Attachment 6
510(k) Summary

REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT

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NAME OF DEVICE

Trade Name: MediCompass® Connect
Common Name: Data Transfer and Management System
Classification Names: Physiological Signal Transmitter and Receiver

Regulation Number	Product Code	Classification Name	Device Class
870.2910	DRG	Physiological Signal Transmitters and Receivers	II

PREDICATE DEVICES

- MediCompass Connect (iMetrikus, Inc): #K042768
- CareMatix Wellness System (CareMatix, Inc.): #K073038, K040966
- Confidant 2.6, (Confidant, Inc): #K083331
- Health Buddy Appliance (Health Hero Network): (#K080091, #K070543, #K063612, #K060843, #K050567, #K042273, K040086, #K993128)

DEVICE DESCRIPTION

MediCompass® Connect is a telehealth gateway to upload biometric data from personal health monitoring devices, including glucose monitors, insulin pumps, blood pressure monitors, digital spirometers, pulse oximeter, PT/INR meter, activity monitor/pedometer, and weight scales. The system conveniently transfers data via a standard phone line or Internet-enabled personal computer using the MetrikLink® connectivity hub, or connection directly to mobile devices via wireless technology.

After connectivity is activated by a health care professional, patients can connect their monitoring device to MediCompass Connect using MetrikLink, adapters or compatible cables provided for their specific medical device and model. The data captured from the personal monitoring medical devices is transferred securely to the MediCompass database or other secure online database, then to the health care provider's remote general purpose health management database.

MediCompass Connect does not provide diagnosis of any disease or medical condition, nor is it 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.

MediCompass Connect is not intended for emergency use 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.

INDICATION FOR USE STATEMENT

The MediCompass® Connect serves as an interface or a gateway between personal monitoring devices and a general-purpose personal health management database. The MediCompass Connect collects physiologic measurements and retrospectively monitors vital signs from defined personal monitoring devices and transmits the data to a central database server, using standard communication technologies. MediCompass Connect is designed for professional, personal and home use.

MediCompass Connect is not intended to provide automated treatment decisions, nor is it to be used as a substitute for a professional healthcare judgment.

SUBSTANTIAL EQUIVALENCE COMPARISON

This submission represents a modification to the existing MediCompass Connect software to support the connection of additional personal medical devices. It is substantially equivalent to the cleared MediCompass Connect (iMetrikus, Inc) in #K042768. The device is also substantially equivalent to Confidant 2.6, Health Buddy Appliance, and to the CareMatix Wellness System, all of which use connections between the personal health monitoring device and management database.

PERFORMANCE TESTING

Verification and validation testing activities were conducted to establish the performance, functionality and reliability characteristics of MediCompass Connect when connected to personal monitoring medical devices using the associated communications methods. The results of all performance testing were acceptable and demonstrated performance as intended.

CONCLUSION

MediCompass Connect is substantially equivalent in technology, features, and indications for use to devices cleared under the Federal Food, Drug and Cosmetic Act. The modified device has the same fundamental scientific technology and intended use as the predicate devices. 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

JUL 15 2009

iMetrikus , Inc.
c/o Mr. Michael Acosta
Vice President, Quality Assurance and Regulatory Affairs
2141 Landings Drive
Mountain View, CA 94043

Re: K091021
MediCompass® Connect
Regulation Number: 21 CFR 870. 2910
Regulation Name: Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: June 03, 2009
Received: June 04, 2009

Dear Mr. Acosta:

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

Attachment 5
Indications for Use

510(k) Number: # K091021

Device Name: MediCompass® Connect

Indications for Use:

The MediCompass® Connect serves as an interface or a gateway between personal monitoring devices and a general-purpose personal health management database. The MediCompass Connect collects physiologic measurements and retrospectively monitors vital signs from defined personal monitoring devices and transmits the data to a central database server, using standard communication technologies. MediCompass Connect is designed for professional, personal and home use.

MediCompass Connect is not intended to provide automated treatment decisions, nor is it to be used as a substitute for a professional healthcare judgment.

Prescription Use_ XX ___ 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) 7/15/08
Division of Cardiovascular Devices
510(k) Number K091021