

NOV 23 1999

K993128

### 510(k) Summary

**Submitter** Health Hero Network, Inc.  
2570 W. El Camino Real Suite 111  
Mountain View, CA 94040

**Contact Person** Joe Schwoebel  
Director, Regulatory Affairs  
Tel: (650) 559-1025  
Fax: (650) 559-1050

**Date** September 15, 1999

**Proprietary Name** Health Buddy® with Device Connect [Glucose Meter]

**Common Name** Accessory to a Blood Glucose Test System

**Classification No. and Name** Class II  
Glucose Test System

**Regulation No.** 21 CFR§862.1345

#### Device Description

Health Buddy with Device Connect [Glucose Meter] is indicated for use in non-clinical settings to collect and transmit historical blood glucose meter data to healthcare professionals to help support effective management of diabetes patients.

#### Intended Use

Health Buddy with Device Connect is intended to be a communication tool to enable healthcare providers to receive patient blood glucose information. The product is intended to be used in conjunction with Health Hero Network Online Service, a communication tool to enable healthcare providers to educate, motivate, and receive patient information. Health Buddy with Device Connect and the Health Hero Network Online Service are not intended to provide automated treatment decisions, nor to be used as a substitute for a healthcare professional's judgment. All patient medical diagnosis and treatment are to be performed under the supervision and oversight of an appropriate healthcare professional.

#### Substantial Equivalence

In Health Buddy with Device Connect [Glucose Meter] is substantially equivalent to the currently marketed LifeScan ONE TOUCH Profile Diabetes Tracking System and the LifeScan IN TOUCH Diabetes Management Software.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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Mr. Joe Schwoebel, RAC  
Director, Regulatory Affairs  
Health Hero Network, Inc.  
2570 W. El Camino Real, Ste. 11  
Mountain View, California 94040

Re: K993128  
Trade Name: Health Buddy® with Device Connect [Glucose Meter]  
Regulatory Class: II  
Product Code: CGA  
Dated: September 16, 1999  
Received: September 20, 1999

Dear Mr. Schwoebel:

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 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 (Pre-market 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.

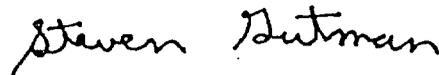
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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"(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/dsma/dsmamain.html>".

Sincerely yours,



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

Indications for Use

510(k) Number (if known): K993128

Device Name: Health Buddy® with Device Connect [Glucose Meter]

Indications for Use:

Health Buddy with Device Connect [Glucose Meter] is indicated for use in non-clinical settings to collect and transmit historical blood glucose data to healthcare professionals to help support effective management of diabetes patients.

Jean Cooper  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K993128

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NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

R.V. ✓

(Optional Format 3-10-98)