

510(k) Summary

JUL 3 2012

Submitted by Constant Care, LLC
Address: 4333 Shreveport Highway
Pineville, LA 71360
Telephone: (318) 861-0497
Facsimile: (866) 551-6030
Contact Name: Jodi Funderburk, VP of Development

Date Submitted: March 27, 2012

Trade Name: Constant Care LILAH Home Health Monitoring System
Common Name: Remote patient monitoring system

Product Code / Regulation: DRG (21 C.F.R. 870.2910)

The Constant Care LILAH Home Health Monitoring System also supports the following medical device product codes by means of separate medical devices:

| Classification Regulation | Product Code | Classification Name | Device Class |
|---------------------------|--------------|---|--------------|
| 21 C.F.R. 870.1130 | DXN | Noninvasive Blood Pressure Measurement System | II |
| 21 C.F.R. 880.2700 | FRI | Stand-on Patient Scale | I |
| 21 C.F.R. 870.2700 | DQA | Oximeter | II |
| 21 C.F.R. 862.1345 | NBW | Glucose Test System | II |
| 21 C.F.R. 890.5050 | NXQ | Daily Activity Assist Device | I |

Description: The Constant Care LILAH Home Health Monitoring System consists of two components: patient-side software to be installed on either an Asus EeeTop PC ET1611PUT 15.6 inch TouchScreen Atom D425 All-in-One PC, or an Acer ICONIA Tab W500-C52G03iss 10.1' LED Tablet PC for use in performing remote patient monitoring, and sending data to the Caretaker Portal secure host server; and caregiver-side software for receiving patient-side data and transmitting that data to healthcare professionals and remote caregivers through the Caretaker Portal secure host server.

The Constant Care LILAH Home Health Monitoring System is a remote patient monitoring device available by prescription designed to be used in the home or healthcare setting of a patient undergoing remote monitoring for maintenance of chronic disease. The Constant Care LILAH Home Health Monitoring System provides guidance in operating medical sensor devices, reminders for medication compliance and connectivity to healthcare professionals through text messaging and real-time video conferencing technology.

Intended Use: The Constant Care LILAH Home Health Monitoring System is intended for use in the home or healthcare setting to provide non-emergency, delayed, remote monitoring of a patient for maintenance of chronic disease; connecting to

commercially available wireless and wired medical devices such as glucose meters, weight scales, blood pressure monitors, medication reminders, and pulse oximeters; and providing guidance in operating medical sensor devices, reminders for medication compliance, and connectivity to healthcare professionals and remote caregivers through text messaging and real-time video conferencing technology.

Substantial Equivalence: The Constant Care LILAH Home Health Monitoring System is similar in intended use and technological characteristics to other Remote Patient Monitoring Devices, including the Honeywell HomMed Genesis Touch™ Personal Health Device (K112858).

Results of software validation and verification activities establish the device as safe and effective for its intended use, which is comparable to other predicate devices.



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

JUL 3 2012

Constant Care, LLC
C/O Seth A. Mailhot
Sheppard Mullin Richter & Hampton LLP
1300 I ST NW, 11th Floor East
Washington, DC 20005

Re: K120941

Trade/Device Name: Constant Care LILAH Home Health Monitoring System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: Class II
Product Codes: DRG, DXN, FRI, DQA, FLL, NBW, NXQ
Dated: May 29, 2012
Received: May 30, 2012

Dear Mr. Mailhot:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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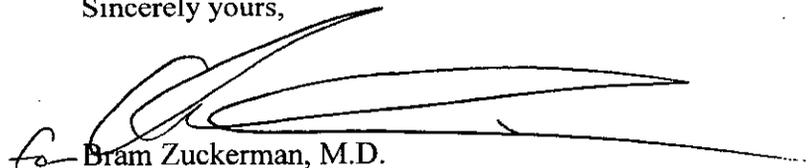
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): _____

Device Name: Constant Care LILAH Home Health Monitoring System.

Intended Use:

The Constant Care LILAH Home Health Monitoring System is a non-emergency, delayed, remote patient monitoring device available by prescription. The Constant Care LILAH Home Health Monitoring System is designed to be used in the home of a patient or healthcare setting to provide remote monitoring for maintenance of chronic disease. The Constant Care LILAH Home Health Monitoring System provides guidance in operating medical sensor devices, reminders for medication compliance and connectivity to healthcare professionals through text messaging and real-time video conferencing technology.

The Constant Care LILAH Home Health Monitoring System connects to commercially available wireless and wired glucose meters, weight scales, blood pressure monitors, medication reminders, and pulse oximeters. The Constant Care LILAH Home Health Monitoring System stores and displays the information on a computer screen and transmits the information to the Caretaker Portal secure host server using connectivity including, but not limited to, FCC approved Wi-Fi, Cellular Wireless, Internet, or Ethernet.

Healthcare professionals and remote caregivers can review the transmitted information utilizing the Caretaker Portal and set thresholds to trigger non-emergency alerts based on specific thresholds being exceeded.

The Constant Care LILAH Home Health Monitoring System is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. The data is made available to the patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention. The system is intended for patients who are willing and capable of managing its use. Judgment and experience by a caregiver or by a family member are required to check and interpret the information delivered.

A list of devices that are compatible with the Constant Care LILAH Home Health Monitoring System will be available in the user's manual and the Constant Care website.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(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

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