Section 5 510(k) Summary K091220

Submitter:	Healthanywhere, Inc.
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Contact person:	Shawn Slade, Director of Product Development and Operations
Date prepared:	8/28/2009
Trade name:	Healthanywhere System
Device classification:	870.2910, DRG, Physiological Transmitter and Receiver
Substantial equivalence claimed to:	The Hermes System, Palaistra Systems Inc, (K050929)

Device Description:
The Healthanywhere (HA) System is a user-friendly software system which provides the ability to remotely monitor basic wellness parameters. The HA System is comprised of an HA Client Application, anHA Server and the Healthcare Professional Portal (HCPP).

The HA Client Application provides capabilities to perform data collection, data transmission, message display, reminders/notifications, and reporting. It is used to collect data including vital measurements from noninvasive, commercially available, off–the-shelf, wireless medical peripherals, and patient care updates. The user data is transmitted though the HA Client Application to the HA Server using off-the-shelf, FCC-approved wireless/cellular/wired connectivity (including but not limited to GPRS, CDMA, WiFi, or Wired Ethernet) which is provided through the FCC-approved host hardware platform or through an external FCC approved wireless adapter.

The HA Server hosts the Healthcare Professional Portal (HCPP), a web application which is used to administer the HA System and users. The HCPP application provides user registration, care management, us configuration set-up, and data management. Based on specific parameters set by Healthcare Professionals, reminders and messages are scheduled and sent from the HA Server to the HA Client Applications.

Intended use:
The intended use of the HA System is for the collection, transmission, and persistence of medical measurement data and patient care data for the sole purpose of encouraging and tracking a patient's progress against the goals set between the Healthcare Professional and the patient. The goals would be established independent of the HA System in the pursuit of providing care for a chronic or post acute condition and/or to promote patient wellness.

The HA System would enable Healthcare Professionals to make use of the persisted information as a guide i delivering ongoing feedback to their patients, to set periodic reminders for patients to act on scheduled activities such as taking a vital measurement, and to receive notifications for events they configure such as a out of range vital measurement.

The HA System can record physiological information such as:

- Blood pressure measurements
- Pulse rate measurements
- Body weight measurements
- Blood glucose levels
- Body temperature measurements
- Blood oxygen saturation (%SpO2) levels

The HA System can be used by Healthcare Professionals to create health related questionnaires, exercise plans and nutrition plans; to forward these items to the patients; and to receive/review patient responses to th related questionnaires, exercise activities, and nutrition activities.

The HA System is not intended for diagnosis or as a substitute for medical care; it is alsonot intended to provide real-time data. The data is not used for time-critical care. The device is contraindicated for patients requiring direct medical supervision or emergency intervention.

Summary of technological characteristics:

There are two distinct subsystems in the HA System – the client software runs on a Microsoft Windows and BlackBerry platforms; and the server components run on a LINUX platform hosted in a secure data centre.

The HA Client Application is distributed on the following hardware platforms: BlackBerry (models: 8100, 8120, 8130, 8300, 8320, 8330, 8820, 8830); PC (models: Samsung NP-Q1U Tablet PC, Dell Inspirion Mini 10 Notebook, Dell Latitude XT Tablet PC, Dell Optiplex SX280, ELO TouchSystems 17A2 Touchcomputer

The HA Client Application is a standalone software application which collects information from off-the-shel Bluetooth-enabled medical peripherals, such as a Blood Pressure monitor, using a Bluetooth wireless connection. To transmit data from the medical peripherals to the Healthanywhere Client Application, the HA Client Application makes use of the embedded Bluetooth software on all of the hardware platforms listed above except for the Dell Optiplex SX280 and ELO TouchSystems 17A2 which require an external D-Link DBT-122 Bluetooth Adaptor. The following wireless, commercially-available medical peripherals are supported by the HA Client Application:

- AND UA-767PBT Blood Pressure Monitor
- AND UC-321PBT Weight Scale
- Nonin 9560 Pulse Oximeter
- Polymap PWR-08-03 Bluetooth Adaptor

Note: The application supports manually entered thermometer measurements; the choice of a thermomet is based on user preference and is independent from the HA Client Application

The HA Client Application uses the internet to route information to the HA Server via HTTPS or SSL over HTTP protocols and maintains the data stack until an acknowledgement is transmitted from the server indicating that the information is successfully persisted in the server-side database. Periodically, the client application connects to the server to resynchronize with the updates set by the Healthcare Professional including patient care settings, reminders, and notifications via a secure connection over HTTPS. All platforms noted above connect to the internet via a customer preferred option and carrier or internet service provider using off-the-shelf, FCC approved wireless/cellular/wired connectivity (including but not limited to

GPRS, CDMA, WiFi, or Wired Ethernet) which is provided through the FCC-approved host hardware platform or through an external FCC approved wireless adapter.

The HCPP web application runs in any standard web browser. HCPP enables Healthcare Professionals to perform program administration and vital signs monitoring. HCPP uses role-based controls and patient group to limit access to the patient care data; only an authorized Healthcare Professional can access patient data within a specific group of patients. HCPP users can configure patient care based on individual patient assessments.

Substantial equivalence:

The Healthanywhere System is substantially equivalent to The Hermes System (K050929) in that it allows patients to record data from equivalent devices using equivalent methods.

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 21 2009

Healthanywhere, Inc.
c/o Mr. Shawn Slade
Director Product Development and Operations
515 Legget Drive, Suite 700
Ottawa, Ontario
CANADA
K2K 3G4

Re: K091220
Trade/Device Name: Healthanywhere (HA) System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II (two)
Product Code: DRG
Dated: August 28, 2009
Received: September 11, 2009

Dear Mr. Slade:

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

Section 4 Indications for Use Statement

510(k) Number: K091220

Device Name: Healthanywhere System

Indications for Use:

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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