Section 1.3

510k Summary

K080091

REGULATORY AUTHORITY

FEB - 5 2008

Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT

Robin Bush
Health Hero Network
2400 Geng Road, Suite 200
Palo Alto, CA 94303
(650) 690-9191 (phone)
(650) 798-3770 (facsimile)

NAME OF DEVICE

Trade Name: Health Buddy® Appliance
Common Name: Data Management System; Accessory to Medical Device
Classification Names: Refer to Table

Regulation Number	Product Code	Classification Name	Device Class
870.2910	DRG	Physiological Signal Transmitters and Receivers	II
Medical Device Product Codes Supported by Health Buddy			
862.1345	CGA	Glucose Test System	II
870.1130	DXN	Noninvasive Blood Pressure Measurement System	II
880.2700	FRI	Patient Weight Scale	I
868.1860	BZH	Meter, Peak Flow, Spirometry	II
870.2700	DQA	Oximeter	II

PREDICATE DEVICES

- Health Buddy® Appliance (#K070543, #K063612, #K060843, #K050567, #K042273, #K040086, #K993128)
- CareMatix Wellness System (#K040966)
- VMS-01, Medic4All Telemedicine System, (#K061502, #K062127, #K062662)

DEVICE DESCRIPTION

The Health Buddy Appliance is a communications product that connects to a telephone line or Ethernet connection. It is used by patients in conjunction with the Health Hero Online service to answer questions and furnish information to their healthcare professional(s) between office visits. The Health Buddy Appliance contains software that can be activated to function with specific medical devices (including blood glucose meters, non-invasive blood pressure cuffs, patient weight scales, peak flow meters and pulse oximeters). The Health Buddy Appliance retrieves data from a specific medical device and stores it for transmission to a healthcare provider.

The physiologic patient parameters available for retrospective display and evaluation include pulse rate, blood pressure, blood glucose level, weight, and Peak Expiratory Flow (PEF) and FEV1 (forced expiratory volume) measurements, and blood oxygen saturation (%SpO_2). The Health Buddy receives connections from these medical devices, and through the data port, wireless hub, or infrared device, downloads readings from the identified attached device and transmits the responses over the telephone or Ethernet connection at predetermined times to the patient's health care professional.

The Health Buddy Appliance is a simple, user-friendly device that connects to the patient's standard home telephone line. The device connects to a Data Center via a toll-free number or an Ethernet connection to send patient responses since the previous data transfer and to retrieve the new dialogue.

The screen displays information sent by the patient's healthcare provider and asks questions about vital signs, symptoms and behaviors, and allows the patient to respond via four large buttons. The Health Buddy will respond to the patient's answers with education, reinforcement and messages that prompt patient action. The patient responses are sent to the patient's health care provider.

INDICATION FOR USE STATEMENT

Health Buddy® Appliance is indicated for use in non-clinical settings to collect and transmit historical data to healthcare professionals to help support effective management of their patients.

The Health Buddy® Appliance is an accessory device, intended to be a communication tool to enable healthcare providers to receive historical patient information. The product is used in conjunction with Health Hero Network's Online Service, a communication tool to enable health care providers to educate, motivate, and receive patient information. Health Buddy Appliance 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 to be performed under the supervision and oversight of an appropriate healthcare professional.

SUBSTANTIAL EQUIVALENCE COMPARISON

This submission represents a modification to the physical design and the software in the Health Buddy® Appliance to support the integration of infrared, Ethernet network connectivity, and a new LCD, in addition to the improvements in manufacturability and serviceability. It is therefore substantially equivalent to the cleared Health Buddy Appliance (#K063612, #K060843, #K050567, #K042273, #K040086 and #K993128). The device is also substantially equivalent to the CareMatix Wellness System (#K040966), and the Medic4All Telemedicine System (VMS-01) (#K062662), which uses an internet wireless connection between the monitoring device and receiving station located inside the home.

PERFORMANCE TESTING

Verification and validation testing activities were conducted to establish the performance, functionality and reliability characteristics of the Health Buddy Appliance. Testing included electrical safety, EMC environmental testing, unit testing, integration testing, signal integrity testing, system testing, shipping/distribution, and functional testing. A hazard risk analysis was also performed and associated risks mitigated through design or labeling. The Health Buddy Appliance performed as intended.

CONCLUSION

The Health Buddy Appliance is substantially equivalent in technology, features, and indications for use to devices cleared under the Federal Food, Drug and Cosmetic Act. Therefore, safety and effectiveness are reasonably assured, justifying 510(k) clearance of this modified device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2008

Health Hero Network, Inc.
c/o Ms. Robin Bush
Regulatory Affairs
2400 Geng Road, Suite 200
Palo Alto, CA 94303

Re: K080091
Health Buddy® Appliance
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiologic Signal Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: January 11, 2008
Received: January 14, 2008

Dear Ms. Bush:

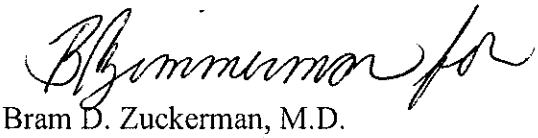
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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

Section 1.2

Indications for Use

510(k) Number: K080091

Device Name: Health Buddy® Appliance

Indications for Use:

Health Buddy® Appliance is indicated for use in non-clinical settings to collect and transmit historical medical information to healthcare professionals to help support effective management of their patients.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D) and/or Over-The-Counter Use _____ (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 K080091