ Oximeter
Device Common Name:	Oximeter
Classification:	Sec 870.2700 Oximeter
Product Code:	MUD
Classification Panel:	Cardiovascular Device Panel

Predicate Devices

Device Trade Name:	Invos™ Somatic Oximeter
Device Common Name:	Oximeter
Classification:	Sec 870.2700 Oximeter
510(k) Number:	K051274
Product Code:	MUD

Device Trade Name:	Hutchinson InSpectra™ StO_2 Monitor
Device Common Name:	Oximeter
Classification:	Sec 870.2700 Oximeter
510(k) Number:	K012759
Product Code:	MUD

Device Trade Name:	Hutchinson SpotCheck™ StO_2 Monitor
Device Common Name:	Oximeter
Classification:	Sec 870.2700 Oximeter
510(k) Number:	K103613
Product Code:	MUD

Device Trade Name:	Spectros T-Stat™ Oximeter
Device Common Name:	Oximeter
Classification:	Sec 870.2700 Oximeter
510(k) Number:	K040684
Product Code:	MUD

Device Description

The CareGuide sensor uses Near Infrared Spectroscopy (NIRS) to calculate muscle oxygen saturation (SmO_2).

Characteristics	**Reflectance Medical CareGuide Oximeter**
Principle of Operation	NIR spectroscopy
Components	Monitor with reusable sensor and disposable pad
Light Source	LEDs
Parameters Measured	Tissue oxygen saturation (SmO_2)

The CareGuide Display is an all-in-one touch screen off-the-shelf computer. The display contains the user interface software, the algorithms that calculate SmO_2 from collected spectra, displays the current SmO_2 result and trends previous results. The CareGuide reusable sensor contains the optical and electronic elements necessary to collect spectra from skin, fat and muscle. The sensor has a 3m long cord with a USB connection to the CareGuide display. The sensor contains 3 major components: (1) light sources to illuminate the skin; (2) a spectroscopic detector to analyze the reflected spectra back from the subject and (3) a microprocessor to

control the optical components. The CareGuide Ray is a disposable sleeve which isolates the sensor optical elements from the patient's skin.

Indications for Use

The CareGuide™ Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The CareGuide displays the most recent value of SmO2, as well as a graphical trend of previous SmO2 measurements. The CareGuide System should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the CareGuide™ Oximeter has not been demonstrated in disease states.

Rationale for Substantial Equivalence

The CareGuide™ Oximeter is substantially equivalent to the Somanetics Invos™ Somatic Oximeter (K051274), the Hutchinson InSpectra™ StO_2 Monitor (K012759) and the Hutchinson Spot Check StO_2 Monitor (K103613).

The CareGuide Oximeter is substantially equivalent to the predicates by intended use and design.

- The principle of operation of the CareGuide Oximeter is identical to that of the predicate devices. They all use NIR Spectroscopy to measure tissue oxygen saturation.
- The CareGuide Oximeter is identical to the predicates in components. All devices have a Monitor with a Sensor.
- The CareGuide Oximeter has the same underlying LED light source as the predicates, with the similar ranges of wavelength (700-900 nm between the three devices).
- The CareGuide Oximeter and the predicates all display output as a numeric trend.
- The Intended Use is identical to the predicates. They are all intended for use as oximeters, to measure tissue oxygen saturation.

Further, the CareGuide Oximeter has multiple number of wavelengths like the T-Stat predicate Oximeter

Summary of Safety and Effectiveness Data

Testing demonstrates that the CareGuide Oximeter is a safe and effective oximeter meeting all relevant consensus and FDA recognized standards. The test results in this submission demonstrate that the CareGuide Oximeter meets the expected performance requirements for an Oximeter, and is therefore equivalent to the predicates relative to safety and mechanical properties. The accuracy of the CareGuide Oximeter against the gold reference standard of a

laboratory co-oximeter was demonstrated in an isolated perfused animal limb GLP study. The ability of the CareGuide Oximeter to measure tissue oxygen saturation in subjects with different skin color (pigmentation) has been demonstrated in the clinical environment.

Conclusion

The CareGuide Oximeter is equivalent to predicate devices in terms of technology (NIR Spectroscopy) and intended use. The CareGuide Oximeter, with its multiple source configuration to overcome the effect of skin pigmentation, does not raise new questions of safety or effectiveness, as compared to the predicates. Therefore, the CareGuide Oximeter is substantially equivalent to the predicate devices.

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Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

JUL 26 2012

Reflectance Medical, Inc.
c/o Nandini Murthy
Rgulatory Consultant, RMI
116 Flanders Road, Suite 100
Westborough, MA 01581

Re: K113656
Trade/Device Name: CareGuide Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter, tissue saturation
Regulatory Class: Class II (two)
Product Code: MUD
Dated: July 20, 2012
Received: July 23, 2012

Dear Ms. Murthy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K113656

Device Name: CareGuide™ Oximeter

Indications for Use:

The CareGuide™ Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The CareGuide displays the most recent value of SmO2, as well as a graphical trend of previous SmO2 measurements. The CareGuide System should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the CareGuide™ Oximeter has not been demonstrated in disease states.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K113650

ORTHOSIZE

Paul Beck
Orthosize LLC
939 W. Madison St.
Unit 306
Chicago, IL 60607
T +1 312 636 8439
Orthosize@me.com

510(k) Summary

Submitter Name and Address:	Paul Beck Orthosize LLC 939 W. Madison St. Unit 306 Chicago, IL 60607
Date Summary Prepared:	January 10, 2012
Telephone:	(312) 636-8439
Trade Name	Orthosize
Common Name:	Picture and Archiving Communications (PACS) System
Classification and Name:	Image Processing System
Predicate Device:	TraumaCAD 2.0, Orthocrat Ltd. (K073714)

Device Description

Orthosize software uses digital templates, template overlays provided by orthopedic manufacturers, to estimate the size of joints. Orthosize software allows the user to place a template overlay over a radiographic image. The user may then select an overlay that best approximates the size of the joint in the image. The user may also translate and rotate the overlay such that it substantially matches the shape and outline of the joint in the image. In this way, Orthosize software enables the user to estimate the size and shape of implant that most closely approximates the joint presented in the image. Orthosize also allows the user to make simple measurements.

Orthosize software can run on computers using the following operating systems: Windows XP or later, Mac OS X, and iOS.

Indications for Use

Orthosize is indicated for assisting healthcare professionals in preoperative planning of orthopedic surgery. The device allows for overlaying of prosthesis templates on radiological images, and includes tools for performing measurements on the image and for positioning the templates. Clinical judgments and experience are required to properly use the software.

Performance Data

Functional requirements as defined by the Orthosize Software Requirements Specification (SRS) were tested and traceability was performed and documented as defined by FDA's *General Principles of Software Validation* (January 2002) guidance document. Validation included boundary values and stress testing as defined by the FDA's *Guidance for the Content of Premarket Submission for Software Contained in Medical Devices* (May 2005) guidance document. Safety requirements were

tested as identified by a safety risk analysis performed in accordance with ISO 14971:2007. The Orthosize software passed all tests. No test faults were found. Additionally, no test variances were found during testing. Final assessment using a requirements coverage matrix showed that all software requirements were addressed by the tests.

Final evaluation showed that testing of all software requirements was completed with passing results. No software changes were required. Evaluation of the test results demonstrates that the software performs as intended and meets product specifications.

Substantial Equivalence

Orthosize is substantially equivalent to the predicate device. Orthosize software has the same intended use and indications, as well as very similar technological characteristics and principles of operation, in comparison to the predicate device. The minor technological differences between the Orthosize software and its predicate device raise no new issues of safety or effectiveness. Thus, the Orthosize software is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Orthosize LLC
% Ms. Yarmela Pavlovic
Attorney
Hogan Lovells
1835 Market Street, 29th Floor
PHILADELPHIA PA 19103

MAR 14 2012

Re: K120115
Trade/Device Name: Orthosize
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 13, 2012
Received: January 13, 2012

Dear Ms. Pavlovic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120115

Device Name: Orthosize

Indications for Use:

Orthosize is indicated for assisting healthcare professionals in preoperative planning of orthopedic surgery. The device allows for overlaying of prosthesis templates on radiological images, and includes tools for performing measurements on the image and for positioning the templates. Clinical judgments and experience are required to properly use the software.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K120115

Page __ of ___

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Ms. Lauren Bronich-Hall
Director, Quality System
WellDoc Incorporated
1501 Saint Paul Street, Suite 118
Baltimore, Maryland 21202

FEB 2 4 2012

Re: K120314
Trade/Device Name: WellDoc DiabetesManager® System and Diabetes Manager®-Rx System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ, LNX
Dated: January 30, 2012
Received: February 1, 2012

Dear Ms. Bronich-Hall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120314

Device Name: WellDoc DiabetesManager® System and DiabetesManager®-Rx

Indications for Use:
DiabetesManager® ***(OTC Use):*** The WellDoc DiabetesManager® System is indicated for use by healthcare providers (HCPs) and their adult patients - aged 21 years and older -who have type 2 diabetes. The DiabetesManager® System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager® System analyzes and reports blood glucose test results and supports medication adherence. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.

The DiabetesManager® System is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for RJC

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K120314

DiabetesManager®-Rx ***(Prescription Use):*** The WellDoc DiabetesManager®-Rx System is indicated for use by healthcare providers (HCPs) and their adult patients - aged 21 years and older - who have type 2 diabetes. The DiabetesManager®)-Rx System is intended to provide secure capture, storage, and transmission of blood glucose data as well as information to aid in diabetes self-management. The DiabetesManager®-Rx System analyzes and reports blood glucose test results and supports medication adherence. In addition, the DiabetesManager®-Rx System provides coaching messages (motivational, behavioral, and educational) based on real-time blood glucose values and trends. It includes software intended for use on mobile phones or personal computers in the home or in professional healthcare settings. The software also allows for entry of other diabetes-related healthcare information and provides educational information.

The DiabetesManager®-Rx System is not intended to replace the care provided by a Licensed healthcare professional, including prescriptions, diagnosis, or treatment.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for R8C

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K120314

Attachment 2 16 Mar 2012 revised section for K120473

5.0 510(k) Summary K120473

Submitters Name and Address
Gauss Surgical, Inc.
22700 Alcalde Road
Cupertino CA 95014

APR - 9 2012

Contact Person
Peggy McLaughlin
Consulting Vice President, Clinical & Regulatory Affairs
Gauss Surgical, Inc.
22700 Alcalde Road
Cupertino CA 95014
Fax: 650 941-8222
Telephone: 650 504-8501
Email: MPMcLaughlin@sbcglobal.net

Date Prepared
16 Mar 2012

Name of Medical Device
Device Classification Name: Counter, Surgical Sponge
Device Classification Number: 21 CFR 880.2740
Device Class: Class 1
Proprietary Name: Gauss Pixel App

Predicate Device
Bag-It™ Sponge Counter Bags (Tyco/Covidien) (K912824)

Device Description
The Gauss Pixel App is a software program used on an iPad tablet to capture images of sponges to assist surgical personnel in the management of surgical sponges after surgical use. The App allows surgical personnel to categorize sponges by sponge type and provides an automated ongoing count of total sponge images and sponge images by tag. It also provides a visual record of images for further evaluation. This program is not intended to replace existing sponge counting practices and sponges should be retained per the user's standard sponge management practice until the case is complete and sponge counting has been finalized.

Intended Use

The Gauss Pixel App is intended to be used to aid current clinical practices in recording the number of surgical sponges and for visibility for assessment of sponge images.

The App is intended to be used in the Operating Theatre to assist users with sponge management practices by providing another method to visually capture and display images of used sponges using software running on an iPad mobile platform. Running the

software, the user captures images of each sponge prior to storing per their standard sponge management practices. The user may categorize the sponge by type. The user may review each image to re-assign sponge type, confirm image quality or delete the image if appropriate. The software counts the images and displays an ongoing count of total sponges and sponges by sponge type as categorized by the user. The software allows users to re-review each sponge image and a display panel of all used sponges to assist in sponge management and review. The sponge image is captured in a fully expanded state, providing a full view of each sponge prior to storage per current clinical practices.

The indications for use for the predicate and proposed device differ in that the proposed device is intended to 'aid current practices' which means it is intended to be used in conjunction with current practices. The software automates the counting procedure and this counting has been verified through verification and validation testing. This difference does not affect the safety or efficacy of the device as it is labeled as an adjunctive product.

Technology

Both the Pixel App and the predicate device utilize visual assessment of sponges to count the number of surgical sponges used in a surgical procedure. The predicate device uses a plastic bag with partitions to separate each sponge for counting and review purposes while the Pixel App uses software running on an iPad mobile platform for counting and review purposes. The Pixel App and the predicate device are intended to be used together so that either method of visual assessment may be used during the surgical procedure and a final sponge count may be made by the user. This software technology has been verified to provide an accurate count of all images and by image type as categorized by the user and does not introduce new questions of safety as the user is advised to retain all sponges using standard sponge management practices and can re-review sponges physically at the end of the procedure if needed.

Technologic Comparison

Technologic method for:	Predicate	Gauss Pixel App
Sponge management	Sponges are collected and stored in partitions within the plastic bag.	Sponges are collected and stored in partitions within the plastic bag or other sponge management method selected by user.
Sponge counting	User manually counts sponges as seen in partitions and calculates a total.	User captures image of each sponge prior to storing per current sponge management practices and software counts each image, providing an ongoing total on the iPad mobile platform.
Sponge typing	Not available unless user opts to use separate containers for each sponge type.	User assigns sponge type for each image captured.

Technologic method for:	Predicate	Gauss Pixel App
Sponge counting by type	Not available unless user opts to use separate containers for each sponge type and totals each type separately.	Software counts each image by assigned type, providing an ongoing total.
Visual assessment of each sponge	User can view and assess each sponge in a wadded up state in partitions.	User can view and assess each sponge in an open/unfolded state by re-reviewing any selected image.
Visual assessment of all sponges used in a clinical procedure	User can view and assess the entire 'sheet' of sponges (or series of sheets) as stored in the individual partitions.	User can view and assess all sponges in an open/unfolded state in a grid-like display of all sponges captured during a procedure.

Performance

Results of performance testing confirmed that the application provided instructions for use, recorded images as indicated by the user, accurately tagged images as indicated by the user, accurately provided automated counting both in total and by type and allowed visual review and management (re-tagging, deletion) of all images as appropriate. Results of performance testing through the software verification and validation process demonstrate that the Gauss Pixel App functions as intended and is substantially equivalent to the predicate device.

Substantial Equivalence

The Gauss Pixel App is as safe and effective as the predicate. The Gauss Pixel App has the same intended uses and indications and utilizes a new technological method (software) which complements current clinical practices and does not raise new issues of safety or effectiveness. Software verification and validation demonstrate that the Gauss Pixel App functions as intended. Thus, the Gauss Pixel App has been shown to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Gauss Surgical, Inc.
% Ms. Peggy McLaughlin
Consulting VP, Clinical and Regulatory Affairs
22700 Alcalde Road
Cupertino, California 95014

APR - 9 2012

Re: K120473
Trade/Device Name: Gauss Pixel App
Regulation Number: 21 CFR 880.2740
Regulation Name: Surgical sponge scale
Regulatory Class: I
Product Code: LWH
Dated: March 16, 2012
Received: March 19, 2012

Dear Ms. McLaughlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1 16 Mar 2012 revised section for K120473

4.0 Indications for Use Statement

Indications for Use Form

510(k) Number: K120473

Device Name: Gauss Pixel App

Indications for Use:

The Gauss Pixel App is indicated for use to aid current practices in recording the number of surgical sponges and for visibility for assessment of sponge images.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard P. Rhoads for Mark Ogden
Branch Chief
6/1/12

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120473

510 K summary K120558

FEB 7 2013

Sponsor	LifeScan Europe, a Division of Cilag GmbH International Landis and Gyr Strasse 1 Zug, Switzerland 6300
Correspondent	Andrea M. Tasker Director, Regulatory Affairs Lifescan Inc. 200 Lawrence Drive West Chester, PA 19380 Phone: 610-651-7282 Fax: 610-651-7271 atasker@its.jnj.com Alternate 510(k) Contact: Amy Smith, WW Director Regulatory Affairs 200 Lawrence Drive West Chester, PA 19380 Phone: 484-568-1257 Email: asmith21@its.jnj.com
Device Trade Name	OneTouch Reveal Diabetes Management Application
Common Name	Diabetes Management Software
Classification	NBW - system, test, blood glucose, over the counter 862.1345 Glucose test system. Class II JQP - Calculator/data processing module for clinical use 862.2100 Calculator/data processing module for clinical use. Class I subject to limiations 862.9 (c)(5) For use in diabetes management

System Description	The OneTouch® Reveal Diabetes Management Application (App) is a diabetes management tool that can help you determine what your blood glucose test results mean. This allows you and your health care professional to better monitor and adjust your diabetes care plan. The App is designed to work in conjunction with the OneTouch® Verio™ Sync Meter. Using the Bluetooth® feature on your meter and Apple® device, blood sugar test results can be sent directly from your meter to the App. Once a blood sugar result is sent to the App you can: • Tag the blood sugar result with a meal flag, • Receive Low and High Pattern messages, • Add carbs, activity, medication data and Notes about your activities, • Manually enter other blood sugar test results, • Review results on graphs, • Share your blood sugar results with others for review and follow-up, and • Set reminders to prompt you to complete certain tasks.
Predicate Device	DiabetesManager® System, WellDoc, Inc. (K100066)
Intended Use/Indications for Use	The OneTouch® Reveal Diabetes Management Application is a software accessory to the OneTouch® Verio Sync Blood Glucose Monitoring System, and is intended for use in the home setting by people with diabetes. It is intended to aid in the review, analysis, and evaluation of patient data to support diabetes management. The OneTouch® Reveal Diabetes Management Application receives (from both manual

	entry and wireless transmission), stores, and sends patient data for display and reporting. The OneTouch® Reveal Diabetes Management Application also communicates with web-based applications. The OneTouch® Reveal Diabetes Management Application is available for use on commercially-available mobile devices and uses generally-available networks and communication protocols.
Comparison to Predicate Device	The OneTouch® Reveal Diabetes Management Application incorporates similar technology and functionality provided by the DiabetesManager System including; • Capture, storage and transmission of patient data; • Analysis and reporting of blood glucose results to aid in blood glucose management; • Entry of diabetes related information to aid in diabetes self-management; Unlike the predicate, the OneTouch® Reveal Diabetes Management Application has a software feature that alerts users to low and high blood glucose patterns. This software feature has also been implemented on another cleared LifeScan blood glucose meter, the OneTouch Verio IQ Blood Glucose Meter, K110637.

Technological Characteristics	The OneTouch® Reveal™ Application is designed to run under Apple iOS 4+ operating systems on the following devices: • iPhone 4 and iPhone 3GS • iPod Touch 3rd and 4th Gen • iPad 1st and 2nd Gen The App stores blood glucose test results, events and user settings. The App's memory capacity is 2500 blood glucose results and events; and is limited to a maximum of 1 year of results and events. In addition to receiving blood glucose measurement readings from the OneTouch Verio Sync Meter via Bluetooth, storing and displaying them, the App provides the following features and tools for the user: • Time Synchronization: Synchronizing the time between the App and the OneTouch Verio Sync Meter. • Tagging of Results: Allows quick settings of meal tags and notes to results just downloaded from the meter. • Pattern Messages: Alerts the user that one or more patterns were found in the results that were downloaded. • Events: Allows the user to manually enter data, such as: manual blood glucose results, carbohydrates consumed, activity performed and medications taken. • Sharing: Allows the user to share blood glucose results via SMS text or eMail.

	• Summary: Allows the user to view results in summary in the following ways: 14-day Glucose Report, last meter "Sync" results and patterns, "Today" results & events. • Logbook: Allows the user to view results by date and time-slot, 14-day graph, time-of-day graph. • Pattern Recognition: Alerts the user of Low patterns and Before-Meal High patterns detected in the last 14-days and allows review of those patterns and their details. • More: Allows the user to personalize/customize the App through the following: "About Me" personal settings, "General" application options, "Reminders", "Help", and "Contact OneTouch" information.

Summary of Performance Characteristics	Full verification and validation testing of the OneTouch® Reveal™ Diabetes Management Application software was performed in accordance with the FDA Guidance Document 'General Principles of Software Validation (2002)'. A user performance evaluation study was conducted to validate the OneTouch® Reveal Diabetes Management Application. Human Factors Formative Usability studies were also conducted to evaluate the usability of the OneTouch Reveal Diabetes Management Application and to inform final design of the product.

Conclusions

The OneTouch Reveal Diabetes Management Application is substantially equivalent in its intended use, performance, safety, effectiveness and underlying scientific and operating principles used to the predicate, the DiabetesManager® System, WellDoc, Inc. (K100066).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 7, 2013

Lifescan, Inc.
c/o Andrea M. Tasker
Director, Regulatory Affairs
200 Lawrence Drive
Mailstop C-5-1
West Chester, PA 19380

Re: k120558
Trade/Device Name: OneTouch® Reveal Diabetes Management Application
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, JQP
Dated: January 22, 2013
Received: January 24, 2013

Dear Ms. Tasker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k120558

Device Name: OneTouch® Reveal Diabetes Management Application

Indications for Use:

The OneTouch® Reveal Diabetes Management Application is a software accessory to the OneTouch® Verio Sync Blood Glucose Monitoring System, and is intended for use in the home setting by people with diabetes. It is intended to aid in the review, analysis, and evaluation of patient data to support diabetes management. The OneTouch® Reveal Diabetes Management Application receives (from both manual entry and wireless transmission), stores, and sends patient data for display and reporting. The OneTouch® Reveal Diabetes Management Application also communicates with web-based applications. The OneTouch® Reveal Diabetes Management Application is available for use on commercially-available mobile devices and uses generally-available networks and communication protocols

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use __X__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Katherine Serrano

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k120558

5. 510(K) SUMMARY

MAY 1 5 2013

510(k) number: k120615

Date Prepared: 15 April 2013

Submitter:	Alere San Diego, Inc.	**Contact:**	Edward Brehm
Address:	9975 Summers Ridge Road		Regulatory Affairs Manager
	San Diego, CA 92121	**Email:**	ed.brehm@alere.com
Phone:	858.805.3071	**Phone:**	858.805.3071
Fax:	858.695.7100	**Fax:**	858.695.7100

Trade name: Alere Cholestech LDX® Lipid Profile•GLU Cassette Alere Cholestech LDX® Analyzer	**Common Name (Device Type):** Alere Cholestech LDX® Lipid Profile•GLU Cassette Alere Cholestech LDX® Analyzer

Glucose:	
Class:	II
Regulation number:	21 CFR 862.1345
Product Code:	CGA
Panel:	Clinical Chemistry
Lipids:	
Class:	I (meets limitation for exemption per 21 CFR 862.9(c)(4) and (9)
Regulation number:	21 CFR 862.1175, 862.1475, 862.1705
Product Code(s):	CHH, LBS, JGY
Panel:	Clinical Chemistry
Analyzer:	
Class:	I (exempt)
Regulation number:	21 CFR 862.2160
Product Code:	JJE
Panel:	Clinical Chemistry

Original 510(k) Submissions:	**Clearance Date:**
K901900 – LDX Lipid Monitoring System	July 24, 1990
K932727 – Lipid Profile•GLU Cassette	Nov 9, 1993

5.1. Intended Use / Indications for Use:

The Alere Cholestech LDX® System is a small, portable analyzer and test cassette system. The System is for in vitro diagnostic use only. The Lipid Profile•GLU Cassette is for the quantitative determination of total cholesterol, HDL (high-density lipoprotein) cholesterol, triglycerides and glucose in whole blood. A TC/HDL (total cholesterol/HDL cholesterol ratio and estimated values for LDL (low-density lipoprotein) and non-HDL cholesterol are calculated by the Alere Cholestech LDX® Analyzer.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

5.2. Summary of Changes:

The revision of the software is being changed from revision v3.30 to v3.41, which incorporates a humidity sensor as part of the ROM pack. This sensor measures the ambient humidity and applies a small correction factor from a lookup table to the result from the assay algorithm.

5.3. Substantial Equivalence:

Version v3.41 of the Alere Cholestech LDX® Analyzer ROM pack software is substantially equivalent to Alere Cholestech LDX® Analyzer ROM pack software version v3.30. The change is invisible to the user. Analytical results when the analyzer is operated between 40% and 60% relative humidity are unchanged and no correction factor is required. In more extreme cases, when the ambient humidity is between 20% RH and 40% RH, or between 60% RH and 80%RH, a small correction factor is applied.

5.4. List of Similarities:

The Intended use is unchanged
The Indications for use is unchanged
The analytical performance has been returned to its original intent
The manufacturing process is unchanged

5.5. List of Differences:

Software version v3.41 contains a humidity sensor which measures the ambient humidity and applies a small correction factor to the analytical results based on a lookup table.

5.6. Conclusion:

Performance testing demonstrates that the software upgrade from revision v3.30 to v3.41 is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 15, 2013

Alere San Diego, Inc.
C/O Edward Brehm, Ph.D.
9975 Summers Ridge Road
SAN DIEGO CA 92121

Re: K120615
Trade/Device Name: Alere Cholestech LDX® Lipid Profile • GLU Cassette
Alere Cholestech LDX® Analyzer
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CGA, CHH, LBS, JGY, JJE
Dated: May 10, 2013
Received: May 13, 2013

Dear Dr. Brehm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k120615

Device Name: Alere Cholestech LDX® Analyzer
Alere Cholestech LDX® Lipid Profile•GLU Cassette

Intended Use / Indications for Use:
The Alere Cholestech LDX® System is a small, portable analyzer and test cassette system. The System is for in vitro diagnostic use only. The Lipid Profile•GLU Cassette is for the quantitative determination of total cholesterol, HDL (high-density lipoprotein) cholesterol, triglycerides and glucose in whole blood. A TC/HDL (total cholesterol/HDL cholesterol ratio and estimated values for LDL (low-density lipoprotein) and non-HDL cholesterol are calculated by the Alere Cholestech LDX® Analyzer.

- Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
- HDL (lipoprotein) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
- Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k120615

510(k) Summary

JUN - 1 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1.0 submitter's information

Name: Andon Health Co., Ltd.
Address: No 3, Jinping Street Ya An Road, Nankai District, Tianjin, P.R. China
Phone number: 86-22-6052 6161
Fax number: 86-22-6052 6162
Contact: Liu Yi
Date of Application: 02/27/2012

2.0 Device information

Trade name: iHealth BP5 Fully Automatic Arm Cuff Wireless Blood Pressure Dock
Device name: KD-936 Fully Automatic Wireless Blood Pressure Monitor
Classification name: Noninvasive blood pressure measurement system

3.0 Classification

Production code: DXN- Noninvasive blood pressure measurement system.
Regulation number: 870.1130
Classification: II
Panel: Cardiovascular

4.0 Predicate device information

Manufacturer: Andon Health Co., Ltd.
Device: iHealth BP3 Fully Automatic Arm Cuff Electronic Blood Pressure Dock
510(k) number: K102939

5.0 Device description

KD-936 Fully Automatic Wireless Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

KD-936 Fully Automatic Wireless Blood Pressure Monitor is designed and manufactured according to ANSI/AAMI SP10--manual, electronic or automated sphygmanometers.

The operational principle is based on oscillometric and silicon integrates pressure sensor technology. it can calculate the systolic and diastolic blood pressure, the measurements results can also be classified by the function of blood pressure classification indicator. If any irregular heartbeat is detected, it can be shown to the user. More over, it also obtains the function of averaging the measurement results.

KD-936 Fully Automatic Wireless Blood Pressure Monitor achieves its function by integrate the device with an iPhone, ipod or ipad. For it does not contain an LCD or other display components, so It's necessary for the new device to connect to an iPhone, iPod or iPad containing a support software to constitute a complete blood pressure measurement system. And the new device connect iPhone, iPod or iPad through bluetooth.

6.0 Intended use

KD-936 Fully Automatic Wireless Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

The intended use and the indication for use of the KD-936 Fully Automatic Wireless Blood Pressure Monitor, as described in its labeling are the same as the predicate device iHealth BP3.

7.0 Summary comparing technological characteristics with predicate device

Technological Characteristics	Comparison result
Design principle	Identical
Appearance	Similar
Patients contact Materials	Identical
Performance	Similar
Biocompatibility	Identical
Mechanical safety	Identical
Energy source	Identical
Standards met	Identical
Electrical safety	Identical
EMC	Identical
Function	Similar

8.0 Discussion of non-clinical and clinical test performed

Non-clinical Tests have been done as follows:

a. Electromagnetic compatibility test according to IEC 60601-1-2;
b. Electrical safety according test to IEC 60601-1 and IEC 60601-1-1
c. FCC test according to FCC part 15 (2009)
d. Safety and performance characteristics of the test according to SP10

None of the test demonstrates that KD-936 Fully Automatic Wireless Blood Pressure Monitor brings new questions of safety and effectiveness.

Clinical Test Concerning the Compliance of ANSI/AAMI SP10

Compared to inflation detection of its predicate device iHealth BP3, KD-936 Fully Automatic Wireless Blood Pressure Monitor is an deflation detection device, so the arithmetic is changed. As a result, a new clinical test is done in accordance with ANSI/AAMI SP10, and the device met all applicable requirements of the standard.

9.0 Performance summary

KD-936 Fully Automatic Wireless Blood Pressure Monitor conforms to the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- UL 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 2003.
- IEC 60601-1-1, Medical Electrical Equipment - Part 1: General Requirements for Safety – 1. Collateral standard: Safety Requirements for Medical Electrical Systems, 2000.
- EN 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests, 2007.
- AAMI SP10:2002, Manual, electronic or automated sphygmomanometers.
- AAMI / ANSI SP10:2002/A1:2003 --, Amendment 1 to ANSI/AAMI SP10:2002 Manual, electronic, or automated sphygmomanometers.
- AAMI / ANSI SP10:2002/A2:2006 --, Amendment 2 to ANSI/AAMI SP10:2002 Manual, electronic, or automated sphygmomanometers.

10.0 Comparison to the predicate device and the conclusion

Our device KD-936 Fully Automatic Wireless Blood Pressure Monitor is substantially equivalent to the Fully Automatic Electronic Blood Pressure Monitor iHealth BP3 whose 510(k) number is K102939.

The two devices are very similar in the intended use, the design principle, the material, the performance and the applicable standards. Only their appearance, the memory time, and the user interface are different. The measure process is also changed, that is the new device will get the measurement results when the device is deflating, while iHealth BP3 gets the result during the inflating period. Both KD-936 Fully Automatic Wireless Blood Pressure Monitor and its predicate device can achieve their function with an iphone, ipod or ipad, the difference is that KD-936 transfer the data through blue tooth while iHealth BP3 transfer the data through a data line.

However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Andon Health Co., Ltd.
c/o Mr. Liu Yi
President
No. 3 Jin Ping Street,
Ya An Road, Nankai District
Tianjin, 300190
CHINA

JUN - 1 2012

Re: K120672
Trade Name: KD-936 Fully Automatic Wireless Blood Pressure Monitor, or iHealth BP5
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: Undated
Received: May 2, 2012

Dear Mr. Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number : K120672

Device name: KD-936 Fully Automatic Wireless Blood Pressure Monitor

Indications for use:

KD-936 Fully Automatic Wireless Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

Prescription use _____ AND/OR Over-The-Counter Use YES
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-COUNTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120672

K121165

JUN 21 2012

510(k) SUMMARY

Section 5.0

Applicant:	Beam Technologies, LLC P.O. Box 17541 Louisville, KY 40217
Applicant Correspondent:	Alex Curry Head of Product Beam Technologies, LLC P.O. Box 17541 Louisville, KY 40217 Telephone: 859.462.7562 Email: curry@beamtoothbrush.com
Date Summary Prepared:	April 13, 2012
Proprietary Name of Device:	Beam Brush/ Beam App
Generic/Classification Name:	Toothbrush, Manual
Product code (Classification):	EFW (Class I, 21 CFR 872.6855)
Legally Marketed Predicate Device:	Oral-B® "sub-brand" manual toothbrush (K073224) (i.e. CrossAction, Advantage, Pulsar, Pro-Health) Procter & Gamble

DEVICE DESCRIPTION AND TECHNOLOGICAL CHARACTERISTICS

The Beam Brush is a manual toothbrush comprised essentially of a shaft with synthetic bristles on one end that are used to remove plaque and food debris from its user's teeth. The bristle material is Nylon 612 or Polyamide 612. The Beam Brush collects brushing usage data based on the principle that the human body possesses the property of being a good capacitor, such that the human body has a detectable capacitance. This capacitance is transferrable through a thermoplastic material. The Beam Brush comprises a capacitive sensor, which is completely enclosed in the toothbrush body. The capacitive sensor detects that the Beam Brush is in use based on the capacitance introduced by the human body when the Beam Brush is utilized for its intended purpose.

The Beam Brush wirelessly transmits the collected data using radio frequency transmission, more specifically Bluetooth® radio. The Bluetooth® standard defines the parameters for transmission of data via radio frequency including a transmitting frequency of 2.4 GHz. The Beam Brush is a Class 2

Bluetooth® device, which has a transmission range of about 30 feet and a maximum power of 2.5 mW. The data is received by a user's own mobile device that runs a software application (Beam App), which is of a minor level of concern. The Beam App is an accessory to the Beam Brush and allows the user to view his/her brushing usage data for the user's convenience and education. The Beam App, collection of data, and transmission of data are not intended for the diagnosis and treatment of disease or to affect the structure or function of the body.

The Beam Brush's capacitive sensor and Bluetooth® radio are powered by a single AA alkaline battery that is replaceable. The Beam Brush also comprises a replaceable brush head that connects to the handle at the base of the neck.

INDICATIONS FOR USE

The Beam Brush is a toothbrush to remove plaque and debris from its user's teeth and aide in the prevention of tooth decay. The Beam Brush collects brushing usage data and wirelessly transmits the data to a software application (Beam App) that runs on the user's own mobile device ("smartphone").

TESTING

The Beam Brush was tested to determine the pull-off force of the brush head when it is improperly removed from the handle. This test demonstrates the substantial equivalence to legally marketed toothbrushes of the replaceable head of the manual toothbrush to remain connected during the normal course of brushing.

The Beam Brush is an alkaline battery operated manual toothbrush. All electrical components including the capacitive sensor and the Bluetooth® radio are housed within thermoplastic enclosures.

The Beam Brush will be evaluated and will comply with the applicable requirements of international standard IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (Second Edition, 1988). The Beam Brush also will be evaluated and comply with the applicable requirements of international standard IEC 60601-1-2 Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests (Second Edition, 2001). Additionally, the Beam Brush will be evaluated and will comply with the applicable requirements of Equipment Authorization by the Federal Communications Commission. Collectively, these evaluations and compliances demonstrate the Beam Brush's substantial equivalence to legally marketed toothbrushes in regard to electrical safety and electromagnetic compatibility.

The Beam Brush/Beam App completed software verification and validation testing. Collectively, these tests demonstrate that the Beam Brush/Beam App is substantially equivalent to legally marketed toothbrushes when using a software application that runs on the user's own mobile device.

CONCLUSIONS

The information provided supports the substantial equivalence to the predicate device of the Beam Brush/Beam App without raising any new safety and effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Alex Curry
Head of Product
Beam Technologies, LLC
P.O. Box 17541
Louisville, Kentucky 40217

JUN 21 2012

Re: K121165
Trade/Device Name: Beam Brush/Beam APP
Regulation Number: 21 CFR 872.6855
Regulation Name: Manual Toothbrush
Regulatory Class: I
Product Code: EFW
Dated: April 13, 2012
Received: April 17, 2012

Dear Mr. Curry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Section 4.0

510(k) Number (if known): K121165

Proprietary Device Name: Beam Brush/ Beam App

Indications for Use: The Beam Brush is a toothbrush to remove plaque and debris from its user's teeth and aide in the prevention of tooth decay. The Beam Brush collects brushing usage data and wirelessly transmits the data to a software application (Beam App) that runs on the user's own mobile device ("smartphone").

Prescription Use ___X___ AND/OR Over-The-Counter Use ___X___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121165

k121197

AUG 10 2012

8 510(k) Summary

Submitter:	Preventice, Inc. 2765 Commerce Drive NW Suite 220 Rochester, MN 55901
Contact Person:	Drew Palin, M.D. Medical Innovation Officer dpalin@preventice.com Mobile: 414-688-6858 Office : 507-322-3712 FAX: 507-281-3630 Preventice 2765 Commerce Drive NW Suite 220 Rochester, MN 55901
Date Prepared:	April 18, 2012
Trade Names:	BodyGuardian System [Preventice BodyGuardian Device (BodyGuardian Control Unit and BodyGuardian SnapStrip), Preventice BodyGuardian Connect, BodyGuardian Application, Preventice PatientCare, PatientCare Portal for the Web, and PatientCare for iPad
Classification:	21 CFR 870.1025 • Patient Physiological Monitor (with arrhythmia detection) • Arrhythmia Detector and Alarm
Product Codes:	MHX, DSI
Predicate Device:	AVIVO Mobile Patient Management System (k083287)
Device Description:	The BodyGuardian System is an ambulatory cardiac monitoring system prescribed by healthcare providers. It monitors and records a patient's electrocardiographic (ECG) data, heart rate, respiration rate and activity level. The complete system consists of components that collect data, send the data to a remote Preventice computer server, store the data in secure databases, and present the data for review by healthcare professionals.

510(k) Summary (Continued)

Intended Use:	The BodyGuardian System detects and monitors non-lethal cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. The BodyGuardian System continuously records, stores and periodically transmits the following physiological data to a remote computer server for up to 30 days at a time: • ECG • Heart rate (including HR variability and HR reliability) • Respiration rate • Activity
Comparison of Technological Characteristics:	Both the predicate system and the BodyGuardian System are small, ambulatory cardiac monitors that measure ECG, heart rate, respiration rate and activity levels. Both transmit their data to an external device which, in turn, broadcasts the data to a remote computer server that allows healthcare professionals to access and review the data. There are no fundamental differences between their technological characteristics.
Non-Clinical Testing:	The following bench testing was conducted on the BodyGuardian System: • EMC and electrical safety testing • ECG performance testing • Activity level measurement validation • Respiration rate measurement validation • Software verification and validation • Biocompatibility testing
Clinical Testing	Not applicable.
Conclusion:	We conclude that the results of testing show the BodyGuardian System to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 10 2012

Preventice, Inc
c/o Drew Palin, M.D.
Medical Innovation Officer
2765 Commerce Drive NW, Suite 220
Rochester, MN 55901

Re: K121197
Trade Name: Preventice BodyGuardian System
Regulatory Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
(including ST-segment measurement and alarm)
Regulatory Class: II (two)
Product Code: DSI
Dated: August 2, 2012
Received: August 3, 2012

Dear Mr. Palin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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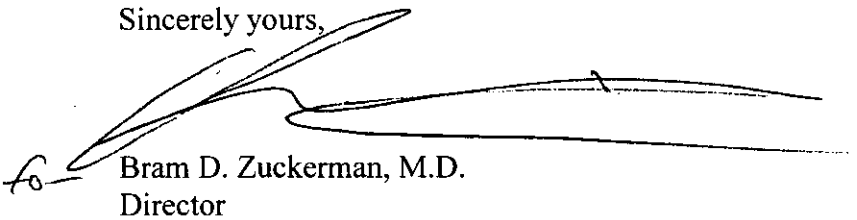
Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7 Indications for Use Statement

510(k) Number (if known):

Device Name: BodyGuardian System

Indications for Use:

The BodyGuardian System detects and monitors non-lethal cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. The BodyGuardian System continuously records, stores and periodically transmits the following physiological data to a remote computer server for up to 30 days at a time:

- ECG
- Heart rate (including HR variability and HR reliability)
- Respiration rate
- Activity

Prescription Use ___ X ____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121197

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 27 2012

Gauss Surgical, Incorporated
% Ms. Peggy McLaughlin
Consulting Vice President, Clinical & Regulatory Affairs
22700 Alcalde Road
Cupertino, California 95014

Re: K121274
Trade/Device Name: Gauss Pixel App
Regulation Number: 21 CFR 880.2740
Regulation Name: Surgical sponge scale
Regulatory Class: Class I
Product Code: LWH
Dated: June 06, 2012
Received: June 11, 2012

Dear Ms. McLaughlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

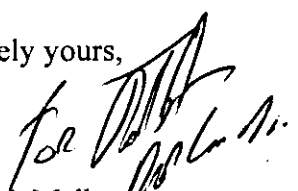
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2 - Indication for Use Form

Indications for Use Form

510(k) Number: K121274

Device Name: Gauss Pixel App

Indications for Use:

The Gauss Pixel App is intended to be used to aid current clinical practices in recording the number of surgical sponges and for visibility for assessment of sponge images.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Neil R Ogden for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121274

K121405

Welch Allyn

DEC 2 0 2012

510(k) Summary

[As described in 21 CFR 807.92]

Submitted by: Welch Allyn Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0220

Contact Person: Kevin Crossen, Director Regulatory Affairs
Phone: (315) 685-2609
Fax: (315) 685-2532
E-mail: Kevin.Crossen@welchallyn.com

Date Prepared: December 11, 2012

Trade Name: Welch Allyn iExaminer

Common Name: iExaminer

Device Classification: Class II

Classification Reference: 886.1120, Ophthalmic Camera

Classification Product Code: HKI

Predicate Devices: Optomed Smartscope M5 EY3, Smartscope M5 ES1
Optomed Oy
510(k) K110986

KOWA Genesis-D
KOWA CO.LTD
510(k) K080681

EyeQuick
EyeQuick, LLC
510(k) K102412

Welch Allyn PanOptic #11800
Welch Allyn, Inc.
510(k) K003376

K121405

Welch Allyn

Description of Device:

The Welch Allyn iExaminer is comprised of the adapter, the iPhone and the software application. The adapter is specifically designed to hold the iPhone 4 and iPhone 4S in a fixed position in order to align the camera in the iPhone with the optics of the Welch Allyn PanOptic.
The software application allows the user to capture, store, send, and retrieve images of the eye as seen through the PanOptic. With the Retinal image application, iExaminer Professional Version, the user has the ability to capture images of the patient's eye by activating the camera icon at the bottom of the iPhone tool bar. Additional icons, buttons and pages allow the user to save images, transfer images and retrieve previously saved images.

Indications for Use:

The iExaminer is an attachment and software used only with the iPhone 4 and iPhone 4S in conjunction with the Welch Allyn PanOptic Ophthalmoscope to allow users to capture, send, store and retrieve images of the eye. The device is intended to be used by trained personnel within a medical or school environment.

Technological Characteristics:

The PanOptic is not being changed. None of the technological characteristics and indications for use of the PanOptic are being changed.

The Welch Allyn iExaminer is composed of two components that are used in combination and in conjunction with the PanOptic. The adapter is a plastic bracket that aligns the optics of PanOptic with the camera of the iPhone 4 and iPhone 4S. The software that can be purchased along with the adapter allows the user to document images of the patient's eyes.
The software allows the user to capture images of the eye by using the Retinal Image button. Next the user can view these images and select the ones to save. The user can name the images for later retrieval. Also, if the iPhone is configured and the user is using the Professional version of the iExaminer software application they can print or email saved images.
The software Application itself has two versions, a Free version and a Professional version. The Free version only allows the user to save ten patient files and does not allow them print or Email the images. These are the only differences between the Free and Professional versions of the iExaminer software.

Non-Clinical Tests:

Verification and validation were conducted to ensure expected performance of the Welch Allyn iExaminer, compliance to applicable standards, and to demonstrate that it does not affect the functionality or performance of the PanOptic. The Welch Allyn iExaminer is an ophthalmic camera that allows the user to document images of the eye as seen through the PanOptic.

The following FDA Guidance and standards were applied to the modified device.

- ISO 14971 Application of Risk Management to Medical Devices
- Off the Shelf Software guidance.
- Guidance for the Content of Premarket Submission for software contained in Medical Devices.
- ISO 10940 2009 Ophthalmic instruments- Fundus cameras
- ISO 15004-1: 2006 Ophthalmic instruments-Fundamental requirements and test methods- Part 1: General requirements applicable to all ophthalmic instruments.
- ISO 15004-2 2:2007 Ophthalmic Instruments- Fundamental Requirements and Test Methods-Part 2: Light Hazard Protection
- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- IEC 60601-1-2 : 2007 Medical Electrical Equipment –Part 1-2 General Requirements for Safety – Collateral standard: Electromagnetic Compatibility.

K121405

WelchAllyn

Device Comparison Tables

Overall Comparison.

The 510(k) consists of using the using the Welch Allyn iExaminer in conjunction with the PanOptic. The Welch Allyn iExaminer compares favorably to the predicate devices listed above in terms of technology, Intended use and Indications for use. The information in the tables below were obtained from 510(k) summaries found on the FDA database along with information obtained from the respective device websites.

Substantial Equivalence Discussion

The Welch Allyn iExaminer is substantially equivalent in intended use and technology. Like the predicate devices classified in product code HKI, the Welch Allyn iExaminer has a camera with the ability to digitally capture images of the eye along with the ability to store images on the device itself. Also, as with the predicates classified as HKI, the Welch Allyn iExaminer has the ability to electronically send/transfer these images to other Information Technology Equipment (e.g., personal computer). The Welch Allyn iExaminer transfers these images via email. The predicate devices transfer the images via a USB. As with the predicate devices, images on the Welch Allyn iExaminer can be retrieved for viewing at a later time.

As part of the clinical study, the electronic transfer of images by the Welch Allyn iExaminer and the subsequent downloading to a Personal computer were compared to the Optomed images that were electronically transferred and downloaded to the same personal computer. The transferred images were determined to be at least as accurate and adequate (carry sufficient imaging details) to discern important clinical information as the predicate Optomed device, and thus substantially equivalent.

The iPhone does not impart any energy into the eye as part of the iExaminer. The energy released into the eye by the Welch Allyn iExaminer is the same as the Welch Allyn PanOptic. The light source for the iExaminer is the Halogen bulb used by the PanOptic, i.e., no additional light source beyond the PanOptic's halogen bulb is utilized by the iExaminer. In addition, the Welch Allyn iExaminer has been tested and found to be in compliance to applicable industry standards.

Summary of Device Performance Confirmed by Bench Testing

Several bench tests were completed to confirm the device is substantially equivalent, based on standards, to the predicate device.

Summary of Device Performance Confirmed by Clinical Testing

As noted above, testing was conducted to confirm that the Welch Allyn iExaminer performed as intended to capture images that have sufficient detail to allow a trained professional to discern clinically important information.

Camera System Technical Specifications

Point of comparison	iPhone 4	iPhone 4S	Optomed Smartscope M5 EY3	EyeQuick EDOC-1000	KOWA Genesis D
Resolution	5.00 megapixel	8 megapixel	5.0 megapixel	Less than 1 megapixel	2 megapixel
Image type	JPEG	JPEG	JPEG	JPEG	JPEG / BMP
Focus type	Autofocus	Autofocus	Autofocus	Manual diopter	Information not available

K121405

Welch Allyn

Point of comparison	iPhone 4	iPhone 4S	Optomed Smartscope M5 EY3	EyeQuick EDOC-1000	KOWA Genesis D
Image size / Resolution	2592 x 1936 (5.0MP)	3264 x 2448 (8.0MP)	2560 x 1920 (5.0 MP)	480 x 672 (< 1 MP)	2 megapixel
Sensor Type	CMOS	CMOS	CMOS	Information not available	CCD
Sensor Size	1/3.2	1/3.2	Information not available	Information not available	Information not available
Focal Length multiplier	7.62	8.20	Information not available	Information not available	Information not available
Aspect Ratio	16:9 / 4:3	16:9 / 4:3	Information not available	Information not available	Information not available
Lens focal length	29mm	35mm	Information not available	Information not available	Information not available
Zoom ratio	1.00x	1.00x	Information not available	Information not available	Information not available
Auto Focus	Yes	Yes	Yes	No	Information not available
Aperture Range	Fixed f/2.8	Fixed f/2.4	Information not available	Information not available	Information not available
ISO	Auto	Auto	Information not available	Information not available	Information not available
White Balance	Auto	Auto	Information not available	Auto	Information not available
Shutter Speed	1/15 – 1/10055	1/15 – 1/30000[2]	Information not available	Information not available	Information not available
First 3 categories reference Apple technical specs. http://www.apple.com/iphone/iphone-4/specs.html http://www.apple.com/iphone/specs.html The remaining categories reference www.imaging-resource.com, www.ephotozine.com.			Technical information was gathered from manufacturer product literature and labeling of devices	Technical information was gathered from manufacturer product literature and labeling of devices	Technical information was gathered from manufacturer product literature

Summary of Pupil diameter size, working distance and magnification.

Point of Comparison	**iExaminer**	**Optomed Smartscope M5 with EY3**	**EyeQuick – EDOC-1000**	**KOWA Genesis D**
Minimal Pupil Diameter Size	2 mm (Per PanOptic Ophthalmoscope)	3.5 mm	Information not available	8 mm recommended
Working Distance	25.4mm (Pupil to first optical surface on the objective lens. Per PanOptic Ophthalmoscope)	1 – 2 cm (from the surface of the eye)	5mm (between top of cornea and ophthalmoscope front)	5mm (between eye and prism)
Pixel Pitch (Per ISO 10940, Magnification of image is only applicable for fundus cameras recording on film. Pixel pitch is the applicable measurement for fundus cameras recording on a digital sensor)	Measured 5.37 um/pixel for iPhone 4 High res, 4.25 um/pixel for iPhone 4S High Res	Measured 8.77 um/pixel	Information not available	Information not available
Optical Magnification	1.183 (Per PanOptic Ophthalmoscope. Magnification: M=h'/h The Optical magnification (M) is defined by the ratio between the image size (h') and the object size (h). (h) = the object size of retinal detail (such as a blood vessel) (h') = the image size of the retinal detail (such as the image of that blood vessel))	Information not available	Information not available	Information not available

Summary of ISO 10940 performance (Predicate device comparison)

Criterion	Requirement		iPhone 4 Standard res	iPhone 4 High res	iPhone 4S Standard res	iPhone 4S High res	Optomed Smartscope M5 EY3
Resolving power on the fundus camera for fundus camera optics. Field of view ≤30°	Centre	≥ 80 lp/mm	82.94 lp/mm				Not possible to observe
	Middle (r/2)	≥ 60 lp/mm	74.12 lp/mm				Not possible to observe
	Periphery (r)	≥ 40 lp/mm	58.82 lp/mm				Not possible to observe
Tolerance of angular field of view	+/- 5%		-1.16 % (Measured 24.71° against 25° claim)	-1.16 % (Measured 24.71° against 25° claim)	-1.16 % (Measured 24.71° against 25° claim)	-1.16 % (Measured 24.71° against 25° claim)	+10.5% (Measured 44.23° against 40°claim by manufacturer)
Tolerance of magnification of image	N.A. (Fundus camera on a digital sensor)		NA	NA	NA	NA	NA
Tolerance of pixel pitch on fundus	+/- 7%		Measured 16.25 um/pixel	Measured 5.37 um/pixel	Measured 16.25 um/pixel	Measured 4.25 um/pixel	Measured 8.77 um/pixel
Range of diopter adjustment of the optical finder (when optical finder is attached)	-5D to +5D		-20D to +20D				At least -20D to +20D
Range of focus adjustment for compensation of patient's refractive error	-15D to +15D		-20D to +20D				At least -20D to +20D

Technical information was gathered from via engineering testing, manufacturer product literature, labeling of devices and by side-by-side comparison

K121405

Device Comparison Table

Point of comparison	iExaminer (K121405)	Optomed Smartscope M5 with EY3(K110986)	KOWA Genesis-D (K080681)	EyeQuick EDOC-1000 (HKI, K102412)	Welch Allyn 11800 Ophthalmoscope (K003376)
Indications for use	The iExaminer is an attachment and software used only with the iPhone 4 and iPhone 4S in conjunction with the Welch Allyn PanOptic Ophthalmoscope to allow users to capture, send, store and retrieve images of the eye. The device is intended to be used by trained personnel within a medical or school environment.	Optomed Smartscope M5 camera with optics modules EY3 and ES1 is a digital ophthalmoscope intended to capture digital images and video of the fundus of the human eye and surrounding area.	To capture and save fundus images with mydriatic	The EyeQuick Digital Ophthalmoscope Camera is intended for use in capturing approximately 8 degrees narrow angle field of view images of the eyelids, retina and anterior segment of the eye.	The Welch Allyn model #11800 Ophthalmoscope is intended to be used to examine the cornea, aqueous, lens, vitreous, and retina of the eye. It has the same operating principles and intended use as many competitive ophthalmoscopes already in commercial distribution. The device is intended to be used by trained personnel within a medical or school environment.
Data output / Output terminals	iExaminer App: Ability to Transfer images via email or print (Performed by the iPhone 4 / 4S operating system)	Image data can be transferred to the PC by using USB connection. USB 1.1 terminal. Compatible with Windows XP/Vista/7.	Image data can be transferred to the PC by using USB connection. USB 1.1 terminal. Compatible with Windows ME/2000/XP.	Image data can be transferred to a PC via a USB memory drive. USB 2.0 terminal	NA
Usage	Prescription Use. Trained personnel within medical or	Prescription Use	Prescription Use	Prescription Use	Prescription Use. Trained personnel within medical or school environment.

K121405

Point of comparison	iExaminer (K121405)	Optomed Smartscope M5 with EY3(K110986)	KOWA Genesis-D (K080681)	EyeQuick EDOC-1000 (HKI, K102412)	Welch Allyn 11800 Ophthalmoscope (K003376)
	school environment.				
Use Conditions	With or without mydriatic	Intended to use without mydriatic but can be used also with mydriatic	With or without mydriatic	With or without mydriatic	With or without mydriatic
Observation light source	As per PanOptic: Halogen lamp, visible light	Visible and infrared LED	Visible LED	Welch Allyn Halogen lamp, visible light	Halogen lamp, visible light. Visible LED
Observation and display system	As per iPhone 4 or 4S: 3.5" widescreen display. 960 x 640 pixel resolution at 326 ppi, 800:1 contract ratio, 500cd/m2 max brightness	2.4" active matrix color TFT LCD	Visual observation	1.75" LCD screen	Visual observation
Photographic light source	As per PanOptic observation light source: Halogen lamp visible light	Visible and infrared LED	Xenon flash lamp	As per observation light source: Welch Allyn Halogen lamp, visible light	NA
Camera spec	5 megapixel / 8 megapixel	5 megapixel	2 megapixel	Less than 1 megapixel	NA
Diopter compensation	As per PanOptic: -20D to +20D	At least -20D to +20D	-15D to +35D	-25D to +40D	-20D to +20D
Apertures	As per Panoptic: Multiple	-	Multiple	Multiple	Multiple
Picture angle	25 degrees	Over 40 degrees	Horizontal 30 degree Vertical 25 degree	8 degrees	25 degrees

K121405

Point of comparison	iExaminer (K121405)	Optomed Smartscope M5 with EY3(K110986)	KOWA Genesis-D (K080681)	EyeQuick EDOC-1000 (HKI, K102412)	Welch Allyn 11800 Ophthalmoscope (K003376)
Storage Media	As per iPhone 4 or 4S: Internal storage capacity.	Flash memory card	Flash memory card	Flash memory	NA
Image data format	As per iPhone 4 /4S: JPEG	JPEG, MPEG-4 (video)	JPEG and uncompressed format	JPEG	NA
Weight	PanOptic: 350g iExaminer adapter: 40g iPhone: 4 ,137g – iPhone 4S 140g	Camera: 400g EY3: 180g	1kg	356g	350g
Power Consumption	As per iPhone 4 / 4S: Built in rechargeable Li-Ion battery As per PanOptic: Re-chargeable battery handle 3.5V	Re-chargeable Ni-MH battery 4.8V	60VAC	Re-chargeable Welch Allyn 711 battery	Re-chargeable battery handle 3.5V
Exposure parameters	As per PanOptic: Compliance with ISO 15004-2	Group 1 instrument according to ISO 15004-2	LED is classified according to IEC 60825-1	Meets ISO 10940	Group 1 ophthalmic instrument compliant with ISO 15004-2

K121405

Welch Allyn

Clinical:

Clinical data were collected to demonstrate substantial equivalence to establish the image quality as generated by the Welch Allyn iExaminer is accurate enough and carries sufficient imaging details to discern important clinical information.

The clinical trial data established that the images as captured by the Welch Allyn iExaminer are accurate enough and carry sufficient imaging details to discern important clinical information.

Conclusion:

The differences between the iExaminer and Predicate devices as noted above in the summary tables do not impact safety and effectiveness based on the bench tests and clinical trial results. Based on the information presented in this 510(k) premarket notification, Welch Allyn's iExaminer is considered substantially equivalent (as safe, as effective and performs as well as) the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 20, 2012

Welch Allyn, Inc.
c/o Mr. Kevin Crossen
Director, Regulatory Affairs
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153

Re: K121405
Trade/Device Name: PanOptic iExaminer
Regulation Number: 21 CFR 882.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: December 13, 2012
Received: December 17, 2012

Dear Mr. Crossen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121405

Device Name: Welch Allyn PanOptic iExaminer

Indications for Use:

The iExaminer is an attachment and software used only with the iPhone 4 and iPhone 4S in conjunction with the Welch Allyn PanOptic Ophthalmoscope to allow users to capture, send, store and retrieve images of the eye. The device is intended to be used by trained personnel within a medical or school environment.

Prescription Use (Part 21 CFR 801 Subpart D) x AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K121405

K121470
p1/3

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

JUN 14 2012

1.0 submitter's information

Name: Andon Health Co., Ltd.
Address: No 3, Jinping Street Ya An Road, Nankai District, Tianjin, P.R. China
Phone number: 86-22-6052 6161 Ext 8060
Fax number: 86-22-6052 6162
Contact: Liu Yi

Date of Application: 05/08/2012

2.0 Device information

Trade name: iHealth BP7-Wireless Blood Pressure Wrist Monitor
Device name: KD-972 Fully Automatic Wireless Blood Pressure Wrist Monitor
Classification name: Noninvasive blood pressure measurement system

3.0 Classification

Production code: DXN- Noninvasive blood pressure measurement system.
Regulation number: 870.1130
Classification: II
Panel: Cardiovascular

4.0 Predicate device information

Manufacturer: Andon Health Co., Ltd.

Device: KD-7964 Fully Automatic Electronic Blood Pressure Monitor

510(k) number: K102906

5.0 Device description

KD-972 Wireless Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system

intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 13.5cm-22cm.

It is designed and manufactured according to IEC 80601-2-30- Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.

The operational principle is based on oscillometric and silicon integrates pressure sensor technology. it can calculate the systolic and diastolic blood pressure, the measurement results can also be classified by the function of blood pressure classification indicator. If any irregular heartbeat is detected, it can be shown to the user. More over, it also obtains the function of averaging the measurement results.

KD-972 Fully Automatic Wireless Blood Pressure Wrist Monitor achieves its function by integrate the device with an iPhone, iPod touch or iPad. For it does not contain an LCD or other display components, so It's necessary for the new device to connect to an iPhone, iPod touch or iPad containing a support software to constitute a complete blood pressure measurement system. And the new device connect iPhone, iPod or iPad through bluetooth.

6.0 Intended use

KD-972 Fully Automatic Wireless Blood Pressure Wrist Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 13.5cm-22cm.

The intended use and the indication for use of KD-972, as described in the labeling are the same as its predicate device KD-7964.

7.0 Summary comparing technological characteristics with predicate device

Technological Characteristics	Comparison result
Design principle	Identical
Appearance	Similar
Patients contact Materials	Identical
Performance	Similar

Biocompatibility	Identical
Mechanical safety	Identical
Energy source	Identical
Standards met	Identical
Electrical safety	Identical
EMC	Identical
Function	Similar

8.0 Performance summary

KD-972 Fully Automatic Wireless Blood Pressure Wrist Monitor conforms to the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- EN 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests, 2007.
- IEC 80601-2-30, Medical electrical equipment-Part 2-30:Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanmeters,2009.

9.0 Comparison to the predicate device and the conclusion

Our device KD-972 Fully Automatic Wireless Blood Pressure Wrist Monitor is substantially equivalent to the Fully Automatic Electronic Blood Pressure Monitor KD-7964 whose 510(k) number is K102906.

KD-972 and KD-7964 are very similar in the intended use, the design principle, the performance and the applicable standards. Only their appearance, the memory time, the average function are different. The measure process is also changed, that is the new device will get the measurement results when the device is inflating, while KD -7964 gets the result during the deflating period. The data transfer method of the new device KD-972 is changed to Bluetooth and the data displayed on iPhone, while KD-7964 transfer the data to PC while receive available command.

However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 14 2012

Andon Health Co., Ltd.
c/o Ms. Liu Yi
President
No. 3 Jin Ping Street, Ya An Road, Nankai District
Tianjin
China 300190

Re: K121470
Trade/Device Name: Fully Automatic Wireless Blood Pressure Wrist Monitor, KD-972
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: May 14, 2012
Received: May 17, 2012

Dear Ms. Yi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number : _____

Device name: KD-972 Fully Automatic Wireless Blood Pressure Wrist Monitor

Indications for use:

KD-972 Fully Automatic Wireless Blood Pressure Wrist Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 13.5cm-22cm.

Prescription use _____ AND/OR Over-The-Counter Use YES

Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-COUNTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121470

SEP 20 2012

510(k) Summary

K Number

K121590

General Information

Classification	Unclassified
Trade Name	Sway Balance™
Submitter	Capacity Sports, LLC 624 S. Boston Ave., Suite 700 Tulsa, OK 74119 Tel: (918) 728-1688 Fax: (918) 712 1833
Contact	Pamela M. Buckman, MSN Buckman Company, Inc. 2800 Pleasant Hill Rd., Suite 175 Pleasant Hill, CA 94523 Tel: 925 980 7007 Fax: 925 705 7381

Indications for Use

The Sway™ Balance System is intended for use to assess sway as an indicator of balance. Individual suitability for assessment must be judged on a case by case basis, by a qualified individual including those certified and/or licensed in their state to prescribe and/or use balance devices such as certified athletic trainers and coaches, physical therapists, nurses and physicians. Conditions affecting postural sway include nausea, headache, orthopedic injury, ear infection, medications, head injury, dehydration and fatigue. The Sway™ Balance System can be used wherever an iOS mobile operating device is available.

Predicate Device(s)

Korebalance™ by SPORTKAT, LLC (K070676)

Device Description

The Sway Balance™ System is a mobile measurement system that analyzes balance through thoracic sway, using the built in accelerometer of a mobile device. The Sway Balance™ System is a stand-alone mobile operating system software application that does not include any peripheral hardware add-ons.

K121590

Materials

The Sway Balance™ System is a software only solution that utilizes the hardware of the Apple iOS mobile operating system for products such as the iPhone 3G, 3GS, 4, 4S, iPad, iPad2 and iPod Touch. The built in accelerometer is accessed to analyze motion during a balance test.

Testing

Device testing was conducted to evaluate conformance to product specification. The results showed the system met specification. Product verification consisted of studies comparing the Sway Balance™ System to force platform technology. Bench testing analyzed the sensitivity of the software program to access data from the ST Microelectronics MEMS Accelerometer built into the smartphone compatible with the Sway Balance™ Software. Sensitivity scores using the Sway Balance™ Software were comparable.

Clinical testing included studies comparing the Sway Balance™ System to force platform assessment tools to establish positive correlations between the two devices. Results showed no significant difference between the two data sets ($p = <0.05$). Mean Actual Stability Scores on the balance platform was 1.41 ± 0.90 compared to 1.38 ± 0.72 using the mobile device.

Studies also analyzed performance of balance tasks of varying difficulty to measure the device's effectiveness in determining levels of stability. Data showed that the Sway Balance™ System results were consistent with expected outcomes. Within subject reliability was evaluated under conditions of instantaneous acceleration forces.

Summary of Substantial Equivalence

The Sway Balance™ System is equivalent to the predicate product. The intended use, targeted population and basic premise underlying the balance assessment are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 20 2012

Capacity Sports, LLC
c/o Pamela M. Buckman, MSN
Buckman Company, Inc.
2800 Pleasant Hill Rd., Suite 175
Pleasant Hill, CA 94523

Re: K121590
Trade/Device Name: Sway Balance™
Regulation Name: Vestibular Analysis Apparatus
Regulatory Class: Unclassified
Product Code: LXV
Dated: August 8, 2012
Received: August 10, 2012

Dear Ms. Buckman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

K121590

Intended/Indications for Use

510(k) Number:	K121590
Device Name:	Sway Balance™ System
Indications for Use:	The Sway™ Balance System is intended for use to assess sway as an indicator of balance. Individual suitability for assessment must be judged on a case by case basis, by a qualified individual including those certified and/or licensed in their state to prescribe and/or use balance devices such as certified athletic trainers and coaches, physical therapists, nurses and physicians. Conditions affecting postural sway include nausea, headache, orthopedic injury, ear infection, medications, head injury, dehydration and fatigue. The Sway™ Balance System can be used wherever an iOS mobile operating device is available.

X
Prescription Use (Per 21 CFR 801 Subpart D)

OR

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

K121590
510(k) Number

X
Prescription Use
(Per 21 CFR 801.109)

JUL 2 2012

510(k) Premarket Notification
Reciprocal Labs Corporation Asthmapolis System

510(k) Summary K121609

Submission Date:	March 8, 2012
Submitter:	Reciprocal Labs Corporation 612 W. Main Street, Ste. 201 Madison, WI 53703
Submitter and Official Contact:	Ms. Inger L. Couture Chief Regulatory Officer Reciprocal Labs 612 W. Main Street, Ste. 201 Madison, WI 53703 +1 (608) 251-0470 +1 (608) 338-0883 (fax) Inger.Couture@asthmapolis.com
Manufacturing Site:	Reciprocal Labs Corporation 612 W. Main Street, Ste. 201 Madison, WI 53703
Trade Name:	Asthmapolis System
Common Name:	Nebulizer
Classification Name:	NEBULIZER (DIRECT PATIENT INTERFACE)
Classification Regulation:	21 CFR §868.5630
Product Code:	CAF
Device Description:	Electronic MDI Accessory
Substantially Equivalent Devices:	SmartTrack System K091803

510(k) Premarket Notification
Reciprocal Labs Corporation Asthmapolis System

Intended Use:

The Asthmapolis System includes the Asthmapolis Sensor which is an electronic accessory device intended for single-patient use to assist physicians and patients in recording and monitoring the actuations of prescribed MDI usage.

The Asthmapolis Mobile Application records, stores, and transmits usage events from the Asthmapolis Sensor to a remote storage system.

The Asthmapolis Web Application is software intended to allow users to review the collected information and characteristics of MDI use, to add detail associated with a recorded usage event, and to share that information with their physician in order to provide additional information associated with the condition for which their MDI medication(s) are prescribed.

The Asthmapolis System may also be used in clinical trials where researchers need to know information about use of a MDI Medication(s) by a participant.

The output of the Asthmapolis System is not intended to diagnose or replace a diagnosis provided by a licensed physician. The Asthmapolis system is not intended for use as a MDI medication dose counter, nor is it intended to indicate the quantity of medication remaining in an MDI.

Technology Comparison:

Technological characteristics of the Asthmapolis System and the SmartTrack System are largely equivalent. Similarities include the indications for use, basic principle of operation, data collection information, time of data recording via internal clock, utilization of software for varying types of data review and modification, dose counting characteristics and internal power source type.

The Asthmapolis System employs these technological characteristics in a similar way as the predicate device. Differences include the method used to detect sensor actuation, and the method used to send the usage data from the sensor to the database. These aspects of the device have been verified and validated in order to establish equivalent performance to the equivalent device. This information indicates that the Asthmapolis System is equivalent to the predicate device in terms of device safety and effectiveness.

Based upon this comparison of the predicate, and the accompanying testing results for the Asthmapolis System, the Asthmapolis System is substantially equivalent to the predicate device.

510(k) Premarket Notification
Reciprocal Labs Corporation Asthmapolis System

Performance Testing Summary:

Non-clinical testing has been carried out to cover functional verification and device performance. This included completion of software verification and validation procedures, with performance testing of the MDI actuation sensor system to ensure data is logged accurately for MDI usage. This established correct functionality of the Asthmapolis System according to the requirements.

Third party testing of the Asthmapolis System for compliance to IEC 60601 series standards for general safety and electromagnetic compatibility and ISO 10993 series standards for biocompatibility was completed by accredited laboratories prior to this submission. Cleaning instructions were validated by an accredited lab and testing in the applicable environments for wireless interference were completed. Complete, detailed reports are included in the application for clearance; summary information is included below where differences between the two devices use non-clinical test data to support equal safety and efficacy.

Software:

Software and Firmware for the Asthmapolis System was designed and developed according to a robust software development process aligned with "*Design Control Guidance for Medical Device Manufacturers*", "*The Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*", "*Guidance for Off the Shelf Software Use in Medical Devices*", and verified and validated using guidance from the "*General Principles of Software Validation*" as recommended by FDA.

Test results indicate that the Asthmapolis System complies with its predetermined specifications.

Electrical Safety:

The Asthmapolis Sensor has successfully completed patient safety testing according to IEC 60601-1.

Electromagnetic Compatibility Testing:

The Asthmapolis Sensor has successfully completed EMC testing according to IEC 60601-1-2.

Performance Testing – Bench:

The Asthmapolis System has successfully completed performance testing according to applicable standards and internal testing. Important to highlight in this summary, is the successful performance testing that was completed for wireless/Bluetooth technology in accordance with specifications and also with, "*FDA's Guidance on Radio-Frequency Wireless Technology in Medical Devices*". In addition, tests required for FCC licensing were successful.

Conclusion:

Hardware testing carried out for the Asthmapolis System indicates it meets design and performance functional requirements. Software verification demonstrates that device features are effective, and that the system configuration functions equivalently to the predicate device. The Asthmapolis System also meets standard requirements for electrical safety, electromagnetic compatibility, biocompatibility, cleaning validation, and wireless technology in medical devices.

This information indicates that the Asthmapolis System is equivalent to the predicate device in terms of device safety and effectiveness.

Based upon this comparison of the predicate, and the accompanying testing results for the Asthmapolis System, the Asthmapolis System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Reciprocal Laboratories Corporation
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, Minnesota 55313

JUL 2 2012

Re: K121609
Trade/Device Name: Asthmapolis System
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: June 18, 2012
Received: June 19, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121609

Device Name: Asthmapolis System

Indications for use:

The Asthmapolis System includes the Asthmapolis Sensor which is an electronic accessory device intended for single-patient use to assist physicians and patients in recording and monitoring the actuations of prescribed MDI usage.

The Asthmapolis Mobile Application records, stores, and transmits usage events from the Asthmapolis Sensor to a remote storage system.

The Asthmapolis Web Application is software intended to allow users to review the collected information and characteristics of MDI use, to add detail associated with a recorded usage event, and to share that information with their physician in order to provide additional information associated with the condition for which their MDI medication(s) are prescribed.

The Asthmapolis System may also be used in clinical trials where researchers need to know information about use of a MDI Medication(s) by a participant.

The output of the Asthmapolis System is not intended to diagnose or replace a diagnosis provided by a licensed physician. The Asthmapolis system is not intended for use as a MDI medication dose counter, nor is it intended to indicate the quantity of medication remaining in an MDI.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121609

510(k) SUMMARY

JUN 2 5 2013

I. GENERAL INFORMATION

A. Submission Applicant and Correspondent:

Name:	EPI Mobile Health Solutions (S) Pte Ltd
Address:	302 Orchard Road, # 18-01 Tong Building, Singapore 238862
U.S. Contact:	Karl M. Nobert, Esq. Squire Sanders LLP 1200 19th Street, NW, Suite 300 Washington, DC 20032 Telephone: 202-626-6630 Fax: 202-626-6780 Email: karl.nobert@squiresanders.com

B. Name of Device:

Trade Name:	EPI Mini ECG Portable Health Monitoring System ("EPI Mini")
Common Name:	ECG Event Recorder (Cardiac Rhythm Monitor)

C. Regulatory Information:

Classification:	Cardiovascular Monitoring Device (21 CFR § 870.2340) Transmitters and Receivers Electrocardiograph, Telephone (21 CFR § 870.2920)
Product Codes:	DPS, DXH, DSH
Class:	Class II

D. Predicate Devices:

Device Trade Name	510(k) No.	Classification Name	Product Code
REKA E100 ECG Event Recorder (Cardiac Rhythm Monitor)	K111438	Cardiovascular Monitoring Device	DPS
Signalife Fidelity 200 Cardiac Event Recorder	K071228	Transmitter and Receivers Electrocardiograph, Telephone	DXH, DSH

II. DEVICE DESCRIPTION:

The EPI Mini ECG Portable Health Monitoring System ("EPI Mini") is a portable recording device which is designed to be used in combination with an individual's smartphone to create a portable health monitoring system. Not only does the EPI Mini record and store a user's physiological data but when paired with smartphone technology is capable of wirelessly transmitting such data to a remote server for review, monitoring and interpretation by a learned intermediary, and subsequent forwarding to the user's physician when necessary.

The device can function as an Rx product when prescribed by and used under the supervision of a physician for the purpose of monitoring a patient's ECG data. It is not a diagnostic device.

The EPI Mini is a portable single-channel device composed of 3 metallic electrode sensors strategically located on 3 sides of the device. The EPI Mini measures electrical differences between two points when in direct contact with the user's skin surface and is capable of recording new Electrocardiograms or ECGs every 30 seconds.

Holding the sides of the device (the metallic sensors) with their left and right hands, the user presses the "Enter" button to begin ECG recording. It takes approximately 30-45 seconds to measure an ECG.

A recorded ECG can then be sent to the user's smartphone (i.e., a mobile or cellular telephone) using patented bluetooth technology that relies on a proprietary EPI mHealth Application or "EPI mHealth App" which can be downloaded from the user's respective App store. The App allows a user to wirelessly transmit the ECG data to a remote server for monitoring by a learned intermediary, processing, storage and when necessary, forwarding on to the user's physician for

review and evaluation. From the remote server and monitoring center, the data can be delivered to a physician by mobile phone, fax, email or internet. The mHealth App also allows storage of ECGs on the user's smart phone.

The mHealth App also allows for the personal storage of a user's own physiological data such as blood pressure, blood glucose levels and cholesterol. Such stored data can be updated and retrieved for later use and also displayed in a line graph format for trend analysis. Additionally, the mHealth App permits a user to view, resend and/or delete saved data as needed.

The EPI Mini is composed of several individual components including (1) the EPI Mini portable ECG recorder, (2) a USB data cable, (3) the mHealth application which can be purchased and downloaded from the user's respective application store, and (4) a 500mAh battery.

III. INDICATIONS FOR USE

The EPI Mini Portable ECG Recorder ("EPI Mini") is intended for use with a patient's smartphone to record, store and wirelessly transmit physiological data to a remote server. It is indicated for individuals who are at risk for cardiac disease, experience transient symptoms suggesting possible cardiac arrhythmia or have existing heart conditions.

The device can function as an Rx product when prescribed by and used under the supervision of a physician for the purpose of monitoring a patient's ECG data. It is not a diagnostic device.

The EPI Mini is intended for use by adults who suffer from cardio-vascular disease, are considered high risk for possible cardiovascular events or are concerned about their heart function and rhythm.

IV. SUMMARY OF TECHNICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES

The EPI Mini is substantially equivalent to the FDA-cleared REKA E100 ECG Event Recorder (Cardiac Rhythm Monitor) (K111438) ("REKA E100") and the Signalife Fidelity 200 Cardiac Event Recorder (K071228) ("Signalife").

All three of the devices are intended to record, store, transmit and receive physiological data via the user's own smartphone. They allow a user to display, send and delete his or her own personal recorded physiological data. The device is designed to measure and record personal health data, including but not limited to, a user's own ECGs.

The EPI Mini and the cited predicate devices are all intended for use by individuals at risk for cardiac disease and those who experience transient symptoms suggesting possible cardiac arrhythmia. They are also indicated for individuals who require monitoring for the detection of non-lethal cardiac arrhythmias.

Similar to the REKA E100, the EPI Mini is a 1 lead ECG event recorder that is capable of recording an ECG every 30 seconds. Both devices are capable of transferring data to a computer or mobile phone. The EPI Mini, like the REKA E100, also comes with its own mobile application software allowing the device to communicate with a user's smartphone. Finally, neither device is designed to diagnose, or signal or trigger an alarm.

As for the identified Signalife predicate device, the EPI Mini is similar in that it is also a battery operated ECG event recorder that can record an ECG in less than one minute. Following recording, both devices allow for ECGs to be transtelephonically transmitted to a cardiac monitoring station for analysis and diagnosis by a learned intermediary. Both devices are capable of storing a user's recorded ECGs for later review.

The minor design differences amongst the three devices do not affect the substantial equivalence of the devices to one another. A Substantial Equivalence Comparison Table is attached for a side-by-side comparison of the EPI Mini and the three cited predicated devices.

V. SUMMARY OF PERFORMANCE TESTING

The EPI Mini has undergone extensive verification and validation testing to confirm that it operates as intended and is safe for use. Testing has included various performance tests and software validation tests to ensure that the device satisfies all applicable functional and performance requirements. Among others, the performed testing included:

- Bench Testing to assess data integrity during the transmission of ECG data from the EPI Mini to representative smartphone technology.

- Hazard Analysis Testing in accordance with the methods suggested in EN ISO 13485 (as an alternative to EN ISO 14971).

Among others, the EPI Mini was also tested against the following performance standards:

- IEC 60601-1

- IEC 60601-2-25

- IEC 62133

- EC 13s

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 25, 2013

EPI Mobile Health Solutions (S) Pte Ltd
c/o Mr. Karl M. Nobert
Squire Sanders (US) LLP
1200 19th Street, NW, Suite 300
Washington, DC 20032

Re: K121628
EPI Mini ECG Portable Health Monitoring System
Regulatory Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: II (two)
Product Code: 74 DXH, DPS, DSH
Dated: June 3, 2013
Received: June 5, 2013

Dear Mr. Nobert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section V

Statement of Indications for Use

510(k) Number (if known): **K121628**

Device Name: EPI Mini ECG Portable Health Monitoring System ("EPI Mini")

Indications for Use:

The EPI Mini Portable ECG Recorder ("EPI Mini") is intended for use with a patient's smartphone to record, store and wirelessly transmit physiological data to a remote server. It is indicated for individuals who are at risk for cardiac disease, experience transient symptoms suggesting possible cardiac arrhythmia or have existing heart conditions.

The device can function as an Rx product when prescribed by and used under the supervision of a physician for the purpose of monitoring a patient's ECG data. It is not a diagnostic device.

The EPI Mini is intended for use by adults who suffer from cardio-vascular disease, are considered high risk for possible cardiovascular events or are concerned about their heart function and rhythm.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _X_ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Bram D. Zuckerman -S
2013.06.25 12:26:13 -04'00'

OCT 15 2012

510(k) Summary K121697

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1.0 submitter's information

Name: Andon Health Co., Ltd.
Address: No 3, Jinping Street Ya An Road, Nankai District, Tianjin, P.R. China
Phone number: 86-22-6052 6161
Fax number: 86-22-6052 6162
Contact: Liu Yi
Date of Application: 05/25/2012

2.0 Device name

Device name: APO-8284 Fingertip Pulse Oximeter

3.0 Classification

Production code: DQA - Oximeter
Regulation number: 870.2700
Classification: II
Panel: Cardiovascular

4.0 Predicate device information

Manufacturer: Beijing Choice Electronic Technology Co., Ltd.

Device: MD300C1 Fingertip Pulse Oximeter

510(k) number: K093757

5.0 Intended use

The APO-8284 Fingertip Pulse Oximeter is a non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The portable fingertip device is indicated for adult patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care, etc). The APO-8284 Fingertip Pulse oximeter is not intended for continuous monitoring.

6.0 Device description

Our device APO-8284 Fingertip Pulse Oximeter is a fingertip device, which can measure the arterial SpO2 and pulse rate value and can display the results to the user.

It is a noninvasive measurement instrument with a pair of small light-emitting diodes (LEDs) facing a photodiode through a fingertip. One LED is red, with wavelength of 660 nm, and the other is infrared, 880 nm. The MCU calculates the ratio of these two wavelengths and get the results of the SPO2. At the same time, by examining only the varying part of the absorption spectrum, a monitor can ignore other tissues or nail, and discern only the absorption caused by arterial blood to detect the pulse rate.

More over, the APO-8284 also has the function of low battery voltage alarm and automatically power off. The power source is 2×AAA batteries.

The device is for prescription. It is neither for life-supporting nor for implanting. It does not contain any drug or biological product and it does not need to be sterile.

The intended use and the indication for use of APO-8284 Fingertip Pulse Oximeter, as described in the labeling are the same as their predicated device MD300C1 Fingertip Pulse Oximeter (K093757)

7.0 Summary comparing technological characteristics with predicate device

Technological Characteristics	Comparison result
Design principle	Identical
Appearance	Similar
Patients contact Materials	Identical
Performance	Similar
Biocompatibility	Identical
Mechanical safety	Identical
Energy source	Identical
Standards met	Identical
Electrical safety	Identical
EMC	Identical
Function	Similar

8.0 Performance summary

APO-8284 Fingertip Pulse Oximeter conforms to the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
- EN 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests, 2007.
- ISO 9919:2005: Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
- ISO 10993: Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process.
- ISO 10993: Biological evaluation of medical devices Part 5: Test for in vitro cytotoxicity.
- ISO 10993: Biological evaluation of medical devices Part 10: Test for irritation and skin sensitization.

9.0 Comparison to the predicate device and the conclusion

The applicant device APO-8284 Fingertip Pulse Oximeter is substantially equivalent to MD300C1 Fingertip Pulse Oximeter whose 510(k) number is K093757.

Similarities and differences comparision		
Characteristics	**Subject device APO-8284**	**Predicate device (K093757)**
Intended use	blood oxygen aturation (SpO2), and pulse rate(bpm) measurement	blood oxygen aturation(SpO2), and pulse rate(bpm) measurement
Design priciple		
Presentation or OTC	Presentation	Presentation
Contact material	Silica gel	Silica gel
SpO2 measuring range	70%-99%	70%--99%
SpO2 Accuracy	±2%	80-99%: ±2% 70-79%: ±3%
Pulse Rate Measuring Range	30-250bpm	30-235bpm
Pulse Rate Accuracy	± 2 bpm during the pulse rate range of 30-99 bpm and 2% during the pulse rate range of 100-235 bpm	± 2 bpm during the pulse rate range of 30-99 bpm and 2% during the pulse rate range of 100-235 bpm
Operation Temperature	5℃-40℃	5℃-40℃
Power Source	2*AAA batteries	2*AAA or rechargeable batteries
Operation Humidity	<80%	15%~80%
Other function	low battery voltage alarm: automatically power off	low battery voltage alarm: automatically power off

As a result, APO-8284 is very similar with its predicate device in the intended use, the design principle, the material, the performance and the applicable standards. Only their appearance, the power source, the pulse rate range and the operation humidity range are a little bit different. However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness to the new devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 15 2012

Andon Health Company, Limited
Mr. Liu Yi
President
Number 3, Jin Ping Street, Ya An Road
Nankai District
Tianjin, China 300190

Re: K121697
Trade/Device Name: APO-8284 Fingertip Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: September 13, 2012
Received: September 13, 2012

Dear Mr. Yi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number : K121697

Device name: APO-8284 Fingertip Pulse Oximeter

Indications for use:

The APO-8284 Fingertip Pulse Oximeter is a non-invasive device intended for spot-checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The portable fingertip device is indicated for adult patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care, etc). The APO-8284 Fingertip Pulse oximeter is not intended for continuous monitoring.

Prescription use ___√___ AND/OR Over-The-Counter Use _____
Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-COUNTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121697

FEB 2 2 2013

5. 510(k) Summary (Revised from Original)

Date prepared: May 24, 2012

K Number K121738

Submitter: Vital Art and Science Incorporated
2725 N. Spring Drive
Richardson, TX 75082-4233

Contact Person: Mike Bartlett
President, Vital Art and Science Incorporated
Phone: 214-929-2931
Fax: 972-238-0420
E-Mail: mike.bartlett@myvisiontrack.com

Name of the Device and Classification

Type of 510(k) Submission:	Traditional
Trade Name:	myVisionTrack™ Model 0003
Common Name:	Home vision function monitor
Reason for Premarket Notification:	New Device
Regulation Number:	21 CFR 886.1605
Regulation Name:	Perimeter, Automatic, AC-Powered
Regulatory Class:	Class I
Product Code:	HPT

Predicate Devices:

The Vital Art and Science Incorporated myVisionTrack™ Model 0003 (mVT™) is substantially equivalent to the following combination of predicate medical devices:

- ForeseeHome supplied by Notal Vision; Perimeter, Automatic, AC-Powered, 21 CFR 886.1605; K091579; Product Code: HPT
- PreView PHP™ supplied by Notal Vision; Perimeter, Automatic, AC-Powered, 21 CFR Part 886.1605; K05350; Product Code: HPT
- Amsler Grid, a Class I Exempt Preamendments Medical Device (21 CFR 886.1330); Product Code: HOQ

K121738

Brief Device Description:

The myVisionTrack™ is a vision function test provided on a commercially available cell phone. The myVisionTrack™ implements a shape discrimination hyperacuity (SDH) vision test which allows patients to perform their own vision test at home. This enables regular monitoring of disease progression, and for timely detection of significant changes in vision function. If a significant worsening of vision function is detected the physician will be notified and provided access to the vision self-test results so that they can decide whether the patient needs to be seen sooner than their next already scheduled appointment.

Indications for Use:

The myVisionTrack™ is intended for the detection and characterization of central 3 degrees metamorphopsia (visual distortion) in patients with maculopathy, including age-related macular degeneration and diabetic retinopathy, and as an aid in monitoring progression of disease factors causing metamorphopsia. It is intended to be used by patients who have the capability to regularly perform a simple self-test at home. The myVisionTrack™ is not intended to diagnose; diagnosis is the responsibility of the prescribing eye-care professional.

Indications for Use as compared to the Predicate Device:

myVisionTrack™ and the three predicate devices provide a method for a user to self-test their own vision function. All are used to detect significant changes in vision, which indicate disease progression.

The Amsler Grid, in various paper chart forms, is the most commonly prescribed method for home vision monitoring today. Studies have shown that most patients cannot use it effectively for a number of reasons, including the requirement for the user to remember previous results and to determine for themselves if a significant change has occurred.

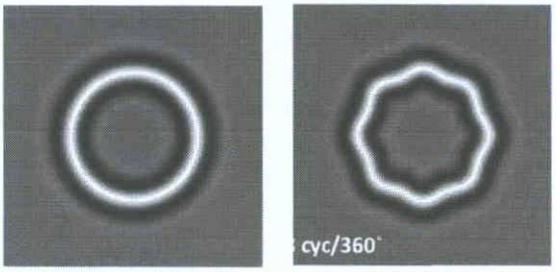
myVisionTrack™ and the two devices from Notal Vision are automated devices which present visual test stimuli, collect user responses and compare current results to previous test results to determine if a significant change in vision function has occurred.

All three devices use a "hyperacuity" algorithm that tests the user's ability to detect differences in multiple stimuli. myVisionTrack™ uses a test algorithm that does not require the user to fixate on a single point during the test. Therefore, it is not limited to users who have a stable fixation, which is a requirement of the Notal Vision devices.

The ForeseeHome and PreView PHP™ test the central and paracentral area of the retina whereas myVisionTrack™ tests only the central 3 degrees of the retina which is a smaller area. The predicate devices are intended for users diagnosed with age-related macular degeneration (AMD) whereas myVisionTrack™ is intended for users diagnosed with maculopathy, of which AMD and diabetic retinopathy (DR) are the primary diseases.

Principles of Operation:

The test images used by myVisionTrack™ are shown in Figure 5.1 where (a) is an undistorted image and (b) is a distorted image. The distorted version is created by modulating the radius of the circle with a sinusoid.



(a) unmodulated (b) modulated

Fig. 5.1. Patterns in the shape discrimination

In the test the user is shown three circles and asked to identify the distorted circle, as shown in Figure 5.2. The test begins with a large amplitude of distortion and moves quickly through a series of test images where the distortion amplitude is reduced in order to determine the lowest detectable level of distortion.

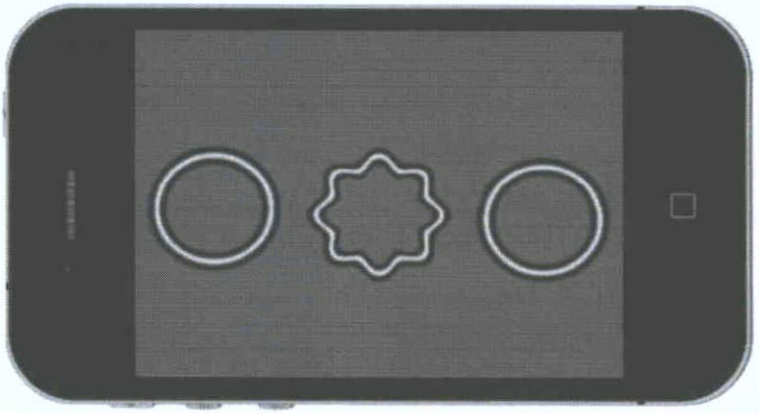


Figure 5.2

Clinical Testing Summary

Numerous published studies have shown that patients with AMD and other forms of maculopathy have significantly poorer results as compared to normal subjects on the shape discrimination test. VAS has performed our own 6-month Clinical Study on the specific shape discrimination hyperacuity test used in myVisionTrack™. This study of diabetic retinopathy (DR) patients did show a significant difference between those patients with mild-to-moderate non-proliferative DR (NPDR) and those with very severe NPDR or proliferative DR (PDR), whereas traditional clinic-based visual acuity and contrast sensitivity tests were not able to detect a significant difference. In this study, where patients were asked to test at least once per week for 6 months, there was an average weekly compliance rate of 84%, and the average number of times the patients performed the test was 1.7. This study verified that patients could and would effectively self-monitor their own vision function at home using myVisionTrack™.

In this 6-month longitudinal study, we collected data on 36 individuals taking weekly measurements for a total of 2338 measurements. Individuals in this study had no significant change of disease condition over the 6-month period based on clinical judgment. Using the 6-month longitudinal study, we found 36 examples where a physician would have been notified according to the 0.2 logMAR notification rule.

Substantial Equivalence Comparison

The substantial equivalence of the myVisionTrack™ to the predicate devices is summarized in Table 5.1 below. Each of these devices provide a vision self-test for the patient.

Item	Function Specification	Amsler Grid Class I Exempt Preamendments Device	Notal Vision, Inc. PreView PHP™ k050350	Notal Vision, Inc. ForeseeHome k091579	VAS myVisionTrack™ Model 0003 (Proposed)
1	Product Code	HOQ	HPT	HPT	HPT
2	Regulation Number	21 CFR 886.1330	21 CFR 886.1605	21 CFR 886.1605	21 CFR 886.1605
3	Indications for Use	Intended to rapidly detect central and paracentral irregularities in the visual field.	The PreView PHP™ is intended for use in the detection and monitoring the progression of Age-related Macular Degeneration (AMD) including, but not limited to, the detection of choroidal neovascularization (CNV).	The ForeseeHome is intended for use in the detection and characterization of central and paracentral metamorphopsia (visual distortion) in patients with age-related macular degeneration as an aid in monitoring progression of disease factors causing metamorphopsia including, but not limited to choroidal neovascularization (CNV). It is intended to be used at home for patients with stable fixation. The ForeseeHome is not intended to diagnose; diagnosis is the responsibility of the prescribing eye-care professional.	The myVisionTrack™ is intended for the detection and characterization of central 3 degrees metamorphopsia (visual distortion) in patients with maculopathy, including age-related macular degeneration and diabetic retinopathy, and as an aid in monitoring progression of disease factors causing metamorphopsia. It is intended to be used by patients who have the capability to regularly perform a simple self-test at home. The myVisionTrack™ is not intended to diagnose; diagnosis is the responsibility of the prescribing eye-care professional.

K121738

Item	Function Specification	Amsler Grid Class I Exempt Preamendments Device	Notal Vision, Inc. PreView PHP™ k050350	Notal Vision, Inc. ForeseeHome k091579	VAS myVisionTrack™ Model 0003 (Proposed)
4	Target Population	Patients at high risk or already diagnosed with Maculopathy	Patients already diagnosed with age-related macular degeneration	Patients already diagnosed with age-related macular degeneration	Patients already diagnosed with Maculopathy, including age-related macular degeneration and diabetic retinopathy
5	Prescription or OTC	OTC	Prescribed by healthcare professional.	Prescribed by healthcare professional.	Prescribed by healthcare professional.
6	How/Where used	Home use for self-testing by the patient.	Healthcare Clinic	Home use for self-testing by the patient.	Home use for self-testing by the patient.
7	Hardware Platform	Paper chart.	Software Application to be run on a customer supplied off-the-shelf PC.	Dedicated unit with processor, display, mouse and software.	Software Application delivered by the supplier on an off-the-shelf cell phone.
8	Vision Test algorithm used	Patient is instructed to identify and record blur, distorted or missing areas on the chart.	Preferential Hyperacuity Test	Preferential Hyperacuity Test	Shape Discrimination Hyperacuity Test with an adaptive staircase algorithm
9	Fixation Point for the patient during testing?	Yes	Yes	Yes	No. The test employs a visual task involving global visual integration. No fixation is required to perform the test.
10	Data upload capability?	No	Not specified	Yes, through a home phone line.	Yes, through the cell phone connection.

K121738

Standards to which Vital Art and Science Incorporated claims conformance for the myVisionTrack™ Model 0003

1) ISO 13485:2003 / EN ISO 13485:2003 / AC:2009 "Medical devices - Quality management systems - Requirements for regulatory purposes"
2) AAMI / ANSI / ISO 14971:2007/(R)2010, "Medical devices – Application of risk management to medical devices"
3) IEC 60234:2006 Ed. 1.0, "Medical device software – Software life cycle processes"
4) IEC 60601-1:2005 + A1:2012, 'Medical electrical equipment Part 1: General requirements for basic safety and essential performance"
5) IEC 60601-1-2:2007, "Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard Electromagnetic compatibility – Requirements and tests"
6) IEC 60601-1-11:2010, "Medical Electrical Equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment"

Conclusion

In conclusion, the proposed myVisionTrack™ as compared to the already cleared predicate devices has:

- Similar indications for use;
- Similar physical composition, in that all use visual testing software delivered on a validated hardware platform and operating system;
- Similar, but with a vision test algorithm that does not require a patient to focus on a single point constantly during testing;
- A similar method of operation for the patient to perform self-testing at home; and
- Similar central monitoring of patient self-test results, but with a mobile device upload method that does not require the patient to have a home phone or to perform any setup.

Based on our non-clinical and clinical testing of the myVisionTrack™ Model 0003 we have concluded that the myVisionTrack™ Model 0003 is as safe, as effective and performs at least as safely and effectively as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 22, 2013

Vital Art and Science Incorporated
% Mr. Mike Bartlett
President
2725 N. Spring Drive
Richardson, TX 75082

Re: K121738
Trade/Device Name: myVisionTrack ™ Model 0003
Regulation Number: 21 CFR 886.1605
Regulation Name: Perimeter
Regulatory Class: Class I
Product Code: HPT
Dated: January 15, 2013
Received: January 17, 2013

Dear Mr. Bartlett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

Deborah L. Falls

for Malvina B. Eydelman, M.D.
Director
Division of Opthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K121738

Device Name: myVisionTrack™ Model 0003

Indications for Use:

The myVisionTrack™ is intended for the detection and characterization of central 3 degrees metamorphopsia (visual distortion) in patients with maculopathy, including age-related macular degeneration and diabetic retinopathy, and as an aid in monitoring progression of disease factors causing metamorphopsia. It is intended to be used by patients who have the capability to regularly perform a simple self-test at home. The myVisionTrack™ is not intended to diagnose; diagnosis is the responsibility of the prescribing eye-care professional.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Charles Chiang
2013.02.22 16:04:51 -05'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K121738

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 3 2012

AirStrip Technologies, LP
c/o Mr. Mark Job
Reviewer
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 53313

Re: K121871
AirStrip Remote Patient Monitoring (RPM) Remote Data Viewing software
Regulatory Number: 21 CFR 870.2300
Regulation Name: Patient Physiological Monitor (without arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: June 26, 2012
Received: June 27, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121871

Indications for Use
510(k) Number (if known):

Device Name: AirStrip Remote Patient Monitoring (RPM) Remote Data Viewing software

Indications for Use:
AirStrip RPM is software capable of displaying physiologic and other patient information. This information is generated by other medical devices and patient information system, and not by AirStrip RPM. AirStrip RPM captures this information from these other systems and displays it for clinicians.

AirStrip RPM is intended to be used by clinicians for the following purposes:
- By using a cellular telephone or other device on which AirStrip RPM is installed, to review physiologic data of a patient when the clinician is not at the hospital
- To view the near real-time waveforms remotely
- To remotely review other standard or critical near real-time patient data from the monitored system
- To provide a request for remote consultation regarding a patient's waveform or other data

The AirStrip RPM software can display the following the physiologic data captured by other medical devices:
- Heart Rate Monitored
- Respiratory Rate
- Oxygen Saturation
- Intracranial Pressure
- Central Venous Pressure
- Pulmonary Capillary Wedge Pressure
- Cardiac Index
- Cardiac Output
- Cerebral Perfusion Pressure
- Urine Output
- Urine/Stool Mix Output
- Systolic Blood Pressure Invasive
- Mean Arterial Pressure Invasive
- Diastolic Blood Pressure Invasive
- Systolic Blood Pressure Cuff
- Mean Arterial Pressure Cuff
- Diastolic Blood Pressure Cuff
- Vasoactive Infusions
- Antiarrhythmics
- Sedation
- Paralytics
- Laboratory Data including
  - Blood Gas
  - Chemistry
  - Hematology
  - Coagulation
- Allergies
- Medications

Contraindications
AirStrip RPM software is intended for installation on cellular telephones and other wireless devices, and is not intended for use anywhere cellular telephones or wireless devices are prohibited. AirStrip RPM is intended for use by clinicians when they cannot be at the hospital. AirStrip RPM is intended for use by clinicians as a diagnostic aid, and not as a replacement for direct viewing of any of the monitoring devices from which it obtains its data.

Prescription Use X
(Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121871

K121916

TERARECON

APR 0 2 2013

Date of Summary: 1st April, 2013

510(k) Summary of Safety and Effectiveness (As required by 21 CFR 807.92(c))	**iNtuition**

Submitter/: Applicant/ Sponsor TeraRecon Inc.
4000 E 3rd Ave, Suite 200
Foster City, CA 94404

Establishment Registration #: 2954793

Contact Person: Robert Taylor
President/ CEO
Ph: 415-577-9036
Fax: 415-680-1573
Email: taylor@terarecon.com

Device Information:

Name of Device:	iNtuition
Model No:	4.4
Common Name:	Medical Imaging System
Classification Name:	§ 892.2050, Picture Archiving and Communication System. ProCode: LLZ
Classification Panel:	Radiology
Device Classification:	Class II device

Substantial Equivalence:

iNtuition, as addressed in this premarket notification, is substantially equivalent to the following commercially available devices:

Aquarius Workstation (K011142),
AquariusNET Server (K012086)
AquariusAPS Server (K061214)
VitreaView (K122136),
IQQA-Liver Software (K061696)

Indications for Use:

To receive, store, transmit, post-process, display and allow manipulation of reports and medical images from acquisition devices, including optical or other non-DICOM format images, DICOM images with modality type XA, US, CR, DR, SPECT, NM and MG, and images from volumetric medical scanning devices such as EBT, CT, PET or MRI. To provide

access to images derived data and derived images via client-server software, web browser and mobile technology.

Visualization in 2D, 3D and 4D are supported for single or multiple datasets, or combinations thereof. Tools are provided to define and edit paths through structures such as centerlines, which may be used to analyze cross-sections of structures, or to provide flythrough visualizations rendered along such a centerline. Segmentation of regions of interest and quantitative analysis tools are provided, for images of vasculature, pathology and morphology, including distance, angle, volume, histogram, ratios thereof, and tracking of quantities over time. A database is provided to track and compare results using published comparison techniques such as RECIST and WHO. Calcium scoring for quantification of atherosclerotic plaque is supported.

Support is provided for digital image processing to derive metadata or new images from input image sets, for internal use or for forwarding to other devices using the DICOM protocol. Image processing tools are provided to extract metadata to derive parametric images from combinations of multiple input images, such as temporal phases, or images co-located in space but acquired with different imaging parameters, such as different MR pulse sequences, or different CT image parameters (e.g. dual energy).

iNtuition is designed for use by healthcare professionals and is intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions.

Interpretation of mammographic images or digitized film screen images is supported only when the software is used without compression and with an FDA-Approved monitor that offers at least 5Mpixel resolution and meets other technical specifications reviewed and accepted by the FDA.

iNtuitionMOBILE provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. Not intended for diagnostic use when used via a web browser or mobile device.

Device Description:

iNtuition is a software device generally used with off-the-shelf hardware, offered in various configurations, with the simplest configuration being a stand-alone workstation capable of image review, communications, archiving, database maintenance, remote review, reporting and basic 3D capabilities described elsewhere in this document. The system can also be configured as a server with some, all, or none of its optional features disabled. Whether provided as a workstation or a server, the iNtuition software is designed to provide access by a local user physically sitting at the computer hosting the iNtuition server software, and/or by

one or more remote users who concurrently connect to the server using a freely-downloadable thin client application (with conference capabilities). iNtuition supports the physician in medical image viewing.

A fully-configured iNtuition system is capable of various image processing and visualization functions, including full-color Volume Rendering, Calcium Scoring, Segmentation Analysis and Tracking (SAT), Vessel Analysis, Flythrough, Multi-phase review, CT/ CTA Subtraction, Lobular Decomposition (LD), iGENTLE, Maxillo-Facial, Volumetric Histogram, Findings Workflow, Fusion CT/ MR/ PET/ SPECT, MultiKV etc. Each of these features may be offered as an independent upgrade option to the basic configuration.

The intended use of the device is to provide solutions to various medical image analysis and viewing problems, which come about as modalities generate more and more images. It also supports image distribution over networks, and is DICOM compliant.

For example, modern CT scanners produce up to several hundred slices per second, which cannot easily be scrutinized one by one. Although the iNtuition software offers this one-by-one viewing capability, it also is capable, when appropriate, of combining many slices to generate a volume-rendered view of the data. Modern MRI, PET and other scanners or imaging devices pose the same problem to the medical imaging professional.

Volume rendering, i.e. the computation of a three-dimensional object and its visualization in semi-transparent style on a screen, also includes segmentation of the volume into multiple irregular volumes of interest, which enhances recognition and analysis of otherwise hidden or overlapping features.

Another use is taking advantage of the 3D/2D-display option, in which the 3D view can be used to identify a location of interest which is then cross-referenced to the two-dimensional cross-section view(s).

Statistical analysis such as a histogram representation of the image density values in an image is supported. Advanced navigation tools for centerline-extracted flight paths and flythrough of any air or dye contrasted structure including, for example, the colon, vessels, or pulmonary airways are supported. When appropriate, the system can generate a sequence of 3D images, adding a 4th dimension of time, and hence providing a 4D analysis capability. Image analysis support for endovascular procedures such as analysis of images of thrombus, calcifications, and endoleaks can be carried out using the iNtuition tools. To study changes in user identified lesion volume and to track growth or shrinkage over time; for example, to analyze and track the progression/regression of tumors identified by the physician, the Segmentation, Analysis and Tracking (SAT) tool is provided. Calcium Scoring based upon established algorithms is possible, for the non-invasive detection and quantification of atherosclerotic plaque. Finally, iNtuition offers convenient tools to support creation of a report, transmitting and storing this

report in digital form, and tracking historical information about the studies analyzed with the software.

The software also facilitates executing any of the above functions on a remote viewer on defined and appropriately secured networks.

Technological Characteristics:
iNtuition will be marketed as a software only solution for the end-user (with recommended hardware requirements) or as a complete workstation for the end user (software package with hardware kit).

Summary of Non-Clinical Performance Tests:
There are no applicable FDA mandated performance standards for this device. However, voluntary standards such as DICOM, various in-house standard operating procedures are in place and utilized in the production of the software.
In all material aspects, iNtuition is substantially equivalent to the predicate devices. Performance testing was carried out according to internal company procedures. Software testing and validation were done according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to formalize after ensuring that the software fully satisfies all expected and previously defined system requirements and features. Test results support the conclusion that actual device performance satisfies the design intent and is equivalent to its predicate devices.

Summary of Clinical Performance Tests:
The subject of this traditional 510k notification, iNtuition, did not require clinical studies to show safety and effectiveness of the software.

General Safety and Effectiveness Concerns:
The introduction of iNtuition has no significant concerns of safety and efficacy. iNtuition in comparison with its predicate devices is a collectively enhanced solution which has the same intended use and technological characteristics.

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Risk management is ensured via risk analysis, which is used to identify and mitigate potential hazards beginning early in the design cycle and continuing throughout the development of the product. These potential hazards are controlled via software development, verification and

validation testing. Furthermore, the operators are healthcare professionals familiar with and responsible for making all final patient management decisions.

Conclusion:

iNtuition as described in this premarket notification has the same intended use and similar technical characteristics to the predicate devices listed above. These devices are substantially equivalent in terms of basic design, features and intended use.

In summary, TeraRecon, Inc. is of the opinion that iNtuition is a collectively enhanced solution which does not include any new potential safety or effectiveness risks and is substantially equivalent to and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 2, 2013

Robert Taylor
President
TeraRecon
4000 East 3rd Avenue, Suite 200
FOSTER CITY CA 94404

Re: K121916
Trade/Device Name: iNtuition
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 1, 2013
Received: April 1, 2013

Dear Dr. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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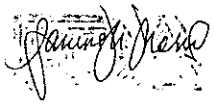
Sincerely yours,



Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121916

Device Name: iNtuition

Indications for Use:

To receive, store, transmit, post-process, display and allow manipulation of reports and medical images from acquisition devices, including optical or other non-DICOM format images, DICOM images with modality type XA, US, CR, DR, SPECT, NM and MG, and images from volumetric medical scanning devices such as EBT, CT, PET or MRI. To provide access to images derived data and derived images via client-server software, web browser and mobile technology.

Visualization in 2D, 3D and 4D are supported for single or multiple datasets, or combinations thereof. Tools are provided to define and edit paths through structures such as centerlines, which may be used to analyze cross-sections of structures, or to provide flythrough visualizations rendered along such a centerline. Segmentation of regions of interest and quantitative analysis tools are provided, for images of vasculature, pathology and morphology, including distance, angle, volume, histogram, ratios thereof, and tracking of quantities over time. A database is provided to track and compare results using published comparison techniques such as RECIST and WHO. Calcium scoring for quantification of atherosclerotic plaque is supported.

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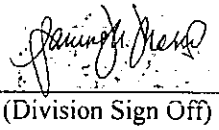
Prescription Use **X**		Over-The-Counter Use _
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

Withings

Section 5 - 510(k) Summary

SEP 27 2012

Date of Summary Preparation: 06/28/2012

1. Submitter's Identifications

Submitter's Name: ZHONGSHAN TRANSTEK ELECTRONICS CO., LTD.
Address: Jin'an Road, Minzhong, Zhongshan City, Guangdong, China
Contact Person: Lisa Li
Contact Email Address: lisha1@transtek.cn
Telephone: +86(760)88282982 ext. 876
Fax: +86(760)85339231

2. Correspondent's Identifications

Correspondent's Name: A03 Lab of BTS
Address: No.1 Fanghua Street, Hi-tech Zone, Chengdu 610041, Sichuan, China
Contact Person: Leo Wang
Contact Email Address: leo.w@hibts.com
Telephone: 086-28-86083300
Fax: 086-20-80727399

3. Name of the Device

Device Classification Name: Analyzer, Body Composition (Impedance Plethysmograph)
Product Name: Smart Body Scale
Trade Name: Withings
Model: WBS01
Classification Panel: Cardiovascular
Common/Usual Name: Body Composition Analyzer/Scales
Product Code: MNW
Device Classification: Class II
Contraindications: Do not use the Body Scale if you have a pacemaker or other internal medical device.

4. The Predicate Devices

TRANSTEK, Glass Body Analyzer, Model GBF-830, K102191

5. Device Description

5.1 Technology of the device:

Bioelectrical Impedance:

WBS01 Smart Body Scale uses the BIA (Bioelectrical Impedance Analysis) technique. This method measures body composition by sending a low, safe electrical current through the body.

The current passes freely through the fluids contained in muscle tissue, but encounters difficulty/resistance when it passes through fat tissue. This resistance of the fat tissue to the current is termed 'bioelectrical impedance', and is accurately measured by WBS01 Smart Body Scale.

Wireless Connectivity:

WBS01 Smart Body Scale embeds a 802.11 (Wi-Fi) module that allows it to connect to the Internet. This module is a product add-on that is entirely independent from the body analyzer function, which does not rely on the wireless connection to carry out a bioelectrical impedance analysis and display its results. The scale uses this connectivity to offer users a complementary web and mobile interface to the scale's display, although users are instructed in the provided user manual that the only reference values are the measures displayed on the scale's display. By design, the body analysis and Wi-Fi functions never are enabled at the same time. The scale only connects to the Internet while no weight or bioelectrical impedance measures are being performed, and if a person steps on the scale while the Wi-Fi module is active, Wi-Fi immediately gets turned off therefore allowing the display and body analysis function to be enabled. The users profile details are stored locally in the scale so that they are immediately available when a bioelectrical impedance analysis needs to be performed. The scale without its Wi-Fi module is therefore an autonomous body fat analyzer, Wi-Fi functionality being a product add-on not being part of the body analyzer function and not affecting the safety and effectiveness of the body analyzer function in any way.

5.2 Device functions

A, Measuring weight, BMI and body fat:

Step on the scale and the scale will display your weight, BMI and body fat.
Unit Switch function: Change the weight unit among KG/LB/ST LB

B, Automatic recognition function:

The scale can automatically recognize you based on your weight reading. Later on, the scale keeps in memory your last weight reading to recognize you. The scale can however only determine your correct identity if no other user weighs within 6.6 pound range, otherwise the scale can only narrow down the choices and displays the various identity options on screen. The appropriate identity is selected by bending left or right.

C, Warning messages Function:

Lo = Low battery warning: Replace the batteries, always replace all batteries at the same time.

D, Wi-Fi Connectivity:

Easily create your profile in Withings' web application and the scale will automatically retrieve it thanks to its Wi-Fi connectivity. You must enter your height, date of birth, gender and activity level (athlete/ non-athlete) while creating your profile. Benefit from a complementary interface to view the history of your weight and body fat readings.

Key function: profile definition, complementary interface.

Withings

6. Intended Use of Device

The Withings WBS01 Smart Body Scale is a body analyzer that measures weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat mass in generally healthy adults 18 years of age or older. It is intended for use in the home/domestic setting only.

It is not intended for being used by pregnant women or children under the age of 18.

7. Summary of Substantial Equivalence

7.1 Difference between proposed device and the predicate device

Table: The comparison of Withings WBS01 Smart Body Scale and the predicate device, TRANSTEK Glass Body Analyzer (Model: GBF-830)

Feature	Proposed Device: Withings WBS01 Smart Body Scale	Predicate Device: TRANSTEK Glass Body Analyzer Model: GBF-830
Manufacturer	ZHONGSHAN TRANSTEK ELECTRONICS CO., LTD	ZHONGSHAN TRANSTEK ELECTRONICS CO., LTD
Classification	21 CFR 870.2770	21 CFR 870.2770
Product Code	MNW	MNW
Indication for use	The Withings WBS01 Smart Body Scale measures weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat mass in generally healthy adults 18 years of age or older. It is intended for use in the home/domestic setting only.	The Transtek Glass Body Analyzer measures weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat, total body water percentage, bone mass, and muscle mass in generally healthy adults 18 years of age or older. It is intended for use in the home/domestic setting only.
Device description	Withings WBS01 Smart Body Scale utilizes a "foot-to-foot" bioelectrical impedance analysis (BIA) technology to determine internal body composition.	TRANSTEK Glass Body Analyzer utilizes a "foot-to-foot" bioelectrical impedance analysis (BIA) technology to determine internal body composition.
Analysis method	BIA (Bioelectrical Impedance Analysis)	BIA (Bioelectrical Impedance Analysis)
Operating parameters	50 KHz	50 KHz
Number of electrodes	4	4
Power source	4*AAA	4*AAA
Operating keys	No operating key, 1 unit switch, 1 pairing button	4
IP Connectivity	802.11b/g (Wi-Fi)	No IP connectivity

The differences between the two devices are WBS01, 1) disable these measure functions, total body water percentage, bone mass, and muscle mass; 2) add-on a Wi-Fi (IEEE 802.11 b/g) data communication, what user option, which can transmit measurement results to PC or cellular.

Withings

7.2 Discussion

The Withings WBS01 Smart Body Scale has an indication for use and BIA technology similar to the predicate device. The only technological difference between Withings WBS01 Smart body Scale and the predicate device is that the WBS01 embeds a 802.11 b/g (Wi-Fi) module. It is an add-on function that is entirely independent from the body analyzer function, which does not rely on the wireless connection to carry out a bioelectrical impedance analysis and display its results.

The scale uses this connectivity to offer users a complementary web and mobile interface to the scale's display, although users are instructed in the provided user manual that the only reference values are the measures displayed on the scale's display.

By design, the body analysis and Wi-Fi functions never are enabled at the same time. The scale only connects to the Internet while no weight or bioelectrical impedance measures are being performed, and if a person steps on the scale while the Wi-Fi module is active, Wi-Fi immediately gets turned off therefore allowing the display and body analysis function to be enabled.

The users profile details are stored locally in the scale so that they are immediately available when a bioelectrical impedance analysis needs to be performed. The scale without its Wi-Fi module is therefore an autonomous body fat analyzer, Wi-Fi functionality being a product add-on not being part of the body analyzer function and therefore not impacting the safety and effectiveness of the body analyzer function.

Design control activities for the modification were performed and bench tests have been done to ensure that user electrical safety and wireless radiation emission is acceptable in use environment. Particular attention has been paid to those concerns and issues highlighted in the "*Radio-Frequency Wireless Technology in Medical Devices Draft Guidance*" FDA January 3, 2007.
Wi-Fi technology is widely used and proved to be safe and reliable. The use of the industry standard IEEE 802.11 b/g provides a high degree of confidence to the users that the coexistence of Withings WBS01 Smart Body Scale within a domestic/home environment is predictable, easily operation, and provides a high degree of assurance that there is a low risk that intentional electromagnetic radiation from the device will result in unacceptable interference with other electrical equipment in the immediate vicinity.
There is an acceptable, low risk that the radio frequency emissions will result in thermal injury to a patient or user. This is based on our FCC ID certification.

Therefore, the device does not create new significant risk.

As a result, the technological difference of the device does not impact its safety and effectiveness vs. the predicate device.

8. Conclusions

The Withings WBS01 Smart Body Scale is substantially equivalent to the predicate device by having the similar indication for use, same BIA technologies and a technological difference that does not impact the safety or effectiveness of the device.

--- End of this section ---

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ZHONGSHAN TRANSTEK ELECTRONIC CO., LTD.
% Mr. Leo Wang, Senior Consultant
A03 Lab of BTS
No. 1 Fanghua Street, Hi-tech Zone
Chengdu Sichuan 610041
CHINA

SEP 27 2012

Re: K121971
Trade/Device Name: Withings Smart Body Scale
Model: WBS01
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: August 30, 2012
Received: August 30, 2012

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Withings

Section 4 - Indications for Use

510(k) Number (if known): K121971

Device Name:

Withings Smart Body Scale
Model: WBS01

Indications for Use:

The Withings WBS01 Smart Body Scale is a body analyzer that measures weight and uses bioelectrical impedance analysis (BIA) technology to estimate body fat mass in generally healthy adults 18 years of age or older. It is intended for use in the home/domestic setting only.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121971

Section 6: 510(k) Summary (21 CFR § 807.92(c))

DEC 2 1 2012

Submitter:	Glooko, Inc. 170A University Avenue Palo Alto, CA 94301
Contact:	Shilpa Mydur Regulatory Affairs Manager Phone: 650.521.0175 Email: shilpa@glooko.com
Date Summary Prepared:	14 December 2012
Device Trade Name:	Glooko Device System for the Glooko Logbook Application & Glooko Logbook Charts
Common Name:	Blood Glucose Meter and Data Management System
Classification Name:	System, Test, Blood Glucose, Over the Counter (21 CFR §862.1345) Calculator/data processing module for clinical use (21 CFR §862.2100)
Product Code:	NBW and JQP
Equivalent Devices:	GlucoFacts Express Data Management Software (K082486)

Device Description:

The Glooko device system for the Glooko Logbook Application includes the following:

- Glooko MeterSync Cable
- Glooko IR Adapter
- Glooko Logbook Application

Glooko MeterSync Cable

The Glooko MeterSync Cable downloads data from compatible, FDA-cleared, commercial blood glucose meters into an iOS device by connecting the two components. One end of the Glooko MeterSync Cable plugs directly into the 30-pin connector slot of the iOS device. The 3.5mm end of the Glooko MeterSync Cable plugs directly into most compatible meters to allow for the transfer of data. Some meters require an additional 3.5mm to 2.5mm adapter to allow for this

connectivity, while other meters transfer data through infrared, and thus require the use of the Glooko IR Adapter.

The Glooko MeterSync Cable is designed to attach to a variety of compatible, FDA-cleared, commercial blood glucose meters. The users simply connect the supported meters to their iOS device and transfer the blood glucose meter data into the Glooko Logbook Application.

Glooko IR Adapter

The Glooko IR Adapter is designed to transmit data via infrared from a variety of compatible, FDA-cleared, commercial blood glucose meters into the Glooko Logbook Application. The user connects the Glooko IR Adapter to the 3.5mm adapter end of the Glooko MeterSync Cable to transmit data from the compatible meters.

Glooko Logbook Application

This iOS Application logs the user's blood glucose values and meal tags that are downloaded from compatible blood glucose meters. The Glooko Logbook Application performs the following functions:

- *Syncs* with compatible meters
- Allows users to *annotate* readings with notes
- Provides multiple *view* options for the data
- *Shares* the collected data in multiple formats to anyone the user selects.

Glooko Logbook Charts

The Glooko™ Logbook Charts is a data management software tool designed to assist people with diabetes who self-manage their Blood Glucose (BG) readings. The Logbook Charts software is used in conjunction with the Glooko MeterSync Cable and the Glooko Logbook Application. The MeterSync Cable and the Glooko Logbook Application allow users to download BG readings from commercially available blood glucose meters to an iOS (iPhone Operating System) device. The Glooko Logbook Charts software tool enables the Glooko Logbook Application users to chart and graph their BG values from the Glooko Logbook Application. Glooko Logbook Charts is a spreadsheet program developed in Microsoft Excel and helps with quantitatively evaluating the BG data downloaded into the Glooko Logbook Application. Users can download the Glooko Logbook Charts sheet template from the Glooko website to generate and display reports on average BG values and BG trends. Several statistical parameters are calculated and the data is plotted as scattergrams relating blood glucose by time of day and by date. Glooko Logbook Charts specifically offers the following charts and table for view:

a. *BG readings By Time of Day*: provides an overview of glucose readings during the day.
b. *BG readings By Date*: provides an overview of glucose readings over a specified date range.
c. *BG readings Analysis By Time Of Day:* provides an overview of analyzed glucose readings during the day with high and low values, percentiles, mean and medians.
BG readings Summary Statistics: provides an overview of the analyzed glucose readings in table format.

Intended Use:

The Glooko device system for the Glooko Logbook Application and Glooko Logbook Charts is data management software intended for use in home and professional settings to aid individuals with diabetes and their health care professionals in review, analysis and evaluation of blood glucose readings to support an effective diabetes management program. The Glooko device system for the Glooko Logbook Application connects to compatible FDA cleared meters and allows users to transfer their blood glucose meter results to their iPhone operating system platform.

The Glooko device system for the Glooko Logbook Application and Glooko Logbook Charts are not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

Summary of Testing:

The Glooko Logbook Application, MeterSync Cable and Charts software underwent verification and validation testing. A brief summary of the tests performed is described below. These studies demonstrated that the Glooko Device System performed according the specifications and the intended use.

Software Verification and Validation

- For Glooko Device system: The Glooko Device system (Glooko Logbook Application, Cable and Adapter) was validated pursuant to the moderate level of concern requirements. Design validation testing confirmed that the Glooko device performs according to the stated intended use. Device evaluation consisted of functional testing performed pursuant to Glooko's design verification protocol, which referenced FDA's guidance document for medical devices containing software. Such testing included Data Integrity Verification, Software Design/features Verification, and error handling testing. All test results fell within the pre-determined specification parameters.

- For Glooko Logbook Charts: The Glooko Logbook Charts software was validated pursuant to the moderate level of concern requirements. Design validation testing

confirmed that the Glooko device performs according to the stated intended use. Device evaluation consisted of functional testing performed pursuant to Glooko's design verification protocol which referenced FDA's guidance document for medical devices containing software. Such testing included Characterization of the Glooko Logbook charts spreadsheet, Data Integrity Verification, Software Design Verification, Microsoft Excel Version Testing and Glooko Logbook Version testing. All test results fell within the pre-determined specification parameters.

Usability Study:

- Glooko Device System: Glooko has conducted a usability performance validation study of the Glooko Logbook Application and MeterSync Cable (version 1.0.0) under an IRB approved protocol. This study was conducted in May 2011. Twenty patients with Type 1 or Type 2 diabetes participated in this study. The test goals for this study were to validate:
  - Accuracy of data download into the Glooko device System
  - Ability to share (transmit, download, save and email) and annotate data
  - Effectiveness of user manual
  - Ease of use of the Glooko MeterSync Cable and the Glooko Logbook Application

The Glooko Logbook Application is at version 1.5.0 at the time of this submission. Glooko has conducted a usability performance validation study with individuals for the first version of the Glooko Logbook Application v1.0.0. Additionally, Glooko has conducted usability / validation studies with individuals and / or healthcare professionals with subsequent versions of the application as part of Glooko's design control procedures. For the purpose of this 510(k), usability studies for Glooko Logbook Application v1.0.0, v1.4.0, and v1.5.0 will be discussed.

Studies from version 1.0.0 were chosen because it included the use of the Glooko MeterSync Cable and the Glooko Logbook Application. Version 1.4.0 included the use of Glooko IR adapter, MeterSync Cable and the Glooko Logbook Application. Version 1.5.0 is chosen because it is the latest version of the Glooko logbook Application and is also subject of this 510(k) submission. The basic operating principles have remained constant across all the versions of the Glooko logbook Application.

Together, the results from the testing of all the Glooko logbook Application versions have demonstrated the proper intended use for the Glooko device system for the Glooko Logbook Application.

- Glooko Logbook Charts: A usability performance validation study was conducted in May 2012 for the Logbook Charts software under an IRB approved protocol. Twenty patients with Type 1 or Type 2 diabetes and fifteen healthcare professionals participated in this study. The test goals for this study were to validate:
  - Effectiveness of the User Manual
  - Ability to transmit, download, save and email csv files
  - Ability to view and print the Logbook Chart graphs

The results from these two usability tests demonstrate that the product performs as intended in the hands of lay users and healthcare professionals. .

Statement of Equivalence:

The Glooko device is substantially equivalent to the predicate device with regards to its intended use and function. Both the subject and predicate devices are intended to download BG meter data to a secondary device. Additionally, the Logbook Chart software tool is similar to the GlucoFacts Express Data Management Software, which allows for the transfer of blood glucose values along with the time, date and certain data markers to a personal computer. Lastly, both the subject and predicate device are able to analyze BG data producing basic statistics and graphs / tables such as: Glucose trend results by date, Glucose results by time of day and summary tabular data.

Summary:

Based on the information provided in this premarket notification, the Glooko Logbook Application, MeterSync Cable and Chart software tool is substantially equivalent to the predicate device and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 21, 2012

Glooko, Inc.
c/o Shilpa Mydur
Regulatory Affairs Manager
170A University Avenue
Palo Alto, CA 94301

Re: k122142
Trade/Device Name: Glooko Device System for Logbook Application & Glooko Logbook Charts
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, JQP
Dated: October 30, 2012
Received: November 2, 2012

Dear Shilpa Mydur,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
In Vitro Diagnostic Devices and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122142

Device Name: Glooko Device System for the Glooko Logbook Application and Glooko Logbook Charts

Indications for Use:
The Glooko device system for the Glooko Logbook Application and Glooko Logbook Charts are data management software intended for use in home and professional settings to aid individuals with diabetes and their health care professionals in review, analysis and evaluation of blood glucose readings to support an effective diabetes management program. The Glooko device system for the Glooko Logbook Application connects to compatible FDA cleared meters and allows users to transfer their blood glucose meter results to their iPhone operating system platform.

The Glooko device system for the Glooko Logbook Application and Glooko Logbook Charts are not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _x_. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K122142

K122184
P1/3

SECTION 5: 510(k) SUMMARY

FEB 1 4 2013

510(k) Summary

Date Prepared:	January 13, 2013
Submitter:	Cardiac Designs, LLC 3293 Niblick Drive Park City, UT 84098 Phone: 1 (512) 582-2453 Facsimile: 1 (713) 589-7964
Contact:	Karim Marrouche, Managing Director 1 (512) 582-2453
Trade/Proprietary Name of Device:	ECG CHECK
Common Name of Device:	Transmitters And Receivers, Electrocardiograph, Telephone
Classification:	Class II per 21 CFR 870.2920, Telephone electrocardiograph transmitter and receiver, Product Code DXH
Legally Marketed Predicate Device:	PMP4 SelfCheck™ ECG (K042254), manufactured by Card Guard Scientific Survival, Ltd.

Description of New ECG CHECK Device:

The ECG Check model ECG01-4S is a personal 1 lead ECG Event Monitor specifically designed to operate with an iPhone 4S handset and allows transmissions to the ECG Check web center. Future iterations will be designed for other handsets, but will not change the fundamental features and capabilities described herein. It will record a preselected amount of user ECG activity, as directed by the user. Typical configuration is to record 30 seconds of ECG per event.

The ECG Check is indicated for monitoring symptoms that may suggest irregular or abnormal heart rhythms. The ECG Check, when used in conjunction with the ECG Check web center, uses standard analysis of ECG by the web-based engine for objective assessment of the user in terms similar to a stoplight (Green, Yellow, Red). With a physician prescription, the user will be provided access to be able to trend their results and generate reports to provide to their physician or other caregivers. The symptoms may include: skipped beats, palpitations, racing

heart, fainting, lightheadedness, irregular rate, or history of other related heart abnormalities.

While performing the recording, the results are continuously sent to the iPhone by secure Bluetooth connection technology and, with a physician prescription, displayed for quality and observation purposes on the iPhone ECG Check application. Users without a physician prescription will not be able to view the waveform. The data can then be stored locally and/or transmitted to the ECG Check web center for analysis and assessment by qualified professionals. The ECG Check web center provides privacy and protection for user medical information and the ability to interact with Cardiac Designs, LLC technicians and engineers, as well as with their own caregivers.

The ECG Check Model ECG01-4S is intended for users that seek to manage their heart rate and rhythms over long periods of time. Additional features will be added to involve health care professionals in the service, with the intent to ensure that the device remains consumer focused and non-diagnostic.

Indications for Use of the New Device:

The ECG CHECK is intended for self-testing by patients at home. This 1-lead cardiac monitor allows remote patients to display and transmit their ECG data to medical professionals via a communication device to a remote server.

Specifically, the ECG CHECK is indicated for patients who are concerned about their heart rhythm and have experienced the following symptoms that are suggestive of abnormal heart rhythms:

- Skipped Beats
- Pounding Heart (Palpatations)
- Heart Racing or Irregular Pulse
- Lightheadedness or Faintness
- History of Arrhythmias

Comparison of the Technological Features of the New (Modified) Device and Predicate Device:

The new ECG CHECK indications for use are equivalent to the predicate PMP4 SelfCheck™ ECG device. The new ECG CHECK and the predicate PMP4 SelfCheck™ ECG device have identical patient populations and places of use. In addition, the parameters that are measured by the new ECG CHECK device are identical to those measured by the predicate PMP4 SelfCheck™ ECG device.

There are few differences between the new ECG CHECK device and the predicate PMP4 SelfCheck™ ECG device. The main difference is as follows:

Leads:

The new ECG CHECK device operates with 1 lead. The predicate PMP4 SelfCheck™ ECG device can operate with 1 lead or with 12 leads. Cardiac Designs, LLC seeks substantial equivalence only to the 1 lead functionality of the predicate PMP4 SelfCheck™ ECG device. Comparisons, testing, and conclusions will be drawn based only on the 1 lead configuration.

Testing:

The ECG CHECK device successfully passed safety and essential performance testing as required by:
IEC 60601-1
IEC 60601-2-47 - Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems.
ISO 10993-5:2009 Cytotoxicity – MEM Elution Test
ISO 10993-10:2010 Maximization Test for Delayed Hypersensitivity
ISO 10993-10:2010 Intracutaneous (Intradermal) Reactivity Test

Conclusion:

The conclusions drawn from the specifications and performance testing of the new ECG CHECK device demonstrate that the new ECG CHECK device is at least as safe and as effective and performs as well as or better than the Card Guard Scientific Survival, Ltd. predicate PMP4 SelfCheck™ ECG (K042254). For these reasons, we believe the new ECG CHECK device is substantially equivalent to the predicate device.

Signed,

Karim Marrouche

Karim Marrouche
Managing Director

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 14, 2013

Cardiac Designs, LLC
c/o Mr. Karim Marrouche
Managing Director
3293 Niblick Drive
Park City, UT 80498

Re: K122184
Trade/Device Name: ECG Check
Regulatory Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitters and Receivers
Regulatory Class: II (two)
Product Code: 74 DXH
Dated: January 18, 2013
Received: January 22, 2013

Dear Mr. Marrouche:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K122184

Device Name: ECG CHECK

Indications for Use:

The ECG Check is intended for self-testing by patients at home. This 1-lead cardiac monitor allows remote patients to display and transmit their ECG data to medical professionals via a communication device to a remote server.

Specifically, the ECG Check is indicated for patients who are concerned about their heart rhythm and have experienced the following symptoms that are suggestive of abnormal heart rhythms:

- Skipped Beats
- Pounding Heart (Palpitations)
- Heart Racing or Irregular Pulse
- Lightheadedness or Faintness
- History of Arrhythmias

Prescription Use X (21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S

aycan
PACS for People

510(k) Summary of Safety and Effectiveness

SEP 12 2012

The following information is in conformance with 21 CFR 807.92.

Submitter's Information: 21 CFR 807.92(a)(1)

aycan Digitalsysteme GmbH
Innere Aumuehlstr. 5
97076 Wurerzburg
Germany

Phone:	+49 - 931 - 270 40 90
Fax:	+49 - 931 - 270 40 91
Contact Person:	Mr. Matthias Broenner
Date Prepared:	July 23th, 2012

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	aycan mobile
Common Name:	Picture Archiving Communications System
Classification Name:	system, image processing, radiological
Product code:	LLZ
Regulation Number:	21 CFR 892.2050

Predicate Device: 21 CFR 807. 92(a)(3)

FDA has classified the predicate device (K103785) as Class II, CFR 892.2050, LLZ. It is our understanding that *aycan mobile* device falls under the same classification as the predicate device. Predicate device details are as follows:

Device Classification Name:	system, image processing, radiological
510(k) Number:	K103785
Regulation Number:	892.2050
Device Name:	MOBILE MIM
Applicant:	MIM SOFTWARE INC. 25200 Chagrin Blvd. Suite 200 Cleveland, OH 44122
Classification Product Code:	LLZ
Decision Date:	02/04/2011
Classification Advisory Committee:	Radiology

Device Description: 21 CFR 807 92(a)(4)

aycan mobile is an App for the Apple iPad. It can be used for receiving and visualization of medical images.

Indications for Use: 21 CFR 807 92(a)(5)

"The *aycan mobile* software program is used to display medical images for diagnosis from CT and MRI modalities only.

aycan mobile provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography."

The Indications for Use of aycan mobile are a subset of the Indications for Use of the predicate device. The predicate device additionally covers registration and fusion of images and it includes the handling of SPECT and PET images. See also the Device Comparison Table below.

The reduction of the Indications for Use (compared to the predicate device) doesn't negatively affect the safety and effectiveness of the devices when used as labeled.

Technological Characteristics: 21 CFR 807 92(a)(6)

aycan mobile is a software for a mobile device (Apple iPad) that receives and visualizes digital medical images.

The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed.

Device Comparison Table between new device and predicate:

Topic	aycan mobile	MOBILE MIM
Intended Use / Indications for Use	The aycan mobile software program is used to display medical images for diagnosis from CT and MRI modalities only. aycan mobile provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. This device is not to be used for mammography.	The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from only the following modalities: SPECT, PET, CT, and MM. Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. This device is not to be used for mammography.
Receive, Store, Retrieve, Display, and Process Digital Medical Images	Yes	Yes
Display of Clinical Patient Data When No Access to a Workstation	Yes	Yes
Image Fusion	No	Yes
Standardized Uptake Value (SUV)	No	Yes
Distance Calculation	Yes	Yes
Window / Level	Yes	Yes
Zoom, Pan	Yes	Yes
User Authentication	Yes	Yes
Modalities	CT, MRI	SPECT, PET, CT, MRI
Remote Handheld Viewing Device	Yes	Yes
Operating Platform	Apple (R) iOS	Apple (R) iOS
Hardware Requirements	Apple (R) iPad	Apple (R) iOS handheld devices

The comparison table shows that – besides a reduction of functionality regarding the application on SPECT and PET images – both Apps are substantially equivalent.

Regarding the hardware aycan mobile is limited to iPad devices compared to MOBILE MIM which can be used on the wider range of all Apple (R) iOS handheld devices.

The differences at the Indications for Use Statement are also based on the fact that MOBILE MIM handles SPECT and PET images additionally.

All these facts provide evidence to facilitate the substantial equivalence determination between aycan mobile and the predicate device, MOBILE MIM (K103785).

Performance Data from nonclinical Testing: 21 CFR 807 92(b)(1)

Designated individuals performed all verification and validation activities and results demonstrated that the predetermined acceptance criteria were met. The system passed all testing criteria.

Extensive performance tests had been conducted regarding the display and other technical aspects. Display tests leveraged capabilities regarding IEC 62563-1 and TG18 guideline. All tests had been passed successfully.

Performance Data from clinical Testing: 21 CFR 807 92(b)(2)

Furthermore a series of studies had been performed by qualified radiologists reading different CT and MRI studies under different environmental lightning conditions. The capability of aycan mobile as a device for diagnostic reading – when used within the indications for use – was confirmed by the results of these studies.

All radiologists came to the conclusion that the devices is safe and effective when used within its defined Intended Use.

Conclusion: 21 CFR 807 92(b)(3)

According to all evidence collected, we come to the conclusion, that aycan mobile is substantially equivalent to the predicate device and it is safe and effective, when used as labeled.

The 510(k) Pre-Market Notification for *aycan mobile* contains adequate information and data to enable FDA-CDRH to determine substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Matthias Broenner
Quality and Regulations Manger
Aycan Digitalsysteme GmbH
Innere Aumuehlstr. 5
WUERZBURG 97076
GERMANY

SEP 12 2012

Re: K122260
Trade/Device Name: aycan mobile
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 23, 2012
Received: July 27, 2012

Dear Mr. Broenner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

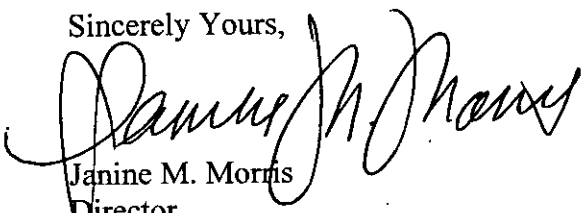
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number: K122260

Device Name: aycan mobile

Indications for Use:

The aycan mobile software program is used to display medical images for diagnosis from CT and MRI modalities only.

aycan mobile provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography.

Prescription Use _X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
510k K122260 OIVD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

NOV 19 2012

Alivecor, Inc.
c/o Mr. Michael Righter
Director, Regulatory Affairs
140 Geary Street, Suite 500
San Francisco, CA 94108

Re: K122356
Trade/Device Name: Alivecor heart monitor for iphone
Regulatory Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: DPS
Dated: October 18, 2012
Received: October 20, 2012

Dear Mr. Righter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AliveCor

510(k) PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: K122356

Device Names: AliveCor Heart Monitor for iPhone

Indications for Use:

The *AliveCor Heart Monitor for iPhone* is intended for use by licensed medical professionals or patients to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.

Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
2012.11.19
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510(k) Summary

Verizon Wireless
Converged Health Management Device (K122458)

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Cellco Partnership d/b/a Verizon Wireless
One Verizon Way
Basking Ridge, NJ 07920
Phone: (202) 515-2454
Facsimile: (202) 289-6781

JUL 3 0 2013

Contact Person: Lolita Forbes, Assistant General Counsel – Mobile Health
lolita.forbes@verizon.com

Date Prepared: July 3, 2013

Name of Device and Name/Address of Sponsor

Verizon Wireless Converged Health Management Device

Cellco Partnership d/b/a Verizon Wireless
One Verizon Way
Basking Ridge, NJ 07920

Common or Usual Name: Telemedicine System

Classification Name:

Radiofrequency Physiological Signal Transmitter and Receiver (21 CFR 870.2910; DRG)

Predicate Devices:

Alcatel-Lucent Telehealth Manager (K092635)
Vignet Telehealth Monitoring System (K113446)

Intended Use / Indications for Use

The CHM Device is a remote monitoring software solution intended to collect and store biometric data from physiological measurement devices intended for use in the home. The CHM Device also allows for the automated transmission of the biometric data to a remote secure server via existing mobile telecommunications and/or Internet infrastructure.

The stored biometric data is accessible by clinicians for analysis and intervention. Patients can also review the stored biometric data and receive educational and motivational content from clinicians.

The CHM Device can be used as a standalone device or in conjunction with supported patient monitoring devices, such as a glucometer, weight scale, pulse oximeter, and blood pressure monitor.

The CHM Device is not intended for use in surgical rooms, intensive care units, intermediate or step-down units or emergency vehicles. It is not interpretive, nor is it intended for diagnosis or as a replacement for the oversight of healthcare professionals. It does not provide real-time or emergency monitoring.

Technological Characteristics

The CHM Device is a software platform for the collection and display of biometric data, primarily from externally supported patient monitoring devices, both to the patient and to the clinician. The CHM Device may also be used as a standalone device. The CHM Device uses existing Internet and telecommunications architecture (cellphones and computers) for the automated transmission of medical data to a remote secure server from where it can be viewed remotely by clinicians and patients for the purposes of storage and basic analysis. The CHM Device also provides educational and motivational functionalities allowing the clinician to send tasks, recommendations, surveys, and educational and motivational messages to patients.

The Verizon Wireless Converged Health Management Device may be used in conjunction with the following externally supported patient monitoring devices:

- Ideal Life Inc., Blood Pressure Cuff (K060504)
- Ideal Life Inc., Glucose Monitor Model GMM0001 (K080283)
- Ideal Life SpO2 Pulse Oximeter (K070371)
- Ideal Life Weight Scale (Class I, 510(k)-exempt)
- Ideal Life Communication Gateway Ideal Life Pod ILP (K080538)

Performance Data

The Verizon Converged Health Management Device is a software application. Software verification and validation testing, including usability validation, was performed successfully, demonstrating that the CHM Device performs appropriately per defined specifications, meets all input requirements, fulfills the device's intended use, and correctly incorporates all required safety mitigations.

Substantial Equivalence

The CHM Device has the same intended use and similar indications for use as its predicate devices. The CHM Device also has similar technological characteristics as its predicate devices. Software verification and validation testing demonstrate that the CHM Device performs as intended and that the differences between the CHM Device and its predicate devices do not raise new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 30, 2013

Cello Partnership D/B/A Verizon Wireless
C/O Ms. Lolita Forbes
Assistant General Counsel - Mobile Health
1300 I St NW, Suite 400 W
Washington, DC 20005

Re: K122458
Trade/Device Name: Verizon Wireless Converged Health Management System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: 06/04/2013
Received: 06/04/2013

Dear Ms. Forbes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122458

Device Name: Verizon Wireless Converged Health Management (CHM) Device

The CHM Device is a remote monitoring software solution intended to collect and store biometric data from physiological measurement devices intended for use in the home. The CHM Device also allows for the automated transmission of the biometric data to a remote secure server via existing mobile telecommunications and/or Internet infrastructure.

The stored biometric data is accessible by clinicians for analysis and intervention. Patients can also review the stored biometric data and receive educational and motivational content from clinicians.

The CHM Device can be used as a standalone device or in conjunction with supported patient monitoring devices, such as a glucometer, weight scale, pulse oximeter, and blood pressure monitor.

The CHM Device is not intended for use in surgical rooms, intensive care units, intermediate or step-down units or emergency vehicles. It is not interpretive, nor is it intended for diagnosis or as a replacement for the oversight of healthcare professionals. It does not provide real-time or emergency monitoring.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.07.30 10:18:20 -04'00'

DEC 5 2012

SECTION 5

510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS FOR
Mobile CareGuide™ 2100 Oximeter

Submitter Information

Name:	Reflectance Medical, Inc. (RMI)
Address:	116 Flanders Road, Suite 1000 Westborough, MA 01581 USA
Telephone Number:	508.366.4700
Registration Number:	NA (RMI will apply for registration number following 510(k) clearance, prior to commencement of commercial shipment.)
Contact Person:	Dr. Babs Soller
Telephone Number:	508.366.4700, Ext 223
Fax Number:	508.366.4770
Email:	Babs.Soller@reflectancemedical.com
Date Prepared:	November 20, 2012

Device Name

Device Trade Name:	Mobile CareGuide™ 2100 Oximeter
Device Common Name:	Oximeter
Classification:	Sec 870.2700 Oximeter
Product Code:	MUD
Classification Panel:	Cardiovascular Device Panel

Predicate Devices

Device Trade Name:	CareGuide™ Oximeter
Device Common Name:	Oximeter
Classification:	Sec 870.2700 Oximeter
510(k) Number:	K113656
Product Code:	MUD

Device Description

The Mobile CareGuide 2100 Oximeter sensor uses Near Infrared Spectroscopy (NIRS) to calculate muscle oxygen saturation (SmO_2).

Characteristics	Reflectance Medical Mobile CareGuide 2100 Oximeter
Principle of Operation	NIR spectroscopy
Components	Monitor with reusable sensor and disposable pad
Light Source	LEDs
Parameters Measured	Tissue oxygen saturation (SmO_2)

The Mobile CareGuide 2100 Oximeter is a self-contained, medical oximeter. The sensor contains algorithms that calculate SmO_2 from collected spectra and communicates the current SmO_2 result to a 3rd party display or patient monitor through a proprietary protocol. The Mobile CareGuide 2100 Oximeter reusable sensor contains the optical and electronic elements necessary to collect spectra from skin, fat and muscle. The sensor has a 3m long cord with either a USB connection or CAN connection to the 3rd party display/patient monitor. The sensor contains 6 major components: (1) light sources to illuminate the skin; (2) a spectroscopic detector to analyze the reflected spectra back from the subject; (3) a microprocessor to control the optical components; (4) a microprocessor to perform the spectral analysis and generate the calculated SmO2; (5) one of two different communications components to transmit in CAN or USB format; (6) a battery to power all components. The Mobile CareGuide 2100 Oximeter Ray is a disposable sleeve which isolates the sensor optical elements from the patient's skin.

Indications for Use

The Mobile CareGuide™ 2100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Mobile CareGuide 2100 Oximeter is intended to allow for display of SmO2 data on a third party device, which would interface with the Mobile CareGuide 2100 Oximeter via USB or CAN connection. The Mobile CareGuide 2100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Mobile CareGuide 2100 Oximeter provides output of the most recent value of SmO2, as well as operational device information. The Mobile CareGuide 2100 Oximeter should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Mobile CareGuide 2100 Oximeter has not been demonstrated in disease states.

Rationale for Substantial Equivalence

The Mobile CareGuide™ 2100 Oximeter is substantially equivalent to the Reflectance Medical CareGuide™ Oximeter (K113656).

The Mobile CareGuide 2100 Oximeter is substantially equivalent to the predicate by intended use and design.

- The principle of operation of the Mobile CareGuide 2100 Oximeter is identical to that of the predicate device. They use the exact same NIR Spectroscopy to measure tissue oxygen saturation. The same software quantitative algorithm is used in both devices.
- The Mobile CareGuide 2100 Oximeter is equivalent to the predicates in components. Both devices use the exact same optical board (light sources, spectrometer and microprocessor).
- The Mobile CareGuide 2100 Oximeter has the identical underlying LED light source as the predicate, with the exact same ranges of wavelength (700-900 nm) and number of wavelengths.
- The Mobile CareGuide 2100 Oximeter produces the same numeric data to be displayed on a 3rd party device as the predicate device.
- The Intended Use is identical to the predicate. Both are intended for use as oximeters, to measure tissue oxygen saturation.

Summary of Safety and Effectiveness Data

Testing demonstrates that the Mobile CareGuide 2100 Oximeter is a safe and effective oximeter meeting all relevant consensus and FDA recognized standards. The test results in this submission demonstrate that the Mobile CareGuide 2100 Oximeter meets the expected performance requirements for an Oximeter, and is therefore equivalent to the predicate relative to safety and mechanical properties. The accuracy and safety of the Mobile CareGuide 2100 Oximeter is the same as the predicate device.

Conclusion

The Mobile CareGuide 2100 Oximeter is equivalent to predicate device in terms of technology (NIR Spectroscopy) and intended use. The Mobile CareGuide 2100 Oximeter, with its embedded microprocessor and supporting components, does not raise new questions of safety or effectiveness, as compared to the predicate. Therefore, the Mobile CareGuide 2100 Oximeter is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DEC 5 2012

Reflectance Medical, Inc.
c/o Nandini Murthy
116 Flanders Rd, Suite 1000
Westborough, MA 01581

Re: K122645
Trade/Device Name: Mobile CareGuide 2100 Oximeter
Regulation Number: 21 CFR §870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: November 21, 2012
Received: November 27, 2012

Dear Ms. Murthy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

Mitchell J. Shein
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Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K122645

Device Name: ___Mobile CareGuide™ 2100 Oximeter___

Indications for Use:

The Mobile CareGuide™ 2100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Mobile CareGuide 2100 Oximeter is intended to allow for display of SmO2 data on a third party device, which would interface with the Mobile CareGuide 2100 Oximeter via USB or CAN connection. The Mobile CareGuide 2100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Mobile CareGuide 2100 Oximeter provides output of the most recent value of SmO2, as well as operational device information. The Mobile CareGuide 2100 Oximeter should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Mobile CareGuide 2100 Oximeter has not been demonstrated in disease states.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of ___

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Bram Zuckerman, M.D.

K123082
Page 1 of 5

(the following information is in conformance with 21 CFR 807.92)

MAY 16 2013

Submitter

Nephosity, Inc.
615 Grant Avenue 3F
San Francisco, CA 94108

Contact Person:
Michael Pan, CEO
615 Grant Avenue 3F
San Francisco, CA 94108
mjpan@nephosity.com
+1 650 429 8917

Date Summary Prepared: April 24, 2013

Device name

Trade Name: MobileCT Viewer
Common Name: Medical Imaging Software
Classification Name: System, Image Processing, Radiological (21 CFR Part 892.2050, Product Code: LLZ)

Predicate device

K103785 MobileMIM MIM Software Inc.

Indications for Use

The MobileCT Viewer software program provides for communication and display of CT, MRI, X-ray medical images on the Apple iPad (4th generation, late 2012) . It is intended for use as a diagnostic, review and analysis tool by trained professionals.

MobileCT Viewer provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography.

Device description

The MobileCT Viewer is a software-based Picture Archiving and Communication System (PACS) used with computing servers and specific mobile devices. DICOM-compliant medical images from CT, MRI, X-ray modalities are stored on the server component. MobileCT Viewer retrieves patent image data securely via a network connection with the server. DICOM files are losslessly compressed for network transfer and downloaded by MobileCT Viewer for display on the mobile device component. Communication and display on the mobile device assist trained professionals in the diagnostic interpretation, review and analysis of the medical images.

MobileCT Viewer includes the capability to perform to the displayed image:

- adjust window width and level (i.e. contrast) values,
- apply view transforms (e.g. zoom, pan, and rotation),
- measure distances, and
- display measurement lines and annotations.

MobileCT Viewer operates on off-the-shelf portable hardware devices and is therefore subject to factors not typical for reading room workstations (e.g. screen size, environmental variability,

network dependencies, etc.). It is therefore required that the user follows the operating instructions properly and utilizes the risk mitigation features in order to make decisions safely and effectively.

MobileCT Viewer provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

Substantial equivalence

Table 1 provides evidence to facilitate the substantial equivalence determination between MobileCT Viewer and our chosen predicate, Mobile MIM (K103785).

There is a direct correlation between the Indication Statement / Intended Use of MobileCT Viewer with Mobile MIM. Both devices are software applications used by medical professionals in the diagnosis of patients by means of medical images.

MobileCT Viewer and MobileMIM run on the same software platform– Apple iOS, and hardware platform– the Apple iPad (4th generation, late 2012) . MobileCT Viewer's technological characteristics are more limited than that of MobileMIM, as MobileCT Viewer provides only viewing and simple image manipulation (which do not alter the image data, such as window and level, pan and zoom, and image annotation) capabilities. MobileCT Viewer does not provide image processing functions which are intended to alter the image data (e.g. filtering, multiplanar reconstruction, and 3D reconstruction).

MobileCT Viewer's capabilities include support for viewing medical images from modalities not indicated in Mobile MIMs submission: X-ray. This difference does not alter the intended effect of the device (that is, the display of medical images) and does not raise any different types of safety and effectiveness questions. Information including performance data is provided in this submission to assess device performance in viewing images from these added modalities.

In addition, MobileCT Viewer does not support the following advanced image manipulations: image fusion, multiplanar reconstruction (MPR), maximum intensity projection (MIP), or standard update values (SUV). Consistently, the Indications for Use Statement for MobileCT Viewer excludes the advanced image manipulations.

TABLE 1: Device Comparison table between new device and predicate

Item	MobileCT	MobileMIM
Intended Use / Indication for Use	The MobileCT Viewer software program provides for communication and display of CT, MRI, X-ray medical images on the Apple iPad (4th generation, late 2012) . It is intended for use as a diagnostic, review and analysis tool by trained professionals. MobileCT Viewer provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. This device is not to be used for mammography.	The Mobile MIM software program is used for the registration, fusion, and/or display for diagnosis of medical images from the following modalities: SPECT, PET, CT and MRI. Mobile MIM provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation. This device is not to be used for mammography.
Receive, Store, Retrieve, Display and Process Digital Medical Images	Yes	Yes
Display of Clinical Patient Data When No Access to a Workstation	Yes	Yes
Image Fusion	No	Yes
3D reconstruction, e.g. Multi-Planar Reconstruction (MPR), Maximum Intensity Projection (MIP)	No	Yes
Standard Uptake Value (SUV)	No	Yes
Distance Measurements	Yes	Yes
Window/Level	Yes	Yes
Zoom/Pan	Yes	Yes
User Authentication	Yes	Yes
Modalities	CT, MRI, X-ray	SPECT, PET, CT, MRI
Remote Handheld Viewing Device	Yes	Yes
Operating Platform	Yes	Yes
Hardware Requirements	the Apple iPad (4th generation, late 2012)	Apple iOS handheld devices

For a complete discussion of how hazards related to the use of MobileCT Viewer as a diagnostic, review, and analysis tool by trained professionals should be addressed during device development as part of the risk management process, see the Device Use Safety discussion in Part XVI (Software) Chapter 3 (Hazard analysis) of this 510(k) premarket notification. Additionally, a summary of the results of the testing (section 9.6 and section 9.7) done during the Alpha and Beta development stages demonstrate that the device, when used according to operating instructions, can be used safely and effectively.

Summary of testing

Nephosity, Inc. has performed multiple studies with qualified medical professionals. These medical professional tested MobileCT Viewer by evaluating the image quality of the medical images of the supported modalities (i.e. CT, MRI, X-ray) under different environmental conditions. Results of these studies affirm the diagnostic viewing capabilities of MobileCT Viewer when used as indicated.

Additionally, Nephosity, Inc. has conducted performance and functional testing on the MobileCT Viewer software. In all cases, the software passed its performance requirements and met specifications. A summary of the results of the testing (section 9.6 and section 9.7) of Part XVI.

No animal or clinical testing was performed.

Conclusion

Based on a comparison between the MobileCT Viewer and the Mobile MIM and on the performance data provided in this premarket notification submission, it is our belief that the new device is as safe and effective as the predicate device, and does not raise different questions of safety and effectiveness than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 16, 2013

Nephosity, Inc.
% Mr. Michael Pan
CEO
615 Grant Avenue, 3F
SAN FRANCISCO CA 94108

Re: K123082
Trade/Device Name: MobileCT Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II .
Product Code: LLZ
Dated: March 30, 2013
Received: April 3, 2013

Dear Mr. Pan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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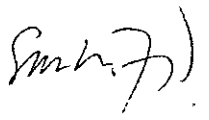
Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123082

Device Name: MobileCT Viewer

Indications for Use:

The MobileCT Viewer software program provides for communication and display of CT, MRI, X-ray medical images on the Apple iPad (4th generation, late 2012) . It is intended for use as a diagnostic, review and analysis tool by trained professionals.

MobileCT Viewer provides wireless and portable access to medical images. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

This device is not to be used for mammography.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123082

K123186

MAR 14 2013

5 510(k) Summary

As required by 21 CFR Part 807.87(h)

Submitter:	Kyle Peterson Director, Regulatory & Corporate Affairs Calgary Scientific Inc. Suite 208, 1210 - 20th Ave. SE Calgary, Alberta T2G 1M8 CANADA
Telephone Number:	(403) 767-7945
Fax Number:	(403) 270-2771
Name / Address of Manufacturer:	Calgary Scientific Inc. Suite 208, 1210 - 20th Ave. SE Calgary, Alberta T2G 1M8 CANADA
Date of Submission:	September 14, 2012

Identification of the Device

Device Proprietary Name:	ResolutionMD Mobile 3.1
Common Name:	Picture Archiving and Communication System
Classification Name:	Picture Archiving and Communication System per 21 CFR 892.2050
Product Code:	LLZ
Device Class:	Class II

Marketed Device to which Equivalence is claimed:

Device	Manufacturer	510(k) Number
ResolutionMD Mobile	Calgary Scientific Inc.	K111346

Device Description:

The ResolutionMD™ Mobile 3.1 software is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and high-resolution Apple Inc. iOS and Google Inc. Android OS-based wireless mobile devices for the display and advanced visualization of medical image data. It provides for communication, storage, processing, rendering on the server and the display of DICOM 3.0 compliant image data derived from CT and MRI on the mobile device.

Indications for Use:

The ResolutionMD™ Mobile software is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and specific mobile devices. It provides for communication, storage, reformatting, rendering on the server component and communication and display of DICOM 3.0-compliant CT and MR medical images as well as reports on the mobile device.

The ResolutionMD Mobile provides wireless and portable access to medical images. The device is intended for use as a diagnostic, review, and analysis tool by trained professionals such as radiologists, physicians and technologists. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

The ResolutionMD Mobile is not to be used for mammography.

Technological Characteristics

The ResolutionMD™ Mobile 3.1 software adds support for mobile devices running the Android operating system and has the same uses and applications as the predicate device. Both the device and predicate are used by the clinician as a diagnostic, review, and analysis tool for radiological images.

Software Verification and Validation Testing

Verification testing consisting of more 160 separate testers, each executed multiple times by different testers, was performed for this device. Testing included functional, smoke and regression tests and was complemented by beta tests performed by Calgary Scientific's OEM distribution partners. The vast majority of tests passed our testing criteria. Any defects found or reported were either fixed or logged in the Unresolved Anomalies report included with this submission and annotated as to any impact on safety or effectiveness including applicable workarounds.

Validation testing based on typical clinical workflows was performed by trained radiology personnel. Validation includes usability assessment and consistency across three client platforms; Web, iOS and Android (the subject of this submission and both phone and tablet devices.

Performance Testing

Performance testing was conducted to qualify an Android smartphone and an Android as devices whose off-the-shelf performance in combination with the overall attributes of the ResolutionMD Mobile solution provides acceptable image quality for diagnostic radiology.

The tests were performed in accordance with the description and requirements described in the AAPM Assessment of Display Performance for Medical Imaging Devices (2005) document by an ISO 17025-certified third party to ensure high quality laboratory results. The test equipment and calibration was certified traceable to NIST.

Nine tests of display performance were conducted for each mobile device running ResolutionMD Mobile and both devices passed all of the tests.

Clinical Testing

Clinical testing was conducted by a panel of three board-certified radiologists in the United States. The radiologists conducted a side-by-side comparative assessment of the Android mobile devices running ResolutionMD Mobile with the predicate iOS devices. A series of typical CT and MR cases were reviewed on each device. Comparative assessments of image quality and diagnostic confidence were made by each radiologist.

All three radiologists agreed that the Android mobile devices, both the smartphone and tablet, were comparable to the predicate iPhone and iPad devices and of adequate quality for clinical use. They were comfortable with the diagnoses made on the Android mobile devices using the ResolutionMD Mobile software. All agreed that the overall clinical image display quality on the Android devices was equivalent to the iOS devices for the identification of clinically-relevant pathology. There were similar comments on image contrast and sharpness with comments including "very comparable" and "is diagnostic". No image artifacts were noted by the reviewers.

All three radiologists indicated that the software and devices provide acceptable quality for regular use and they were comfortable reviewing images on the devices.

Safety and Effectiveness

The device is designed and manufactured under Quality System Regulations as outlined in 21 CFR 820. All requirements of Picture Archiving and Communications System (21 CFR 892.2050) are met, and software is in compliance with ISO 14971 and ISO 62304.

Substantial Equivalence:

Based on the above considerations, Calgary Scientific Inc. believes that the ResolutionMD Mobile 3.1 software is substantially equivalent to the predicate device. The device and the predicate are both post-processing and provide the same features of visualization of radiological data on mobile devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 14, 2013

Kyle Peterson
Director, Regulatory and Corporate Affairs
Calgary Scientific Inc.
Suite 208, 1210 - 20th Avenue SE
CALGARY, ALBERTA T2G 1M8
CANADA

Re: K123186
Trade/Device Name: ResolutionMD™ Mobile 3.1
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 14, 2013
Received: February 19, 2013

Dear Mr. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

4 Indications for Use Statement

Applicant: Calgary Scientific, Inc., Suite 208 – 1210 20th Ave. SE, Calgary, Alberta, CANADA T2G 1M8

510(k) Number: K123186

Device Name: ResolutionMD™ Mobile 3.1

Indications for Use:

The ResolutionMD™ Mobile software is a software-based Picture Archiving and Communication System (PACS) used with general purpose computing servers and specific mobile devices. It provides for communication, storage, reformatting, rendering on the server component and communication and display of DICOM 3.0-compliant CT and MR medical images as well as reports on the mobile device.

The ResolutionMD Mobile provides wireless and portable access to medical images. The device is intended for use as a diagnostic, review, and analysis tool by trained professionals such as radiologists, physicians and technologists. This device is not intended to replace full workstations and should be used only when there is no access to a workstation.

The ResolutionMD Mobile is not to be used for mammography.

Prescription Use __X__	OR	Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K123186

5. 510(k) Summary

Name of 510(k) sponsor:	InTouch Health, Inc.
Address:	6330 Hollister Ave. Goleta, CA 93117
Contact information:	Steve Sidwell Director of Regulatory Affairs & Quality Assurance InTouch Health 6330 Hollister Ave. Goleta, CA 93117 Phone: 805 562 8686 (ext. 254) Fax: 805 562 8663
Date summary prepared:	October 11, 2012
Proprietary name of device:	Remote Presence System, Model RP-VITA™
Generic/classification name:	Transmitters and Receivers, Physiological Signal, Radiofrequency
Product code (classification):	21 C.F.R. § 870.2910, Product Code DRG; Class II

NOV 2 0 2012

Legally Marketed Predicate Device: InTouch Remote Presence System, Model RP-7i; K120895; May 24, 2012.

Device Description and Technological Characteristics:

The Remote Presence System, Model RP-VITA™ is a telecommunications platform that enables real-time videoconferencing and clinical communications, and provides a means for transmitting, receiving, and storing real-time audio and video, and patient data. The Remote Presence System, Model RP-VITA™ consists of a Control Station ("CS") (*i.e.*, desktop or laptop computer) and the RP-VITA™ end point that is controlled by an input device (*e.g.*, mouse or joystick) that the operator uses to control the movement of the RP-VITA™ from a remote location. The RP-VITA™ and CS are each equipped with various combinations of cameras, displays, microphones, and speakers, depending upon the specific CS used, which facilitate two-way audio-video communication. One accessory is a Class II, integrated electronic stethoscope, which is used for the same purpose for which it received 510(k) clearance. Communication between the CS and the RP-VITA™ end point is established via a wired broadband Internet connection or an 802.11 wireless broadband network connection.

Like the predicate device, the Remote Presence System, Model RP-VITA™ provides a real-time link between the patient and the healthcare professional. This link occurs over a wired or wireless broadband connection, and includes real-time audio and video to facilitate communication between the patient, patient-side healthcare professionals, and remote healthcare professionals. Also like the predicate, the Remote Presence System, Model RP-VITA™ provides connections for the transfer of data from 510(k)-cleared devices between the patient and the healthcare professional. Like the predicate device, these 510(k)-cleared devices are not controlled or manipulated through the Remote Presence System, Model RP-VITA™, and consequently, no additional risk is presented.

Expanding on the predicate device, the Remote Presence System, Model RP-VITA™ is available with an optional autonomous navigation system ("autonavigation"), providing the ability to autonomously navigate and position the RP-VITA™ end point to a pre-determined location. Developed in partnership with iRobot, the RP-VITA™ contains similar Auto Drive technology that is already being used successfully by the defense and

public safety communities (e.g., PackBot bomb disposal robots), as well as by consumers in household environments (e.g., Roomba vacuum cleaners). With a single click or tap, a bedside nurse or a remote clinician will be able to send the RP-VITA™ to the target destination. The RP-VITA™ features mapping and Obstacle Detection Obstacle Avoidance ("ODOA") technologies that support safe, fast, and highly flexible navigation in a clinical environment. As the technology name suggests, the ODOA system allows the RP-VITA™ to steer clear of obstacles in its path and maneuver around them. The RP-VITA's™ mapping technology creates and stores a digital map of a clinical environment that it can access in the future, labeling rooms, controlling device speed in certain areas, and marking areas where the RP-VITA™ should not travel. Risk analysis and the necessary verification and validation testing were performed to demonstrate that the design outputs of the RP-VITA™ meet the design input requirements.

Redundant safeguards are designed into the Remote Presence System, Model RP-VITA™ to address risks associated with both autonavigation and hardware and software improvements. The safety and effectiveness of these improvements were demonstrated by the verification and validation testing performed on the Remote Presence System, Model RP-VITA™. One article of the RP-VITA™ verification plan states that if a component critical to the ODOA system fails in autonavigation mode, the device will halt and not move as specified. Another article of the RP-VITA™ verification plan states that the device base has LED light strips that are capable of changing color to indicate various states of the device (e.g., autonavigation mode). An article of the RP-VITA™ validation plan states that when the device is in autonavigation mode, the device will slow down in narrow spaces (e.g. doorways less than three (3) feet) as well as slow down whenever un-mapped obstacles are detected nearby. The RP-VITA™ was tested successfully against these and other verification and validation articles to ensure the design outputs of the RP-VITA™ meet the design input requirements. In addition, the communication channel used by the electronic stethoscope was proven safe and effective by independent tests.

The performance data discussed in this 510(k) application demonstrate that the Remote Presence System, Model RP-VITA™ is as safe and effective as, and performs as well as or better than, the predicate device.

Intended Use:

The Remote Presence System, Model RP-VITA™ is a clinical communications tool that provides a means of transmitting, receiving, and storing real-time audio and video, and patient data. The Remote Presence System, Model RP-VITA™ may also be used in conjunction with 510(k)-cleared devices that transmit patient biometric data including vital signs information. The Remote Presence System, Model RP-VITA™ transmits and receives information over a high speed connection between patients, and health professionals. The Remote Presence System, Model RP-VITA™ can be used in communications for active patient monitoring in high acuity clinical environments where immediate clinical action may be required, e.g., pre-, peri-operative and post-surgical, cardiovascular, neurological, pre-natal, psychological and critical care assessments and examinations. Clinical judgment and experience are required to review and interpret the information transmitted.

Comparison with Predicate Device

A substantial equivalence table comparing the InTouch Remote Presence System, Model RP-VITA™ to the predicate device is provided below.

Table 5-1: Substantial Equivalence Comparison Table

	New Device	Predicate Device
510(k) #	To be assigned	K120895
Company	InTouch Health	InTouch Health
Name/Model #	Remote Presence System, Model RP-VITA™	Remote Presence System, Model RP-7i®
Indications for use	The Remote Presence System, Model RP-VITA™ is a clinical communications tool that provides a means of transmitting, receiving, and storing real-time audio and video, and patient data. The Remote Presence System, Model RP-VITA™ may also be used in conjunction with 510(k)-cleared devices that transmit patient biometric data, including vital signs information. The Remote Presence System, Model RP-VITA™ transmits and receives information over a high-speed connection between patients and health professionals. The Remote Presence System, RP-VITA™ can be used in communications for active patient monitoring in high acuity clinical environments where immediate clinical action may be required, e.g., pre-, peri-operative and post-surgical, cardiovascular, neurological, pre-natal, psychological, and critical care assessments and examinations. Clinical judgment and experience are required to review and interpret the information transmitted.	The Remote Presence System is a clinical communications tool that provides a means of transmitting, receiving, and storing real-time audio and video, and patient data. The Remote Presence System may also be used in conjunction with 510(k)-cleared devices that transmit patient biometric data, including vital signs information. The Remote Presence System transmits and receives information over a high-speed connection between patients, health professionals and critical transport teams. The Remote Presence System can be used in communications for active patient monitoring in high acuity clinical environments where immediate clinical action may be required, e.g., pre-, peri-operative and post-surgical, cardiovascular, neurological, pre-natal, psychological, and critical care assessments and examinations. Clinical judgment and experience are required to review and interpret the information transmitted.
Intended use	Telemedicine system	Telemedicine system
Intended users	Healthcare professional, inpatient, outpatient	Healthcare professional, inpatient, outpatient
Site of use	Hospital, clinic	Hospital, clinic, patient transport
Data collection software	Proprietary software	Proprietary software
Communication method with remote care management system	Broadband internet connection	Broadband Internet connection

K123229 pg. 4 of 5

	New Device	Predicate Device
510(k) #	To be assigned	K120895
Company	InTouch Health	InTouch Health
Name/Model #	Remote Presence System, Model RP-VITA™	Remote Presence System, Model RP-7i®
Types of devices that can be interfaced (wired or wirelessly) to receiver hub	Electronic Stethoscope (K102893) and other cleared medical devices that transmit patient data.	Electronic Stethoscope (K034046) and other cleared medical devices that transmit patient data.
Implementation method of collecting data from device	External communication device	External communication device
Sensor software	Additional object detection and collision avoidance software	Object detection and collision avoidance software
Connectivity	Wired, wireless to hub	Wireless to hub
Communication method of hub with devices	RS-232, Serial communication, USB	RS-232, Serial communication, USB, Bluetooth®
Communications protocol	Proprietary or Session Initiation Protocol	Proprietary or Session Initiation Protocol
Wireless frequency	802.11 A, B, G or N (varies based on the customer)	802.11 A, B, or G (varies based on the customer)
Power source	Batteries with AC-DC battery chargers built in	Batteries with AC-DC battery chargers built in
Display	VGA Monitors on computers and end points	VGA Monitor on computers and end points
Video conferencing	2-way video conferencing via a broadband internet or cellular connection	2-way video conferencing via a broadband internet or cellular connection

K123229 pg 5 of 5

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

NOV 2 0 2012

InTouch Health, Inc.
c/o Mr. Steve Sidwell
Director of Regulatory Affairs & Quality Assurance
6330 Hollister Avenue
Goleta, CA 93117

Re: K123229
Trade/Device Name: Remote Presence System, Model RP-VITA™
Regulatory Number: 21 CFR 870.2910
Regulation Name: Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulatory Class: II (two)
Product Code: DRG
Dated: October 12, 2012
Received: October 15, 2012

Dear Mr. Sidwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Applicant: InTouch Health, Inc.

510(k) Number: ~~Not assigned~~. K123229

Device Name: Remote Presence System, Model RP-VITA™

Indications for Use: The Remote Presence System, Model RP-VITA™ is a clinical communications tool that provides a means of transmitting, receiving, and storing real-time audio and video, and patient data. The Remote Presence System, Model RP-VITA™ may also be used in conjunction with 510(k)-cleared devices that transmit patient biometric data including vital signs information. The Remote Presence System, Model RP-VITA™ transmits and receives information over a high speed connection between patients, and health professionals. The Remote Presence System, Model RP-VITA™ can be used in communications for active patient monitoring in high acuity clinical environments where immediate clinical action may be required, e.g., pre-, peri-operative and post-surgical, cardiovascular, neurological, pre-natal, psychological and critical care assessments and examinations. Clinical judgment and experience are required to review and interpret the information transmitted.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
2012.11.20
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PREMARKET NOTIFICATION 510(k) SUMMARY
As required by 21 CFR §807.92(c)

JUL 30 2013

Submitter

510(k) Owner:	MedApps, Inc., DBA Alere Connect
Owner / Operator:	10027842
Registration:	3005916763
Address:	8767 E. Via De Ventura, Suite 300, Scottsdale, AZ 85258
Telephone:	480-305-6323
Fax Number:	480-305-6328
Contact Person:	Kent Dicks
Contact Person Title:	CEO
Date Prepared:	December 12, 2012

Device Information

Trade Name:	MedApps 2.0 - Remote Patient Monitoring System
Common Name:	Remote Patient Monitoring System
Classification Status:	Class II per regulations 870.2910
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG)

A. LEGALLY MARKETED PREDICATE DEVICE

Legally marketed predicate devices are:

K080798	Intel Health Guide PHS6000
K040966	Carematix Modified System
K083862	MedApps 2.0 - Remote Patient Monitoring System

B. INDICATIONS FOR USE

The MedApps (Alere Connect) 2.0 - Remote Patient Monitoring System consists of 1) a cellular communication hub (MedApps' HealthPAL or MobileLink) an over-the-counter device that resides with the end-user (patient), which connects to commercially available FDA cleared accessory devices, specifically glucose meters, scales, blood pressure monitors, pulse oximeters, and PT/INR monitors and 2) web-based health data management application (MedApps' HealthCOM), that provides access to collected data stored on a secure host server system.

MedApps Inc., DBA Alere Connect Remote Patient Monitoring devices receive and store measurements collected from the described accessory devices, either wirelessly using short-range radio protocols (e.g. Bluetooth, Zigbee, WiFi, Bluetooth Low Energy (BLE), Fitlinxx Radios) or tethered via cable (e.g. USB, serial, etc). Regardless of connectivity mode, the MedApps / Alere Connect monitoring devices do not alter the indications for use of the described peripheral accessory health devices.

MedApps/Alere Connect devices indicate successful or failed data reception and transmission with visual and audio feedback using a combination of any of the following: OLED Display, LED Lights, verbal messages, and/or audio tones/chimes. MedApps/Alere Connect devices store collected data and forward/transmit to server for access in HealthCOM via commercially available, FCC compliant, wireless telecommunication protocols (including but not limited to cellular GSM, CDMA and WiMax).

Healthcare professionals, clinicians and other authorized personnel can review the transmitted information within the MedApps HealthCOM system, where they can review collected readings, establish parameters to indicate readings exceptions to set thresholds, or trigger Interactive Voice Response (IVR) messages to the patient remotely to issue information such as reminders (e.g. "We haven't received readings from you today, please take and send your readings") or possibly educational information for conditions such as diabetes, hypertension, CHF, etc. Additionally, HealthCOM can port collected data to the healthcare providers' clinical back-end system(s) of choice.

The MedApps 2.0 (Alere Connect) - Remote Patient Monitoring System is not intended for diagnosis or as a substitute for medical care, nor is it intended to provide real-time / time-critical data. The device is contraindicated for patients requiring direct medical supervision or emergency intervention.

C. MedApps 2.0 SYSTEM DESCRITPION

The MedApps 2.0 - Remote Patient Monitoring System consists of:

(1) HealthPAL hardware:

The physical component of the HealthPAL is an electronic device contained in a plastic enclosure with an OLED screen, built-in M2M cellular chip, speaker, smart cable connection, smart cables, wireless module, LED lights to indicate activity, timer button to assist patients with their reading schedule (i.e. remind them to take their reading in X minutes), last reading button, volume up and down buttons. The HealthPAL Model 105 contains a GSM cellular module while the HealthPAL Model 106 contains a CDMA cellular module.

(2) HealthHUB hardware / software:

The HealthHUB hardware is an extension of the HealthPAL functionality. HealthHUB acts as a "docking" station for the HealthPAL in order to act as a conduit for the AC power adaptor connecting the electrical wall outlet to the HealthPAL providing power and battery charging capability. The Hubs also provide additional connections to off the shelf Glucose Meters, Scales, Blood Pressure Monitors and Pulse Oximeters, via smart cables (per validated in HealthPAL software). The HealthHUB model MA200 allows for multiple wired connections for accessory devices. HealthHUB Model 205 is specific for the HealthPAL MA105, and the HealthHUB 206 is specific for the HealthPAL MA 106 with both Hubs having one wired connector.

(3) HealthPAL firmware / software:

The firmware captures data from commercially available health monitors, and stores and transmits the information to the HealthCOM server, via the embedded communication chip / platform.

The firmware allows HealthPAL to receive information via wire or via embedded wireless module from accessory medical devices that are compatibly wireless enabled, which have been paired to the MedApps HealthPAL.

The firmware has many additional functions including:

- Download of user profiles from the server to configure HealthPAL remotely.
- HealthPAL has audio capability to deliver verbal announcement of readings and acknowledgment of data transmission from all connected accessory medical devices, time settings, volume control, educational content and reminders, in any language that is loaded to the device.
- Timer capability, activated by the user to provide assistance with adhering to a reading schedule (reminders to take readings within a set timeframe).
- OLED screen displays information regarding the HealthPAL's status including battery level, volume level, data transmission status, transmission pending indicator, activity icons / messages and other information to provide ease of use and promote patient adherence; as well as information received from accessory medical devices, such as the type of device, measurement, date and time of the last reading collected.
- Battery charging, isolation circuits, and interfaces to individual accessory medical devices / protocols via the smart cable.

(4) MobileLink (formally HealthAIR) hardware / software:

AC020 MobileLink is a modified MA105 HealthPAL device. The physical component of the MobileLink is an electronic device contained in a plastic enclosure with built-in M2M cellular chip, speaker, standard USB cable and USB Smart Cable connection, OLED screen to review the reading, and LED lights to indicate activity regarding the receiving and transmitting of collected data.

Like the HealthPAL, MobileLink's firmware / software captures, data from commercially available retail health monitors, and stores and transmits information to the HealthCOM server, via the embedded communication chip / platform.

The firmware allows MobileLink to receive information via wire, either standard USB or with a customized USB Smart Cable, from accessory medical devices.

The firmware has many additional functions including:

- Download of user profiles from the server to configure MobileLink remotely.
- MobileLink's Audio feature uses audio tones to indicate acknowledgment of collected readings from all connected accessory

medical devices as well as reading transmission via the cellular network.

- MobileLink's visual user interface utilizes an OLED display to display collected readings from attached accessory medical devices as well as reading transmission acknowledgements. MobileLink's visual interface also contains a LED light to show power and provide reading request indication capability.

(6) MedApps HealthCOM software application:

The HealthCOM software application allows caregivers access to review patient data collected from accessory medical devices using MedApps hardware on the secure HealthCOM website. HealthCOM software allows professional caregivers to set patient readings.

HealthCOM software also allows the patient to establish an account and to direct / authorize their data to be directed to an outside, validated Personal Health Record (PHR), Electronic Health Record or Medical Record (EHR or EMR).

(7T) MedApps IVR software application:

The IVR (Interactive Voice Response) software application provides the ability to contact the patient remotely, by phone (designated in the user profile), and executes an pre-approved ("canned") scripts to deliver pre-approved ("canned") reminder messages ("Your nurse would like to talk to you, can I connect you now", "We haven't received a reading from you today, please send us your readings"), educational content and gather survey information.

In addition, the MedApps IVR application will send out Email, SMS / Text Messages, Paging, IM and other forms of communications in order to contact patients or caregivers. This will include reminders and alerts, based on clinically defined parameters / thresholds established in HealthCOM by the professional care provider.

The MedApps 2.0 - Remote Patient Monitoring System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention.

D. TECHNOLOGICAL CHARACTERISTICS SUMMARY – as required by 807.92(a)(6)

Feature	**Intel Health Guide PHS6000** **K080798**	**Carematix Modified System** **K040966**	**MedApps Submission** **K083862**	**MedApps 2.0 Submission** **K124000**
Indications of Use	Enables healthcare providers to monitor and manage chronic conditions of patients remotely	Physiological monitoring system that collects, accumulates and transmits patient vital isgnes and other physiological data from a patient who may be remote form the	The MedApps 2.0 - Remote Patient Monitoring System consists of a patient device, MedApps HealthPAL, ...	Same as MedApps with the exception of updates to include MobileLink device and PT/INR monitors
Intended Use	Telemedicine System	Telemedicine System	Telemedicine System	Same as PHS6000, Carematix, and MedApps
Intended Users	Home users and Healthcare providers	Same	Same	Same
Site of Use	Home & Clinic	Same	Same Home (HealthPAL) Clinic (HealthCOM)	Same Home (HealthPAL/ MobileLink); Clinic (HealthCOM)
Data Collection Software	Intel Care Management Suite Software	Proprietary Software	MedApps Proprietary Software	MedApps Proprietary Software
Data Collection Software Functionality	Transmit data from Sensor devices to Central	Same	Same	Same
Communication method of hub with Central Server	Via DSL or Phone Line Connection	Via modem over telephone line	Via Embedded Cellular Technology	Via Embedded Cellular Technology
Types of sensors which can be interfaced (wired or wirelessly) to receiver hub	Medical Devices designed for Home: Glucose Scale Blood Pressure Pulse Ox Peak Flow	Medical Devices designed for Home use: Glucose, Scale Blood Pressure Pulse Ox, FEX/PEF,PT/INR Temperature	Medical Devices designed for Home use: Glucose,Scale Blood Pressure Pulse Ox	Same as MedApps (Glucose, Scale, BP, Pulse Ox with PT/INR) Same as CareMatix
Maximum number and type of measurement devices that can be connected to the devices	Determined by vital sign devices that are designed for Home use, and have a data port. (Wireless or Wired)	Same	Same	Same

MedApps, Inc., DBA Alere Connect
510(k) SUMMARY

Feature	Intel Health Guide PHS6000 K080798	Carematix Modified System K040966	MedApps 2.0 Submission K083862	MedApps 2.0 Submission K124000
Maximum data throughput under worst case conditions	Multiple readings are stored on the medical devices and act as a backup if data needs to be re-sent to the server	Same	Same	Same
Time Delay in the processing of data collected and transmitted	Readings stored in the medical devices can be sent up to the server when the connection is restored.	Same	Same	Same
Implementation method of collecting data from sensors	Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables.	Modify OTS sensors with previous 510k approval by adding communications	Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables.	Short range radio system using Wired (tethered)
Sensor Software	Sensor Software unchanged	Same	Same	Same
Connectivity	Short range radio system using Bluetooth and Wired (tethered) cables.	Wired or wireless to hub	Short range radio system using Bluetooth and Wired (tethered) cables.	Short range radio system using Wired (tethered)
Communication method of hub with devices	Short range radio system using Bluetooth and Wired (tethered) cables.	Wireless RF protocol	Short range radio system using Wireless (Bluetooth) and Wired (tethered) cables.	Short range radio system using Wired (tethered)
Communications Protocol	Bluetooth V2.0 and Wired (Tethered)	Proprietary	Wireless (Bluetooth) V2.0 and Wired (Tethered)	Wired (Tethered)
Communication Frequency	Bluetooth : 2.402 to 2.480 GHz	915 MHz FCC assigned channel	Bluetooth : 2.402 to 2.480 GHz (HealthPAL) GSM: 850 / 900 / 1800 / 1950 Mhz	(HealthPAL or MobileLink) GSM: 850 / 900 / 1800 / 1950 Mhz
Power Source	Wall power plug (120 VAC/50-60)	Wall power plug (120 VAC/50-60) and Batteries in Device	Wall power plug (120 VAC/50-60) or Rechargeable Battery (HealthPAL)	Wall power plug (120 VAC/50-60) or Rechargeable Battery (HealthPAL or MobileLink)
Display	On devices and hub, and monitors connected to central server	Same	Same	Same

Communication with Patients	On screen display	Same	On screen display of Readings, Voice Output and Interactive Voice	On screen display with audio tones instead of voice.
Use of Thresholds / Algorithms for determining how Thresholds are set and changed	Thresholds are set by Healthcare professionals in Server Software	Same	Same	Same
Information presented to the user, if it is different from that presented by the measurement devices	On screen display	Same	Audio/visual reading feedback on screen and by speaker; and Interactive Voice Response (IVR) System for patient contact	Visual reading feedback on screen and audio tone by speaker; and Interactive Voice Response (IVR) System for patient contact
Messages and Instructions that can be sent to the User.	On screen display	Same	On screen display of Readings, Voice Output and Interactive Voice Response (IVR)	On screen display of Readings, Voice Output and Interactive Voice Response (IVR)

MedApps, Inc., DBA Alere Connect
510(k) SUMMARY

Below is a Technological Characteristics Summary Comparison between the MA105 HealthPAL and the AC020 MobileLink medical devices:

Feature	MA105 HealthPAL	AC020 MobileLink
Indications of Use	Enables healthcare providers to monitor and manage biometirc patient data collected remotely	Same
Intended Use	Telemedicine System	Same
Intended Users	Home users and patients outside of the clinical setting, as well as Healthcare providers for HealthCOM	Same
Site of Use	Remote setting (e.g. Home / Work), Clinic	Same
Data Collection Software & firmware	MedApps Proprietary Software	Same
Data Collection Software Functionality	Transmit data from Sensor devices to Central Database	Same
Communication method of device hub with Central Server	Via Embedded Cellular Technology (GSM or CDMA)	Same
Types of sensors which can be interfaced (wired or wirelessly) to receiver hub	Medical Devices designed for Home use: Glucose, Scale, Blood Pressure Pulse Ox (adding PT/INR with this submission)	Same
Transmission	Transmits information to the MedApps secure host server called "HealthCOM"	Same
Implementation method of collecting data from sensors and general Connectivity	Short range radio system using Wireless (Bluetooth) and Wired / tethered (Smart Cables).	MobileLink uses wired / tethered connection (USB, Smart Cables)
Communication method of hub with devices	Short range radio system using Wireless (Bluetooth) and Wired / tethered (Smart Cables).	MobileLink uses wired / tethered connection (USB, Smart Cables)
Communication Frequency	Bluetooth : 2.402 to 2.480 GHz GSM: 850 / 900 / 1800 / 1950 Mhz	No Bluetooth capability GSM: 850 / 900 / 1800 / 1950 Mhz
Power Source	AC adaptor Wall power plug (120 VAC/50-60) and Rechargeable Batteries in Device	AC Adaptor that is 60601-1 3rd Edition compatible with Lithium battery only used for soft shut down functionality and not powering device.
Device Communication with Patients	On screen display and audio voice feedback	On screen display with audio tones instead of voice.
Certification Testing	Safety 60601-1, EMC/EMI/FCC (60601-1-2), ESD & Radiated Immunity, FCC Bluetooth, (PTCRB), CTIA (battery), ETSI	Safety 60601-1 3rd Edition, EMC/EMI/FCC (60601-1-2), ESD & Radiated Immunity, (PTCRB- in process), ETSI *(See Declaration of Conformity)*

Data Collection:
The 2 predicate devices and the MedApps solution connect to medical devices (designed for home use) by either wired (cable) connection or wireless (HealthPAL- Bluetooth). The data is collected from the devices and sent to a secure central server using various communication methods.

Telecommunication Platform to Central Server:
Intel Health uses DSL connectivity (wired point of care), Carematrix uses modem off telephone line; MedApps uses embedded Machine to Machine (M2M) module to transmit data via cellular connectivity.

Patient Feedback Technology:
The 2 predicate devices and the MedApps solution allow data and messages to be displayed on a screen (for the HealthPAL) for the patient to read and acknowledge. MobileLink also uses audio and visual acknowledgement / feedback. The MedApps solution also uses an Interactive Voice Response (IVR) system in order to communicate with the patient and ask questions, gather survey information, or issue reminders.

Backend Data Storage:
All systems (both 2 predicate devices and the MedApps solution), provide a backend system that allows data to be stored, and healthcare professionals to access and monitor collected patient data.

Types of sensors which can be interfaced (wired or wirelessly) to receiver hub:
CareMatix Modified System and the proposed MedApps 2.0 System both include PT/INR monitor as an FDA cleared accessory device to the receiver hub. The CareMatix uses wireless connectivity to the hub whereas the MedApss 2.0 systems uses both wired and wireless connectivity to the hub. CareMatix System 510k (K040966) clearance summary letter includes the predicate Avid Care (K011779 and K010029) telemedicine system that connects to PT/INR monitor as an accessory device.

E. NON-CLINICAL PERFORMANCE DATA TESTING AND REVIEW – as required by 807.92(b)(1)

Non-Clinical Testing
The submitted 2.0 System has undergone MedApps' design control verification and validation testing. MedApps 2.0 validation testing include testing of all executable code and functionality and confirmation that all identified risks have been adequately addressed by software functionality, the user interface, documentation or user SOP.

MedApps 2.0 System verification and validation activities as part of the design control process include testing of all Design Specifications (Design Control Inputs) based on risk analysis, certification standards, and Verification plans. MedApps Product Verification and Release Plan execution on both HealthPAL and MobileLink ensure both medical devices work with each type of user accessory medical device (glucose, blood pressure monitor, scale, pulse oximeter and PT/INR) as part of the MedApps 2.0 System including integration to HealthCOM backend software application. The output of these design control verification analysis documents **MedApps 2.0 - Remote Patient Monitoring System** shall meet its requirements and design specifications as intended.

Lastly, all relevant certification testing such as EMC (60601-1-2) and Safety (60601-1) are described in MedApps' Declaration of Conformity.

F. SUBSTANTIAL EQUIVALENT

The MedApps 2.0 Remote Patient Monitoring System is substantially equivalent to the predicate devices in terms of data collection software functionality, operating system for the patient device, communication method of patient device with central server, types of sensors which can be integrated to the patient medical device, implementation methods of collecting data from sensors, sensor software, connectivity, communication protocol, power source and general display method.

The MobileLink (formally called HealthAIR communication hub device, described in 510(k) K112559) is substantially equivalent to the HealthPAL (described in 510(k) K083862) as both devices, as part of the MedApps 2.0 System, connect to commercially available Glucose Meters, Scales, Blood Pressure Monitors, Pulse Oximeters, and PT/INR; data is collected, stored and transmitted using off-the-shelf FCC approved wireless / cellular connectivity. Both provide audio and visual feedback / acknowledgement that readings have been collected and transmitted to MedApps' secure host server called "HealthCOM".

G. SAFETY AND EFFICACY

The MedApps 2.0 Remote Patient Monitoring System does not rely on an assessment of clinical performance data. The device conforms to FDA's recognized consensus standards and relies on its conformity to demonstrate its safety and efficacy. The device does not introduce any new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 30, 2013

MedApps, Inc. DBA Alere Connect
C/O Mr. Kent E. Dicks
CEO
8767 E. Via De Ventura, Suite 300
Scottsdale, AZ 85258

Re: K124000
Trade/Device Name: MedApps 2.0 Remote Patient Monitoring System
Regulation Number: 21 CFR 870.2910
Regulation Name: Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulatory Class: Class II
Product Code: DRG
Dated: January 18, 2013
Received: July 3, 2013

Dear Mr. Kent E. Dicks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MedApps, Inc., DBA Alere Connect
STATEMENT OF INDICATIONS FOR USE

510(k) Number: K124000_____

Preparation Date: December 12, 2012

Device Name: **MedApps (Alere Connect) 2.0 - Remote Patient Monitoring System**

Indications For Use:

The MedApps (Alere Connect) 2.0 - Remote Patient Monitoring System consists of 1) a **cellular communication hub** (MedApps' HealthPAL or MobileLink) an over-the-counter device that resides with the end-user (patient), which connects to commercially available FDA cleared accessory devices, specifically glucose meters, scales, blood pressure monitors, pulse oximeters, and PT/INR monitors and 2) web-based health data management application (MedApps' HealthCOM), that provides access to collected data stored on a secure host server system.

MedApps Inc., DBA Alere Connect Remote Patient Monitoring devices receive and store measurements collected from the described accessory devices, either wirelessly using short-range radio protocols (e.g. Bluetooth, Zigbee, WiFi, Bluetooth Low Energy (BLE), Fitlinxx Radios) or tethered via cable (e.g. USB, serial, etc). Regardless of connectivity mode, the MedApps / Alere Connect monitoring devices do not alter the indications for use of the described peripheral accessory health devices.

MedApps / Alere Connect devices indicate successful or failed data reception and transmission with visual and audio feedback using a combination of any of the following: OLED Display, LED Lights, verbal messages, and / or audio tones / chimes. MedApps / Alere Connect devices store collected data and forward / transmit to server for access in HealthCOM via commercially available, FCC compliant, wireless telecommunication protocols (including but not limited to cellular GSM, CDMA and WiMax).

Healthcare professionals, clinicians and other authorized personnel can review the transmitted information within the MedApps HealthCOM system, where they can review collected readings, establish parameters to indicate readings exceptions to set thresholds, or trigger Interactive Voice Response (IVR) messages to the patient remotely to issue information such as reminders (e.g. "We haven't received readings from you today, please take and send your readings") or possibly educational information for conditions such as diabetes, hypertension, CHF, etc. Additionally, HealthCOM can port collected data to the healthcare providers' clinical back-end system(s) of choice.

The MedApps 2.0 (Alere Connect) - Remote Patient Monitoring System is not intended for diagnosis or as a substitute for medical care, nor is it intended to provide real-time / time-critical data. The device is contraindicated for patients requiring direct medical supervision or emergency intervention.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use_____X_____
(Per 21 CFR 801.109)

Digitally signed by
Owen P. Faris -S
Date: 2013.07.30
09:07:15 -04'00'

SECTION 5

JUL 19 2013

510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS FOR
Multi-Parameter Mobile CareGuide™ 3100 Oximeter

Submitter Information

Name:	Reflectance Medical, Inc. (RMI)
Address:	116 Flanders Road, Suite 1000 Westborough, MA 01581 USA
Telephone Number:	508.366.4700
Registration Number:	NA (RMI will apply for registration number following 510(k) clearance, prior to commencement of commercial shipment.)
Contact Person:	Dr. Babs Soller
Telephone Number:	508.366.4700, Ext 223
Fax Number:	508.366.4770
Email:	Babs.Soller@reflectancemedical.com

Date Prepared:	June 12, 2013

Device Name

Trade name of New Device:	Multi-Parameter CareGuide™ Oximeter
Model Number:	3100
510(k) Holder/Submitter:	Reflectance Medical, Inc. (RMI)
510(k) Number:	N/A
Proposed Additional product codes:	CBZ, 21 C.F.R. § 868.1170, Anesthesiology
Classification Panel:	Anesthesiology

Predicate Devices

Predicate Device #1:	Multi Parameter Catheter
Trade name of Device:	Paratrend™ Multi parameter Sensor and Satellite Monitor System with Paratrend 7 Plus multi-parameter catheter
Model #:	7
510(k) holder/Submitter:	Diametrics Medical Limited

510(k) Number:	K970906
Product codes:	CBZ, 21 CFR 868.1170, Anesthesiology
Predicate Device #2:	Terumo Khuri
Trade name of device:	Terumo Khuri™ Myocardial pH Monitoring System
Model #:	N/A
510(k) holder/Submitter:	Terumo Cardiovascular Systems Corporation
510(k) Number:	K020967
Product codes:	CBZ, 868.1170, Anesthesiology
Predicate Device #3:	Masimo multi-parameter oximeter
Trade name of Device:	Rainbow SET™ Radical 7 Co-oximeter
510(k) holder/Submitter:	Masimo Corporation
510(k) Numbers:	K080238, K061204
Product Codes:	DQA, 21 CFR 870.2700, Anesthesiology JKS, 21 CFR 862.3220, Clinical Toxicology DPZ, 21 CFR 870.2710, Cardiovascular (K080238)
Predicate Device #4:	CareGuide
Trade Name of Device:	Mobile CareGuide Oximeter
Model #:	1100, 2100
510(k) Holder/Submitter:	Reflectance Medical Inc.
510(k) Number:	K113656, CareGuide 1100 K122645, CareGuide 2100
Product code:	MUD, 21 CFR 870.2700, Cardiovascular

Device Description

The Multi-Parameter Mobile CareGuide 3100 Oximeter sensor uses Near Infrared (NIR) Spectroscopy to calculate muscle oxygen saturation (SmO_2) and muscle pH (pHm).

Characteristics	Reflectance Medical Multi-Parameter Mobile CareGuide 3100 Oximeter
Principle of Operation	NIR spectroscopy
Components	Monitor with reusable sensor and disposable pad
Light Source	LEDs
Parameters Measured	Tissue oxygen saturation (SmO_2) and muscle pH (pHm)

The Multi-Parameter Mobile CareGuide 3100 Oximeter is a multiple parameter oximeter. The sensor contains algorithms that calculate SmO_2 and pHm from collected spectra and communicates the current SmO_2 and pHm results to a 3rd party display or patient monitor through a proprietary protocol. The Multi-Parameter Mobile CareGuide 3100 Oximeter reusable sensor contains the optical and electronic elements necessary to collect spectra from skin, fat and muscle. The sensor has a 3m long cord with either a USB connection or CAN connection to the 3rd party display/patient monitor. The sensor is identical to the predicate (K122645) Mobile CareGuide 2100 Oximeter hardware containing six major components: (1) light sources to illuminate the skin; (2) a spectroscopic detector to analyze the reflected spectra back from the subject; (3) a microprocessor to control the optical components; (4) a microprocessor to perform the spectral analysis and generate the calculated SmO2 and pHm; (5) one of two different communications components to transmit in CAN or USB format; (6) a battery to power all components. The Multi-Parameter Mobile CareGuide 3100 Oximeter uses the same disposable element as the Mobile CareGuide 2100 Oximeter, a disposable sleeve that isolates the sensor optical elements from the patient's skin.

Indications for Use

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on a third party device, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB or CAN connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter provides output of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter should not be used as the sole basis for diagnosis or

therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter has not been demonstrated in disease states.

Rationale for Substantial Equivalence

This device's oximetry feature has been already cleared under classification regulation 21 C.F.R § 870.2700, Oximeter. The remaining component of the device is pH (21 CFR 868.1170)-.

The Multi-Parameter CareGuide 3100 has the same intended use as one of the identified predicates, the Terumo Khuri Regional pH monitor (K020967).

There is no change in how the User would use the information generated by the Multi-Parameter Care Guide 3100 relative to the predicate devices. They are all intended for monitoring of respective parameters. Neither the Multi-Parameter CareGuide 3100 nor any of the predicate devices identified by RMI provide diagnostic output.

The Multi-Parameter CareGuide 3100 has the same principle of operation (an optical technological platform that relies on light absorption) as the Paratrend 7 Sensor (pH) (K970906) predicate device. The Multi-Parameter Mobile CareGuide 3100 includes a sensor and monitor and, outputs a numeric trend like these predicate devices.

While the optical technology used in the Multi-Parameter CareGuide 3100 is not identical to that of the Paratrend monitor, the accuracy of the CareGuide 3100 is comparable to that predicate device. Much like the testing strategy used by other multi-parameter monitors, accuracy of the CareGuide 3100 was established via a bridging study, comparing CareGuide 3100 values against direct blood measurements using a laboratory analyzer.

The Multi-Parameter CareGuide 3100 also has the same technological characteristics as the previously cleared RMI devices, the CareGuide 1100 (K113656) and the Mobile CareGuide 2100 (K122645).

- The principle of operation of the Multi-Parameter Mobile CareGuide 3100 Oximeter is identical to that of the predicate CareGuide devices. They use the exact same NIR spectroscopic platform to measure tissue oxygen saturation and muscle. The same software quantitative algorithm for SmO2 is used in both devices.
- The Multi-Parameter Mobile CareGuide 3100 Oximeter is equivalent to the Mobile CareGuide 2100 predicate in reusable components. Both devices use the exact same sensor hardware: main sensor CPU board, battery, optical board (light sources, spectrometer and microprocessor), CAN/USB interfaces, plastic housing and cables.
- The Multi-Parameter Mobile CareGuide 3100 Oximeter is equivalent to the CareGuide predicates in disposable components. Both devices use the exact same disposable sheath ("Ray") and disposable sensor check device ("Cradle").

- The Multi-Parameter Mobile CareGuide 3100 Oximeter has the identical underlying LED light source as the CareGuide predicates, with the exact same range of wavelength (700-900 nm).

Summary of Safety and Effectiveness Data

Testing demonstrates that the Multi-Parameter Mobile CareGuide 3100 Oximeter is a safe and effective oximeter meeting all relevant consensuses and FDA recognized standards. The test results in this submission demonstrate that the Multi-Parameter Mobile CareGuide 3100 Oximeter meets the expected performance requirements for an Oximeter, and is therefore equivalent to the predicate relative to safety and mechanical properties. The accuracy and safety of the Multi-Parameter Mobile CareGuide 3100 Oximeter is the same as the predicate device.

Conclusion

The Multi-Parameter Mobile CareGuide 3100 Oximeter is equivalent to predicate device in terms of technology (NIR Spectroscopy) and intended use. The Multi-Parameter Mobile CareGuide 3100 Oximeter does not raise new questions of safety or effectiveness, as compared to the predicate. Therefore, the Multi-Parameter Mobile CareGuide 3100 Oximeter is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 19, 2013

Reflectance Medical, Inc.
c/o Ms. Nandini Murthy
116 Flaunders Road, Suite 1000
Westborough, MA 01581

Re: K130079
Trade/Device Name: Multi-Parameter Mobile CareGuide 3100 Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD CBZ
Dated: June 13, 2013
Received: June 18, 2013

Dear Ms. Nandini Murthy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K130079

Device Name: Multi-Parameter Mobile CareGuide™ 3100 Oximeter

Indications for Use:

The Multi-Parameter Mobile CareGuide™ 3100 Oximeter is intended for use as an adjunct, non-invasive monitor of the hemoglobin oxygen saturation and pH of microvascular blood in a region of skeletal muscle tissue beneath the sensor. The sensor may be positioned on pigmented skin. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended to allow for display of SmO2 and pHm data on a third party device, which would interface with the Multi-Parameter Mobile CareGuide 3100 Oximeter via USB or CAN connection. The Multi-Parameter Mobile CareGuide 3100 Oximeter is intended for prescriptive use (Rx only) by a trained healthcare professional in a hospital. The Multi-Parameter Mobile CareGuide 3100 Oximeter provides output of the most recent values of SmO2 and pHm in a trend, as well as operational device information. The Multi-Parameter Mobile CareGuide 3100 Oximeter should not be used as the sole basis for diagnosis or therapy. Note: The prospective clinical value of data from the Multi-Parameter Mobile CareGuide 3100 Oximeter has not been demonstrated in disease states.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Date: 2013.07.19 08:19:45 -04'00'

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

September 6, 2013

Alivecor, Inc.
Michael Righter
30 Maiden Lane, 6th Floor
San Francisco, CA 94108 US

Re: K130409
Trade/Device Name: Alivecor Heart Monitor
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: July 30, 2013
Received: August 6, 2013.

Dear Michael Righter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AliveCor

K130409

510(k) PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Names: AliveCor Heart Monitor

Indications for Use:

The *AliveCor Heart Monitor* is intended for use by licensed medical professionals or patients to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Date: 2013.09.06
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K130624
Page 1 of 5

510(k) Summary
GlobalMedia Group, LLC.
CONi™

MAY 0 7 2013

Date Prepared: January 8, 2013

Submitter's Information:

GlobalMedia Group, LLC
15020 N. 74th St.
Scottsdale, AZ 85260

Contact: Nicholas Campbell
Phone: (480) 398-7430
Fax: (480) 922-1090

Trade Name, Common Name and Classification:

Trade Name: CONi®
Device Classification Regulation: 892.2050 – Picture Archiving Communication System
Product Code: LLZ – System, Image Processing, Radiological

Predicate Device:

Trade Name: ALZ Web PACS (Version 1.0)
Device Classification Regulation: 892.2050 – Picture Archiving Communication System
Product Code: LLZ – System, Image Processing, Radiological
Applicant: ALZ, Inc.
510(k) Number: K081304

Device Description:

CONi (Capture Over Network Interface) is a secure cloud-based application for viewing and archiving medical images. The CONi software system is comprised of a Picture Archiving and Communication System (CONiPACS) and an image viewer (CONiView). CONi supports imaging studies from the following DICOM modalities: Computed Tomography (CT), Magnetic Resonance (MR), X-ray (CR), Ultrasound (US), and Visible Light (External Camera (XC) and Other (OT)). Images and information can be viewed and stored via a secure Internet connection.

Studies can be shared with a specialist at another facility quickly with a study-specific passcode. This facilitates remote consultation and expedites the study transfer process in emergency situations when a patient is being transported. No physical media such as CDs are needed because collaboration occurs entirely over an internet connection. Secondary over-triage can even be avoided.

Intended Use:

CONi provides for the archiving and viewing of medical images from the following DICOM modalities: Computed Tomography (CT), Magnetic Resonance (MR), X-ray (CR), Ultrasound (US), and Visible Light (External Camera (XC) and Other (OT)). Images and information can be viewed and stored via a secure Internet connection.

CONi is not intended for use in mammography.

Technological Characteristics and Substantial Equivalence

The proposed and predicate devices provide a web-based system for the archiving and viewing of medical images. The proposed and predicate devices are to be used with general purpose computing hardware to acquire, transmit, or view the stored medical images. Equivalent with the predicate device, CONi consists of a software application that is installed in a hosted server environment that will communicate with the client's PCs via an internet connection. Communication between the CONi application and client's PCs utilizes DICOM protocols and encrypted browser communications. Both the proposed and predicate devices are hosted by HIPAA compliant facilities. File acquisition, sending functions, and image view and manipulation are included in the proposed and predicate devices.

Substantial Equivalence Table:

	GlobalMedia Group CONi	**ALZ Web PACS (Version 1)**
Device Description	CONi (Capture Over Network Interface) is a secure cloud-based application for viewing and archiving medical images. The CONi software system is comprised of a Picture Archiving and Communication System (CONiPACS) and an image viewer (CONiView). Images and information can be viewed and stored via a secure Internet connection.	The ALZ Web PACS (Version 1.0) is designed for management, viewing, and processing of DICOM images. The ALZ Web PACS consists of the ALZ Web PACS software application installed on a server and the ALZ Web PACS viewer running on client computers connecting to the server via HTTPS protocol.
Regulation Number	892.2050	892.2050
Product Code	LLZ	LLZ
Intended Use	CONi provides for the archiving and viewing of medical images from the following DICOM modalities: Computed Tomography (CT), Magnetic Resonance (MR), X-ray (CR), Ultrasound (US), and Visible Light (External Camera (XC) and Other (OT)). Images and information can be viewed and stored via a secure Internet connection. CONi is not intended for use in	The ALZ Web PACS (Version 1.0) is an imaging software system intended to be used by trained healthcare professionals. ALZ Web PACS is used with general purpose computing hardware to acquire, transmit, store, view, and process DICOM images. The device is not intended for mammography.

	GlobalMedia Group CONi	ALZ Web PACS (Version 1)
	mammography.	
Technological Characteristics (Server)	Reliable hardware platform, preconfigured and pretested	Reliable hardware platform, preconfigured and pretested
	Multiple simultaneous DICOM associations	Multiple simultaneous DICOM associations
	Multi-modality, multi-vendor functionality and compatibility	Multi-modality, multi-vendor functionality and compatibility
	RIS incorporated	RIS incorporated
	Server monitored by GlobalMed and hosting site (FireHost)	Server instance monitoring
	Shared archive	Shared archive
	Studies are marked as reviewed after a report is written	Studies are marked as read after a DICOM query (this feature is set if client requests)
Technological Characteristics (Communication)	Not a feature	DICOM query/retrieve
	DICOM Worklist Client	DICOM Print client and DICOM Worklist client
	Automatic study routing based on administrative routing rules	Auto forward of data sets
	Compiles with DICOM standards	Complies with all HL7 and DICOM, standards
	Email notification upon arrival of new study or finished report	Email notification upon arrival of new study
	Not a feature	Emailing images as JPEG
Technological Characteristics (Licensing)	Supports all modalities except mammography	Available for all DICOM modalities
	Unlimited number of web users	Unlimited number of web users
Technological Characteristics (Web)	User-friendly web interface layout	User-friendly web interface layout
	Coherent overview of studies with search and filter possibilities	Coherent overview of studies with search and filter possibilities
	Automatic browser logout	Automatic browser logout
	Unlimited number of users and concurrent users	Unlimited number of users and concurrent users
	Display of all color/grayscale images	Display of all color/grayscale images
	PDF reports	Display of structured reports
	Transfer of images via web to DICOM destinations	Transfer of images via web to DICOM destinations
	Not a Feature	File attachments to images or studies
Technological Characteristics (Import)	Not a Feature	Import of any DICOMDIR media
	Not a Feature	Directory registration of DICOM data
Technological Characteristics (Export)	Not a Feature	DICOM export function by burning the DICOM images to a CD or by using a USB
Technological Characteristics	Automatic synchronization with remote servers	Automatic synchronization with remote servers

	GlobalMedia Group CONi	ALZ Web PACS (Version 1)
(Database)	Not a Feature	Configurable overflow management (high water/low water, study date, custom settings) if setting is requested by client
Technological Characteristics (Data Access)	Admin user	Admin user
	Predefined privileges for physicians, nurses, and technicians	Privilege settings for each user/group are customizable
	User access control	User access control
Technological Characteristics (Service)	No client software updates required	Software updates/upgrades optional
Technological Characteristics (Languages)	English, Spanish, and Portuguese	English
Technological Characteristics (Web Viewer)	Available to an unlimited number of viewers and concurrent viewers	Available to an unlimited number of viewers and concurrent viewers
	Viewing of any kind of images and PDF reports	Viewing of any kind of images and structured reports
	Center/window	Center/window
	Not a feature	Comparison of multiple studies
	Stack mode/cine mode	Stack mode/cine mode
	Not a Feature	Measurements (distance, ROI, angle)
	Thumbnail preview	Thumbnail preview
	Background preload	Background preload
	Supports DICOM compressions. Server does not compress DICOM files.	JPEG DICOM compressions vary per modality
Typical User	Trained professionals, physicians, nurses, clinicians and technicians.	Healthcare professionals
Software Level of Concern	Moderate	Moderate

Summary of Non-Clinical Tests

The following quality assurance measures were applied to the development of the CONI system:

- Establishment of Requirements
- Risk Analysis (software and system)
- DICOM Standard Conformance Statement
- HIPAA Compliance Statement
- Software Unit Testing
- Software Integration Testing
- Software System Testing
- Software Hazard Testing

Safety and Effectiveness Summary

The CONi software application provides a safe and secure location for the archiving and

viewing of medical images. CONi does not diagnosis any medical condition and is intended to be used by trained individuals. The software utilizes DICOM communication protocols and has been designed and tested to meet HIPAA requirements. CONi does not control the function of any other medical device. GlobalMedia Group considers the CONi software application to be as safe and effective for use as the previous cleared predicate device.

Conclusion

The GlobalMedia Group CONi software application has similar functionality, intended use, technological characteristics, and typical users as the predicate device. As a result, the CapSure software application will fall under the same FDA classification number and product code as the predicate device. The GlobalMedia Group CONi software introduces no new issues or concerns of safety and effectiveness, and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 7, 2013

Globalmedia Group LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K130624
Trade/Device Name: CONi™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 23, 2013
Received: April 24, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130624

Device Name: CONi®

Indications for Use:

CONi provides for the archiving and viewing of medical images from the following DICOM modalities: Computed Tomography (CT), Magnetic Resonance (MR), X-ray (CR), Ultrasound (US), and Single Frame Visible Light Photography (External Camera (XC) and Other (OT)). Images and information can be viewed and stored via a secure Internet connection.

CONi is not intended for use in mammography.

CONi is not intended for diagnostic use on mobile devices

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) _____ K130624_____

JUL 0 8 2013

510(k) SUMMARY

510(k) Owner:	Arrayent Health LLC /dba Ambio Health	
	Contact: Kevin Jones, CEO	
Date Summary Prepared:	March 15, 2012	
Device:	Trade Name:	Ambio Remote Health Monitoring System
	Common/Classification Name:	Remote Patient Monitoring System
	Classification:	Class II
Predicate Devices:	K062377 MedApps 2.0 – Remote Patient Monitoring System K111932 Positive ID – iglucose[tm] Device, Secure Database, Diabetes Management Portal K080798 Intel Health Guide PHS6000	

Intended Use: The Ambio Remote Health Monitoring System ("System") consists of Ambio Wireless Connectors to send readings from off-the-shelf blood pressure and blood glucose meters, the Ambio Scale with built in wireless connectivity to send readings through the Ambio Gateway to the Ambio Care Portal. The Care Portal is used by patients and their authorized caregivers ("Users") to view readings, set reminders, set personalized thresholds which will trigger alert messages. Reading history can be printed or exported. Users can set goals and rewards for taking readings per their schedule and for achieving reading targets. Users can maintain an exercise log, food log and records of doctor visits and lab tests. Users can create patient surveys to gather qualitative information. Users can coordinate using a shared calendar and message board. Health information from accredited sources can also be displayed.

The Ambio Remote Health Monitoring System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention. The System does not alter the indicated use of the described blood pressure or blood glucose monitors.

System Description:

The System consists of:

(1) Ambio Wireless Connectors (Wireless Connectors):

The Wireless Connector is an electronic device that plugs into the USB port of compatible Blood Pressure Monitors and Blood Glucose Monitors to read the log, encrypt the data, and wirelessly transmit the data to the Ambio Gateway. Readings are sent automatically based on a schedule stored in the Wireless Connector or, the User can push the button on the Wireless Connector to initiate reading the Monitor log and transferring the data.

(2) Ambio Scale

The Ambio Scale is a stand on digital weight scale with an embedded Ambio Wireless Connector. When the User takes a weight reading, it is then encrypted by the Ambio Wireless Connector and wirelessly transmitted to the Ambio Gateway.

(3) Ambio Gateway

The Ambio Gateway is an electronic device that connects to the Patient's existing home Internet router using an Ethernet cable. The Ambio Gateway wirelessly receives encrypted data from the Ambio Wireless Connector and transmits it through the user's home broadband internet router to the Ambio Care Portal.

(4) Ambio Care Portal

The Ambio Care Portal is a secure, web based data base and software application that allows Users to review patient data collected from the described health devices using the Ambio Wireless Connector and Ambio Gateway.

The Care Portal is used by patients and their authorized caregivers ("Users") to view readings, set reminders, set personalized thresholds which will trigger alert messages. Reading history can be printed or exported. Users can set goals and rewards for taking readings per their schedule and achieving readings target. Users can maintain an exercise log, food log and records of doctor visits and lab tests. Users can create patient surveys to gather qualitative information. Users can coordinate using a shared calendar and message board. Health information from accredited sources can also be displayed.

Technological Characteristics: The operation of the System is the same as the predicate devices in all respects other than the wireless protocol and frequency used to communicate readings from the health meter / Wireless Connector to the Gateway. Predicate devices use Bluetooth (2.402 to 2.48 GHz) or GSM Cellular (850 / 900 / 1800 / 1950 MHz) as the wireless technology and the subject device uses the 900MHz (902 – 928MHz) band approved by the FCC for unlicensed communication equipment.

Attribute	**MedApps Remote Patient Monitoring Device** **K112559**	**IDEAL LIFE Pod** **K080538**	**Positive ID Iglucose System** **K111932**	**Subject Device (Ambio Health Remote Health Monitoring System)**
Indications of Use	Enables healthcare providers to monitor and manage chronic conditions of patients remotely Flag readings based on specific thresholds being exceeded. Maintain compliance to schedules. Graphic trending.	Enables people at home and healthcare providers to review and evaluate historical blood glucose, weight and blood pressure test results	Enables people at home and healthcare providers to review and evaluate blood glucose data as an aid in supporting diabetes management. Graphic trending.	Enables people at home and healthcare providers to monitor and manage chronic conditions of patients remotely Flag readings based on specific thresholds being exceeded. Maintain compliance to schedules. Graphic trending.
Intended use	Telemedicine System	Same	Same	Same
Intended Users	Home users and Healthcare Providers	Same	Same	Same
Site of Use	Home, Clinic	Same	Same	Same

Data Collection Software Functionality	Transmit data from sensor devices to Central Database	Same	Same	Same
Communication method of hub with Central Server	Cellular	Internet or Telephone line	Cellular	Internet
Types of sensors which can be interfaced (wired or wirelessly) to receiver hub	Medical Devices designed for Home Use: Glucose Scale Blood Pressure PulseOx	Medical Devices designed for Home Use: Glucose Scale Blood Pressure	Medical Device design for Home Use: Glucose	Medical Devices designed for Home Use: Glucose Scale Blood Pressure
Sensor Software	Sensor Software unchanged	Same	Same	Same
Implementation Method of collecting data from sensors	Wireless (Bluetooth) and Wired (tethered) cables	Wireless	Data cable	Data cable (one end of Wireless Connector)
Connectivity	Wireless (Bluetooth) and Wired (tethered) cables	Wireless (Bluetooth) and Wired SmartCable	Data cable	Wireless (900 MHz - other end of Wireless Connector)
Communication method of hub with devices	Wireless (Bluetooth) and Wired (tethered) cables	Wireless (Bluetooth) and Wired (tethered) cables	Cellular	Wireless (900MHz)
Communication Protocol	Wireless (Bluetooth) and Wired (tethered) cables	Wireless (Bluetooth) and Wired (tethered) cables	Cellular	Wireless (900MHz)

Communica-tion Frequency	Bluetooth 2.402 to 2.480 GHz GSM: 850 / 900 / 1800 / 1950 MHz	Bluetooth 2.402 to 2.48 GHz	GSM: 850 / 900 / 1800 / 1950 MHz	900MHz (902-928 MHz)
Power Source	Wall power plug (120 VAC/50-60) Rechargeable Batteries in HealthPAL	Wall power plug (120 VAC/50-60)	Wall power plug (120 VAC/50-60) and rechargeable battery in iGlucose	Wall power plug (120 VAC/50-60) and coin cell battery in Wireless Connector
Visual Feedback / Display	LED Light indicators	Same	Same	Same
Communica-tion with Patients	Audio/visual reading feedback from LED light indicators & audio tones; Interactive Voice Response (IVR) system for patient contact	Data is viewed in a web-based application; sent via email, SMS text and fax.	Data is viewed in a web-based application; sent via email, SMS text and fax.	Data is viewed in a web-based application; sent via email, SMS text and IVR.

Performance Data:

Non-clinical Testing

The submitted system was found to be compliant to the following standards based on testing performed by Intertek Testing Services:

1. IEC 60601-1 Issue1988/12/01 Ed:2 Medical Electrical Equipment Part 1: General Requirements for Safety; (Amd. 1-1991) (CENELEC EN 60601-1: 1990) (Amd. 2-1995) (Corrigendum-1995)
2. IEC 60601-1-1 Issued:2000/12/01 Ed:2 Medical Electrical Equipment - Part 1-1: General Requirements for Safety - Collateral Standard: Safety

3. Requirements for Medical Electrical Systems

4. IEC 60601-1-4 Issue:2000/04/01 Ed:1.1 Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems; Edition 1:1996 Consolidated
5. IEC/EN 60601-1-2 (Ed. 2): 2001 +A1: 2004 - Medical electrical equipment, Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests. with Amendment 1:1999

The submitted system has undergone Ambio Health's design control verification and validation testing. Ambio Health validation testing includes testing of all executable code and functionality and confirmation that all identified risks have been adequately addressed by software functionality, the user interface, documentation or the User Guide.

Ambio Health System verification and validation activities as part of the design control process include testing of all Design Specifications based on risk analysis and verification plans. Ambio Health System test plan execution ensures each type of user accessory medical device (glucose, blood pressure, scale) works with the Ambio Wireless Connector and Gateway components and the Ambio Care Portal software. The output of these design control verification analysis documents Ambio Remote Health Monitoring System shall meet its requirements and design specifications as intended.

Arrayent Health used its Risk Management Plan to perform risk analysis regarding human factors for usability to determine that there are no significant risks.

Conclusions: The performance data discussed in this 510(k) application demonstrate that the Ambio Health - Remote Patient Monitoring System is as safe and effective, as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 8, 2013

Arrayent Health LLC d/b/a Ambio Health
c/o Mr. Kevin Jones
CEO
1266 E Main Street
Stamford, CT 06902

Re: K130676
Trade/Device Name: Ambio Remote Health Monitoring System
Regulatory Number: 21 CFR 870.2910
Regulation Name: Transmitters and Receivers, Physiological Signal, Radiofrequency
Regulatory Class: II (two)
Product Code: 74 DRG
Dated: May 13, 2013
Received: May 14, 2013

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K130676

Indications for Use

510(k) Number (if known): Not assigned.

Device Name: Ambio Remote Health Monitoring System

The Ambio Remote Health Monitoring System ("System") consists of Ambio Wireless Connectors to send readings from off-the-shelf blood pressure and blood glucose meters; the Ambio Scale with built in wireless connectivity to send readings through the Ambio Gateway to the Ambio Care Portal. The Care Portal is used by patients and their caregivers ("Users") to view readings, set reminders to take meter readings and pills, set reading thresholds which will trigger alert messages and set who will get reminder and alert messages. Reading history can be printed or exported. Users can maintain an exercise log, food log and records of doctor visits and lab tests. Users can set goals and rewards for taking readings and for keeping readings in target ranges. A patient survey tool can be used to gather qualitative health information. The System also has a shared calendar and message board to coordinate among Users. General health information from accredited sources is also available.

The Ambio Remote Health Monitoring System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention. The System does not alter the indicated use of the described blood pressure or blood glucose monitors.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _X_ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

May 29, 2013

Cardiac Designs, LLC
Raymond Kelly, IV
Regulatory Consultant
57 Lazy Brook Rd
Monroe, CT 06468 US

Re: K131045
Trade/Device Name: Enterprise ECG Analysis / Interpretation Software
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DPS
Dated: April 12, 2013
Received: April 15, 2013

Dear Raymond Kelly, IV:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K131045

Section 4

INDICATIONS FOR USE

510(k) Number (if known):_____

Device Name: Enterprise ECG Analysis / Interpretation Software

Indications For Use:

The "Enterprise ECG Analysis / Interpretation Software" is a tool used by qualified medical professionals to assist with the assessment of arrhythmias using ambulatory EGG data. The software supports downloading and analyzing data recorded in compatible formats from devices used for arrhythmia diagnostics such as Holter, Event Monitor, ambulatory or resting EGG devices, or other similar devices when assessment of the rhythm is necessary. The software can be electronically interfaced, and perform analysis with data transferred from other computer based EGG systems, such as an EGG management system. The software provides EGG signal processing and analysis on a beat by beat basis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis for the captured data. The software is not for use in life supporting or life sustaining systems or EGG Alarm devices. The software can be integrated into computerized EGG monitoring devices. In this case the medical device manufacturer will identify the indication for use depending on the application of their device. Analysis metrics are provided in a report which is available for clinician review and printing. The reported ECG metrics include beat by beat heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the care provider to render a diagnosis based on clinical judgment and experience.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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K131209

510(k) Summary
Teratech Corporation
Terason™ uSmart3200T Ultrasound System

MAY 2 4 2013

1. **Sponsor:**

Teratech Corporation
77-79 Terrace Hall Ave.
Burlington, MA 01803

Contact Person: Ben Chiampa,
Quality Assurance and Regulatory Affairs
Telephone: 781-270-4143

Date Prepared: March 21, 2013

2. **Device Name**

Proprietary Name: Terason™ uSmart3200T Ultrasound System
Common / Usual Name: Diagnostic Ultrasound System
Classification Name: Diagnostic Ultrasound Transducer

(21 CFR 892.1570, 90-ITX)
Ultrasonic Pulsed Echo Imaging System
(21 CFR 892.1560, 90-IYO)
Diagnostic Ultrasonic Transducer
(21 CFR 892.1570, 90-ITX)

3. **Predicate Devices**

Terason™ t3000 Ultrasound System (K112953) and Terason™ t3200 Ultrasound System (K110020)

4. **Device Description**

The Terason™ uSmart3200T ultrasound system is equivalent to the previously cleared version of the t3200 and t3000 Ultrasound Systems described in the following 510(k) submissions (K110020 and K112953). This system contains a proprietary ultrasound engine for controlling the acoustic output of the transducer and processing the return echoes in real time. These data are then transferred to the tablet (previously laptop computer) over a FireWire (aka IEEE 1394) connection for further processing and generation and display of the ultrasound image.

The Terason™ uSmart3200T ultrasound tablet weighs 4.9 pounds (2.21 Kg) and has an 11.5" backlit touch screen. The tablet dimensions (8.82"(H) x 12.64"(W) x 1.25"(D)) are chosen to allow portability. A Lithium-Polymer battery (integrated into the tablet) provides 2 hours of continuous ultrasound scanning. The tablet includes a docking station (for charging) that uses a medical-grade power supply. The ultrasound transducer connector is identical to that used in the Terason™ predicate device, the t3200. Optional accessories include a cart and printer.

5. Intended Use

The Teratech Corporation Terason™ uSmart3200T is a general purpose Ultrasound System intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal, Abdominal, Pediatrics, Small Organ (Thyroid, Breast, Testes); Neonatal and Adult Cephalic; Musculo-skeletal (Conventional and Superficial); Cardiac (Adult & Pediatric); Peripheral Vascular.

6. Technology Characteristics

The design and construction of the Terason™ uSmart3200T is similar to the Terason™ t3200 Ultrasound system. These systems utilize a tablet (or laptop) computer running Windows 7 to execute the ultrasound application and a custom designed engine for control of the acoustic array and processing of the return echoes. For the uSmart3200T, the engine is housed in a compartment that is attached to the backside of the tablet computer.

The similarity and difference between the Terason™ uSmart3200T and the Terason t3200 Ultrasound System (the predicate device) include the following:

- The engines are the same with no modification in the custom beamformer chip (as compared to earlier versions of Terason ultrasound systems) that provides for improved filtering of the return signal for wider bandwidth and better resolution across the entire image field.
- The ultrasound application software has been modified to improve the user workflow and ease of use commensurate with a tablet application. The screen layout has been modified and the user controls have been changed for finger touch control to improve the efficiency for the targeted exam types.

Transducers: The Terason uSmart3200T and the BenQ UP200 will support 3 transducers. These transducers have been previously cleared.

- 12L5A: Cleared in 510k submission K112953 (February 3, 2012)
- 5C2A: Cleared in 510k submission K112953 (February 3, 2012)
- 4V2A: Cleared in 510k submission K112953 (February 3, 2012).

The following provides additional details of the three transducers, presented in this submission, that were previously cleared.

- 12L5A: equivalent indications for use, frequency settings, shape of transducer head and needle guide/software brackets. Same manufacturer, same acoustic array and patient contact materials.
- 5C2A: equivalent indications for use, frequency settings, and needle guide bracket / software. Same manufacturer, same shape, same acoustic array and patient contact materials.
- 4V2A: equivalent indications for use, frequency settings, and needle guide bracket / software. Same manufacturer, same shape, same acoustic array and patient contact materials.

B1. Non Clinical Tests

The Terason™ uSmart3200T system has been tested for compliance to the following standards (with the corresponding report referenced for each standard).

- IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety.
    - Intertek Test Record Number 100825075BOX-001.

- IEC 62366, Medical Devices: Application of usability engineering to medical devices.
    - Intertek Project: 100825075BOX-004.

- IEC60601-1-6, Medical Electrical Equipment – Part 1-6: General requirements for safety– Collateral standard: Usability
    - Intertek Project: 100825075BOX-003.

- IEC 60601-1-2:2007, Medical Electrical Equipment – Part 1-2; General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests
    - IEC60601-1-2 Intertek Test Record Number, 100933162BOX-017.

- IEC 60601-2-37 / EN60601-2-37 Medical Electrical Equipment Part 2: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
    - Transducer Model 5C2A: Intertek Report Number IEC60601-2-37 uSmart3200T 5C2A: 100825075BOX-006
    - Transducer Model 12L5A: Intertek Report Number IEC60601-2-37 uSmart3200T 12L5A: 100825075BOX-007
    - Transducer Model 4V2A: Intertek Report Number IEC60601-2-37 uSmart3200T 4V2A: 100825075BOX-005.

- NEMA UD 3 Acoustic Output Display
  Terason uSmart3200T Ultrasound System User Guide (16-3301).

- Biocompatibility Tests, ISO 10993 Part 5 and Part 10
    - Biocompatibility reports for all transducers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 24, 2013

TeraTech Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K131209
Trade/Device Name: Terason™ uSmart3200T Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, and ITX
Dated: May 15, 2013
Received: May 16, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Terason™ uSmart3200T Ultrasound System, as described in your premarket notification:

Transducer Model Number

12L5A
5C2A
4V2A

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

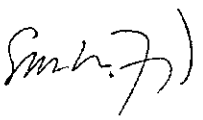
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy, Ph.D. at (301) 796-6242.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosures

Indications for Use

510(k) Number (if known): K131209

Device Name: Terason uSmart3200T Ultrasound System

Indications for Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

The Teratech Corporation Terason™ uSmart3200T is a general purpose Ultrasound System intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal, Abdominal, Pediatrics, Small Organ (Thyroid, Breast, Testes); Neonatal and Adult Cephalic; Musculo-skeletal (Conventional and Superficial); Cardiac (Adult & Pediatric); Peripheral Vascular.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) K131209

Indications for Use Form

510(k) Number (if known): K131209

Device Name: Terason uSmart3200T Ultrasound System

Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]	N	N	N		N	N	N
	Abdominal[d]:	N	N	N		N	N	N
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	N	N	N		N	N	N
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	N	N	N		N	N	N
	Neonatal Cephalic[d]:	N	N	N		N	N	N
	Adult Cephalic[d]:	N	N	N		N	N	N
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	N	N	N		N	N	N
	Musculo-skel. (Superfic)[d]:	N	N	N		N	N	N
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N		N	N	N
	Cardiac Pediatric	N	N	N		N	N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	N	N	N		N	N	N
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.

[b] B+M; B+PWD; B+CD; B+DPD; B+PD.

[c] Harmonic Imaging (HI)

[d] Includes ultrasound guidance for placement of needles, catheters.

[e] Abdominal, thoracic and peripheral vessel.

[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): K131209

Device Name: Terason uSmart3200T – 5C2A Transducer

Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	N	N	N		N	N	N
	Musculo-skel. (Superfic)[d]:	N	N	N		N	N	N
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N		N	N	N
	Cardiac Pediatric	N	N	N		N	N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.

[b] B+M; B+PWD; B+CD; B+DPD; B+PD.

[c] Harmonic Imaging (HI)

[d] Includes ultrasound guidance for placement of needles, catheters.

[e] Abdominal, thoracic and peripheral vessel.

[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.

Additional Comments: P[1]: uses previously cleared under K112953

Prescription Use ___x___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): K131209

Device Name: Terason uSmart3200T - 12L5A Transducer

Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]							
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Neonatal Cephalic[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Adult Cephalic[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Musculo-skel. (Superfic)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.

[b] B+M; B+PWD; B+CD; B+DPD; B+PD.

[c] Harmonic Imaging (HI)

[d] Includes ultrasound guidance for placement of needles, catheters.

[e] Abdominal, thoracic and peripheral vessel.

[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.

Additional Comments: P[1]: uses previously cleared under K112953

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k)_____

Indications for Use Form

510(k) Number (if known): K131209

Device Name: Terason uSmart3200T - 4V2A Transducer

Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Adult Cephalic[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:							
	Musculo-skel. (Superfic)[d]:							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Cardiac Pediatric	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.

[b] B+M; B+PWD; B+CD; B+DPD; B+PD.

[c] Harmonic Imaging (HI)

[d] Includes ultrasound guidance for placement of needles, catheters.

[e] Abdominal, thoracic and peripheral vessel.

[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.

Additional Comments: P[1]: uses previously cleared under K112953

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k) K131209

510 (k) Summary

807.92(c)

JUN 2 4 2013

SPONSOR	**807.92(a)(1)**
Company Name:	Rijuven Corporation
Company Address:	624 Whispering Pines Drive Pittsburgh PA, 15238
Telephone:	+1 (301) 335-9163
Fax:	+1 (412) 967-9393
Contact Person	Evens Augustin
Summary Preparation Date:	March 2, 2013

DEVICE NAME	**807.92(a)(2)**
Trade Name:	CardioSleeve
Common/Usual Name:	Electronic Stethoscope / Heart Sound Analyzer
Classification Name:	Electronic Stethoscope; Phonocardiograph
Regulation Number:	21 CFR 870.1875, 870.2390
Product Code:	DQD, DQC
Device Class:	Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
Diacoustic Medical Devices (Pty) Ltd	Sensi with Diagnostic Heart Murmur Software	K110704

DEVICE DESCRIPTION 807.92(a)(4)

The CardioSleeve with Diagnostic Heart Murmur Application, (application identical to the FDA cleared Sensi with Diagnostic Heart Murmur Software-K110704), is a decision support device intended to acquire, record, and analyze heart sounds. It is used to distinguish between normal and pathological heart murmurs by recording the acoustic signal of the heart and the ECG signal simultaneously and analyzing these signals, and to acquire, record and display 3 Lead ECG signals for diagnostic support.

The complete system comprises of: a) Diagnostic Heart Murmur Algorithm (algorithm identical to the FDA cleared Diagnostic Heart Murmur Algorithm in K110704), that runs on a hosted server environment with Linux operating system, b) a mobile device software application that captures patient data, displays patient data and instructions for use and c) a stethoscope front-end recorder device with integrated ECG to acquire the acoustic and electrical heart signals. The CardioSleeve Front-end recorder device will interface via Bluetooth with the clinician's hand held mobile device.

DEVICE INDICATIONS FOR USE 807.92(a)(5)

The CardioSleeve System consisting of the CardioSleeve Front-End stethoscope with integrated ECG device, mobile heart sound and ECG recording application and the remote diagnostic heart murmur software is a decision support device intended to be used on a single patient to assist the qualified clinician in analyzing cardiac sounds and electrical signals for the identification and classification including of suspected murmurs. It is used to distinguish between normal/physiological and pathological heart murmurs by recording the acoustic signal of the heart and the ECG signal simultaneously and analyzing these signals. The acoustic heart signal is analyzed to identify specific heart sounds that may be present. Identified sounds include S1, S2, and suspected murmurs.

CardioSleeve indicates whether or not a recorded heart sound contains a suspected heart murmur. The device must be used in a clinical setting by trained personnel with the prescribed accessories and all relevant patient information must be taken into consideration before a diagnosis is made.

The interpretations of heart sounds offered by the CardioSleeve device are only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.

CardioSleeve is not intended to be a diagnostic device. It does not supersede the judgment of the clinician. The device is intended to aid the physician in the evaluation of heart sounds. The clinicians are responsible for reviewing and interpreting the results, along with the auscultatory findings and medical history, when making a referral decision.

Caution: Federal (USA) law restricts this device to sale by or on the order of a clinician

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

The CardioSleeve device features were directly compared with the FDA cleared Sensi with Diagnostic Heart Murmur Software, WelchAllyn Master Elite Stethoscope and the WelchAllyn Meditron Analyzer (K110704).

Synopsis of the comparison analysis:

- Intended Use:

  CardioSleeve and Sensi with Diagnostic Heart Murmur Software do have an equivalent intended use.

- Indications for Use:

  CardioSleeve and Sensi with Diagnostic Heart Murmur Software do have identical indications for use.

- Composition

  CardioSleeve and Sensi with Diagnostic Heart Murmur Software compromises equivalent functions system composition.

- Physical Properties

  CardioSleeve with Front-end unit and Diagnostic Heart Murmur Software, and Sensi with Diagnostic Heart Murmur Software, the WelchAllyn Master Elite Stethoscope and the WelchAllyn Meditron Analyzer share equivalent physical characteristics (K110704).

- Technology Characteristics

  CardioSleeve consists of a front-end recorder device with a Bluetooth interface connected to a standard acoustic stethoscope recording both the acoustic heart sound and/or ECG signal. The Sensi consists of an electronic stethoscope and ECG recorder connecting to a PC by means of a USB interface for recording of acoustical body sounds.

  CardioSleeve and Sensi with Diagnostic Heart Murmur Software are using identical heart murmur analysis algorithm.

  CardioSleeve and Sensi with Diagnostic Heart Murmur Software are using equivalent user interface properties.

SAFETY AND EFFECTIVENESS 807.92(b)

A comprehensive list of verification and validation testing was performed in accordance to Rijuven's Design Control procedures.

Software validation was performed for all aspects of the CardioSleeve System and Software. The graphical user interface and usability were compared to the predicate devices.

Validation of the CardioSleeve was performed to ensure that the CardioSleeve system consistently fulfills its intended use and the needs of the user. A clinical software validation was performed to insure the performance of the software algorithm.

1	Biocompatibility Testing	CardioSleeve material presented no issues of biocompatibility
2	Electrical Safety Testing	The CardioSleeve meets the requirements of IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007).
3	Feasibility & Usability Study	Intended users performed usability validation within real life clinical settings. On average all users scored the usability of the CardioSleeve Software more than 4 out of 5.
4	Comparative study between FDA approved CardioSleeve and Sensi system	CardioSleeve and Sensi achieve comparable accuracy of 70.8%
5	Design verification of a CAA algorithm	Specificity of 94% and Sensitivity of 91%
6	Validate algorithms used to distinguish between functional and pathological heart murmurs in the pediatric population.	1568 heart sounds were accepted to meet the criteria of good quality and match the recorded pathological conditions
7	Verification of the acoustic performance of the CardioSleeve front-end	The CardioSleeve Front-End perform favorably, in responding to heart sound frequency of 20hz to 500hz

CONCLUSION **807.92(b)(3)**

Based upon the indications for use, technology characteristics and safety and performance testing, it is the conclusion of Rijuven that the CardioSleeve device consisting of the CardioSleeve Front-End stethoscope and ECG device, mobile heart sound recording application and the remote diagnostic heart murmur software is as safe and effective as the predicate devices and raises no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

June 24, 2013

Rijuven Corp
Mr. E.J. Smith
Regulatory Consultant
1468 Harwell Ave.
Crofton, MD 21114 US

Re: K131287
Trade/Device Name: Cardiosleeve
Regulation Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope / Heart Sound Analyzer
Regulatory Class: Class II
Product Code: DQD, DQC
Dated: May 9, 2013
Received: May 9, 2013

Dear Mr. E.J. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known):

Device Name: CardioSleeve

Indications For Use:

The CardioSleeve System consisting of the CardioSleeve Front-End stethoscope with integrated ECG device, mobile heart sound and ECG recording application and the remote diagnostic heart murmur software is a decision support device intended to be used on a single patient to assist the qualified clinician in analyzing cardiac sounds and electrical signals for the identification and classification including of suspected murmurs. It is used to distinguish between normal/physiological and pathological heart murmurs by recording the acoustic signal of the heart and the ECG signal simultaneously and analyzing these signals. The acoustic heart signal is analyzed to identify specific heart sounds that may be present. Identified sounds include S1, S2, and suspected murmurs.

CardioSleeve indicates whether or not a recorded heart sound contains a suspected heart murmur. The device must be used in a clinical setting by trained personnel with the prescribed accessories and all relevant patient information must be taken into consideration before a diagnosis is made.

The interpretations of heart sounds offered by the CardioSleeve device are only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.

CardioSleeve is not intended to be a diagnostic device. It does not supersede the judgment of the clinician. The device is intended to aid the physician in the evaluation of heart sounds. The clinicians are responsible for reviewing and interpreting the results, along with the auscultatory findings and medical history, when making a referral decision.

Caution: Federal (USA) law restricts this device to sale by or on the order of a clinician

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 10, 2013

GlobalMedia Group, LLC
Mr. Nicholas Campbell
Quality and Regulatory Manager
15020 North 74th Street
Scottdale AZ 85260

Re: K131338
Trade/Device Name: Derma Hood
Regulation Number: 21 CFR 880.6320
Regulation Name: AC-Powered Medical Examination Light
Regulatory Class: I
Product Code: PEQ
Dated: April 23, 2013
Received: May 9, 2013

Dear Mr. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131338

Device Name: Derma Hood

Indications For Use:

The Derma Hood is an accessory for the TotalExam HD Examination Light. The Derma Hood utilizes standard off-the-shelf light filters and lenses. The Derma Hood accessory is designed for use within healthcare facilities (Doctor's offices, clinics, hospitals, etc.).

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
2013.07.10 11:20:17
-04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K131338

K971650

SECTION 2
510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

DEC - 4 1997

Submitter's Name: Data Critical Corporation
100 North Broadway, Suite 2200
Oklahoma City, OK 73102
Telephone: (405) 236-4441
Contact Person: David E. Albert, MD, Chief Scientist

Date of Summary: May 5, 1997

Device Name: Rhythm*Stat XL* System

Device Classification: Telephone electrocardiograph transmitter and receiver (74 DXH); 21 CFR § 870.2920

Legally Marketed Devices To Which Equivalence Is Claimed: The legally marketed predicate devices are the Hewlett-Packard M1490A Wireless Patient Data Communicator (PalmVue System) (K945277); the Instromedix® LifeSigns™ Receiving Center (a preAmendment device); and the Micromedical Industries BIOLOG (K915624).

Device Description: The Rhythm*Stat XL* System is a telephone electrocardiograph (ECG) receiving system used for recording and reporting of ECG data from a cardiac event recorder. The System has three main components:

- A ***commercially available cardiac event recorder such as the Micromedical Industries BIOLOG or the Instromedix® Heart Card™***, that conditions and transmits ECG data in the form of a frequency-modulated acoustic waveform to the PSION Series 3 palmtop computer;
- ***Two proprietary software programs***, contained in the commercially available PSION Series 3 palmtop computer, that 1) recondition the received signal into its original format and display the signal to the physician on the computer screen, then 2) transmit the ECG data, along with the physician's comments, from the PSION palmtop computer to the Reporting Server via modem; and
- The Data Critical ***Reporting Server*** that accepts the ECG data and commentary and generates a printed report that is automatically transmitted to the physician's office via fax.

Intended Use: The Rhythm*Stat XL* System is indicated for use in the diagnostic evaluation and recording of ECG waveforms from a cardiac event recorder. It is intended to provide remote access to ECG data by transtelephonic transmission from an ambulatory cardiac event monitor to the portable PSION palmtop computer with Rhythm*Stat XL* software, where the ECG waveforms are demodulated, recorded, displayed and stored.

Descriptive Summary Of Technological Characteristics And Those Of Predicate Devices: The Rhythm*Stat XL* System is indicated for use in the diagnostic evaluation and recording of ECG waveforms from a cardiac event recorder. It is intended to provide remote access to ECG data by transtelephonic transmission from an ambulatory cardiac event monitor to the portable PSION palmtop computer with Rhythm*Stat XL* software, where the ECG waveforms are demodulated, recorded, displayed and stored. The waveforms and accompanying information are then transmitted via modem to the Data Critical Reporting Server for generation of a printed report, which is then faxed to the physician's office. In addition, the PSION palmtop computer with Rhythm*Stat XL* software has the capability of relaying the most recently acquired ECG data as an acoustic signal to another PSION with Rhythm*Stat XL* software or to a conventional transtelephonic ECG receiving system such as the Instromedix LifeSigns Receiving Center.

The Hewlett-Packard M1490A Wireless Patient Data Communicator (PalmVue System) is intended to provide remote access to data from an HP patient monitoring system by transmitting data from a patient monitor through a PalmVue dispatch station and paging service provider to a portable hand-held Medical Palmtop personal computer. The HP system requires the use of a Hewlett Packard monitoring system and dispatch station, PalmVue transmission software, an interface card, modem, and a paging service to support the system functions.

The Instromedix® LifeSigns™ Receiving Center is intended to receive, by telephone, ECG data from patients using ambulatory cardiac event monitors or pacer data transmitters. This tabletop device is line-powered and provides a printed record of ECG data; with an optional interface, it allows data to be communicated to a computer.

The Micromedical Industries BIOLOG is intended to acquire, record and store single-lead or 12-lead ECG waveforms via direct patient contact or through a patient cable with electrodes. This portable, hand-held device has an LCD screen, is battery-powered, and is capable of transtelephonic data transmission or receipt. It interfaces directly with the Micromedical Printer to provide a printed record of ECG data.

Performance Data: Testing was conducted by Data Critical Corporation on the Rhythm*Stat XL* System to compare its performance to that of two legally marketed predicate devices, the Micromedical Industries BIOLOG recorder and the Instromedix LifeSigns Receiving Center. Subjects were tested using the PSION palmtop computer with Rhythm*Stat XL* software and the BIOLOG recorder; additional testing was then conducted with three devices: the PSION with Rhythm*Stat XL* software, the BIOLOG recorder, and the Instromedix LifeSigns Receiving Center. ECG recordings were obtained with the BIOLOG, then played back to and recorded by the PSION/Rhythm*Stat XL* and printed by the Rhythm*Stat XL* Reporting Server. The same recording was then printed out by the predicate devices, the BIOLOG and the LifeSigns Receiving Center. For each ECG printout the amplitude and duration of the first ten QRS segments were analyzed and measured, along with the total duration of all QRS segments. The Rhythm*Stat XL* System demonstrated acceptable performance, producing ECG waveforms which were measurably comparable and of equivalent quality to the waveforms of the Micromedical and Instromedix products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 1997

Ms. Lisa S. Jones
Data Critical Corporation
c/o Devices For The Future, LLC
9223 Ilona Lane
Houston, Texas 77025-4218

Re: K971650
RhythmStat XL System
Regulatory Class: II (two)
Product Code: 74 DXH
Dated: September 29, 1997
Received: October 1, 1997

Dear Ms. Jones:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K971650

SECTION 2
510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

DEC - 4 1997

Submitter's Name: Data Critical Corporation
100 North Broadway, Suite 2200
Oklahoma City, OK 73102
Telephone: (405) 236-4441
Contact Person: David E. Albert, MD, Chief Scientist

Date of Summary: May 5, 1997

Device Name: Rhythm*Stat XL* System

Device Classification: Telephone electrocardiograph transmitter and receiver (74 DXH); 21 CFR § 870.2920

Legally Marketed Devices To Which Equivalence Is Claimed: The legally marketed predicate devices are the Hewlett-Packard M1490A Wireless Patient Data Communicator (PalmVue System) (K945277); the Instromedix® LifeSigns™ Receiving Center (a preAmendment device); and the Micromedical Industries BIOLOG (K915624).

Device Description: The Rhythm*Stat XL* System is a telephone electrocardiograph (ECG) receiving system used for recording and reporting of ECG data from a cardiac event recorder. The System has three main components:

- A ***commercially available cardiac event recorder such as the Micromedical Industries BIOLOG or the Instromedix® Heart Card™***, that conditions and transmits ECG data in the form of a frequency-modulated acoustic waveform to the PSION Series 3 palmtop computer;
- ***Two proprietary software programs***, contained in the commercially available PSION Series 3 palmtop computer, that 1) recondition the received signal into its original format and display the signal to the physician on the computer screen, then 2) transmit the ECG data, along with the physician's comments, from the PSION palmtop computer to the Reporting Server via modem; and
- The Data Critical ***Reporting Server*** that accepts the ECG data and commentary and generates a printed report that is automatically transmitted to the physician's office via fax.

Intended Use: The Rhythm*Stat XL* System is indicated for use in the diagnostic evaluation and recording of ECG waveforms from a cardiac event recorder. It is intended to provide remote access to ECG data by transtelephonic transmission from an ambulatory cardiac event monitor to the portable PSION palmtop computer with Rhythm*Stat XL* software, where the ECG waveforms are demodulated, recorded, displayed and stored.

Descriptive Summary Of Technological Characteristics And Those Of Predicate Devices: The Rhythm*Stat XL* System is indicated for use in the diagnostic evaluation and recording of ECG waveforms from a cardiac event recorder. It is intended to provide remote access to ECG data by transtelephonic transmission from an ambulatory cardiac event monitor to the portable PSION palmtop computer with Rhythm*Stat XL* software, where the ECG waveforms are demodulated, recorded, displayed and stored. The waveforms and accompanying information are then transmitted via modem to the Data Critical Reporting Server for generation of a printed report, which is then faxed to the physician's office. In addition, the PSION palmtop computer with Rhythm*Stat XL* software has the capability of relaying the most recently acquired ECG data as an acoustic signal to another PSION with Rhythm*Stat XL* software or to a conventional transtelephonic ECG receiving system such as the Instromedix LifeSigns Receiving Center.

The Hewlett-Packard M1490A Wireless Patient Data Communicator (PalmVue System) is intended to provide remote access to data from an HP patient monitoring system by transmitting data from a patient monitor through a PalmVue dispatch station and paging service provider to a portable hand-held Medical Palmtop personal computer. The HP system requires the use of a Hewlett Packard monitoring system and dispatch station, PalmVue transmission software, an interface card, modem, and a paging service to support the system functions.

The Instromedix® LifeSigns™ Receiving Center is intended to receive, by telephone, ECG data from patients using ambulatory cardiac event monitors or pacer data transmitters. This tabletop device is line-powered and provides a printed record of ECG data; with an optional interface, it allows data to be communicated to a computer.

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Performance Data: Testing was conducted by Data Critical Corporation on the Rhythm*Stat XL* System to compare its performance to that of two legally marketed predicate devices, the Micromedical Industries BIOLOG recorder and the Instromedix LifeSigns Receiving Center. Subjects were tested using the PSION palmtop computer with Rhythm*Stat XL* software and the BIOLOG recorder; additional testing was then conducted with three devices: the PSION with Rhythm*Stat XL* software, the BIOLOG recorder, and the Instromedix LifeSigns Receiving Center. ECG recordings were obtained with the BIOLOG, then played back to and recorded by the PSION/Rhythm*Stat XL* and printed by the Rhythm*Stat XL* Reporting Server. The same recording was then printed out by the predicate devices, the BIOLOG and the LifeSigns Receiving Center. For each ECG printout the amplitude and duration of the first ten QRS segments were analyzed and measured, along with the total duration of all QRS segments. The Rhythm*Stat XL* System demonstrated acceptable performance, producing ECG waveforms which were measurably comparable and of equivalent quality to the waveforms of the Micromedical and Instromedix products.

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Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

May 5,1997

510(k) Number:

Device Name: Rhythm*Stat XL* System

Indications for Use: The Rhythm*Stat XL* System is indicated for use in the diagnostic evaluation and recording of ECG waveforms from a cardiac event recorder. It is intended to provide remote access to ECG data by transtelephonic transmission from an ambulatory cardiac event monitor to the portable PSION palmtop computer with Rhythm*Stat XL* software.

(Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971650

Prescription Use ✓ OR Over-the-Counter Use ____
(Per 21 CFR 801.109)