Section 1.3

Summary of Safety and Effectiveness

REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT

Geoffrey J. Clapp
Health Hero Network
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NAME OF DEVICE

Trade Name:	Health Buddy® with Buddylink
Common Name:	Accessory to Glucose Test System
Device Product Code:	CGA
Classification Name:	Glucose Test System (21 CFR 862.1245)
Device Panel:	75, Clinical Chemistry
Device Classification:	Class II

PREDICATE DEVICES

- Health Buddy® with Buddylink (K993128)
- In Touch Diabetes Management Software (K984527)
- HomMed Central Station (K020184)

DEVICE DESCRIPTION

The Health Buddy appliance is a communications product that connects to a telephone line. 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 (such as blood glucose meter, non-invasive blood pressure cuff and patient weight scale). The Health Buddy with Buddylink retrieves data from a medical device (blood glucose meter, non-invasive blood

pressure cuff, or patient weight scale) and stores it for later transmission to a healthcare provider. The device has a data port that allows it to download readings from the attached device, only activated upon appropriate patient enrollment.

The Health Buddy with Buddylink is a simple, user-friendly device that connects to the patient's standard home telephone line. The device connects to the Data Center via a toll-free number to send responses from the previous day and to retrieve the current day's dialogue.

The screen displays the information or questions about vital signs, symptoms and behaviors sent by the patient's healthcare provider, 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 information is sent to the patient's health care provider.

INDICATION FOR USE STATEMENT

Health Buddy® with Buddylink 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® 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 with Buddylink is not intended to provide automated treatment decisions, nor 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 software in the Health Buddy® with Buddylink, and is therefore substantially equivalent to the cleared Health Buddy device (#K993128). The device is substantially equivalent to LifeScan ONE TOUCH Profile Diabetes Tracking System (#K950727) and the LifeScan IN TOUCH Diabetes Management Software (#K984527), and HomMed Central Station (#K020184).

CONCLUSION

The Health Buddy with Buddylink is substantially equivalent 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

MAR 1 0 2004

Health Hero Network, Inc.
c/o Mr. Geoffrey J. Clapp
Chief Technical Officer and Chief Operating Officer
2570 W. El Camino Real, Suite 111
Mountain View, CA 94040

Re: K040086
Trade Name: Health Buddy® with Buddylink
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: January 14, 2004
Received: January 16, 2004

Dear Mr. Clapp:

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) 594-4646. 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 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
Divison of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): # K040086

Device Name: Health Buddy® with Buddylink

Indications For Use:

Health Buddy® with Buddylink 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 __X___ (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)

James R. Vochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040086