K00745
p1/3

APR 15 2010

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| Submitted By | Hoana Medical, Inc.<br>828 Fort Street Mall, Suite 620<br>Honolulu, HI 96813<br>Phone: (808) 523-[????]<br>Fax: (808) 523-5480 |
| Contact: | |
| Date Summary Prepared | |
| Trade Name | LifeBed Network Patient Vigilance System |
| Common/Classification Name | Monitor, Cardiac<br>74DRT, 870.2300 |
| Substantially Equivalent Devices | LG1 Patient Vigilance System (K052446)<br><br>LifeBed Patient Vigilance System (K082366)<br><br>LifeBed Network Patient Vigilance System (K083534)<br><br>Verathon, Corp BVI 9400 with ScanPoint (K071217)<br>Diagnostic Ultrasound BVM6500 with ScanPoint (K030763) |

**Description of the LifeBed Network Patient Vigilance System**

This submission is an update to the LifeBed Network Patient Vigilance System (K083534), incorporating **three changes to the software of the LifeBed Controller:**

- A software delay in the reporting of physiologic data has been removed.
- The "dashboard" screen has been modified to display the current heart and respiratory rate, a historical graph of the rates, and the currently active alerts.
- The time intervals of available reports have been modified from a range of eight hours to one month to a range of one hour to one week

Except for the LifeBed Controller, **no changes to the software of any other component** of the system have been made, and no changes to any hardware component of the system have been made.

This version of the LifeBed Network Patient Vigilance System is compatible with the Vigilance Display (K0902037).

The LifeBed Network Patient Vigilance System ("LifeBed Network") is composed of a bedside unit (either a LifeBed Display or Vigilance Display, generically referred to as a Display), a sensor array packaged in the form of a mattress coverlet, and the LifeBed Controller. The LifeBed Displays are optionally equipped with a wireless adapter.

The LifeBed Network Patient Vigilance System collects, stores, and reports patient medical and status information.

Each Display is a bedside unit that collects and processes data from a sensor array on the patients' bed. It reports patient heart rate, respiratory rate, whether the patient is in bed, and any alerts. The configuration of a Display may be changed on the Display or remotely from the LifeBed Network.

The Displays are connected to the LifeBed Controller via a TCP/IP network which is provided by the customer. This network may be wired (using Ethernet), or wireless (using WiFi) as required by the facility.

The hub of the LifeBed Network is the LifeBed Controller ("Controller"), which serves one unit (e.g., a hospital ward). From the Controller a user has access to the collected information and the ability to view and modify the configuration of connected Displays.

The LifeBed Network provides an interface which may be used to integrate with a Clinical Information System (CIS). When used in this way an auxiliary adapter isolates and translates the protocols between the LifeBed Network and the CIS. This interface allows the CIS to access the collected data and stored configuration for the Displays.

The LifeBed Network centralizes information access and configuration for a group of Displays. It DOES NOT change the manner in which alerts are communicated by the Display to the Nurse Call system of the hospital.

All user access to the LifeBed Network is constrained by a security system. Each user is authenticated by a user name and password and their ability to access data is controlled by their assigned role.

**Indications for Use**

The LifeBed Network Patient Vigilance System is intended for use with adult patients by health care professionals in the continuous measurement of heart rate, respiratory rate, and as an integral part of fall prevention protocols.

**Electrical, Mechanical, and EMC Testing for the LifeBed Network Patient Vigilance System**

No changes were made to the hardware of any component of the LifeBed Network; this submission relies upon the testing done for the LG1 Patient Vigilance System (K052446), LifeBed Patient Vigilance System (K082366), and the LifeBed Network Patient Vigilance System (K083534)

**Biocompatibility Testing**

No changes were made to patient contact surfaces; no biocompatibility testing was performed as part of this submission.

**Clinical Testing**

No changes were made to the LifeBed Patient Vigilance System (K082366) which contains the algorithm and control of the patient interface. The LifeBed Network only adds the networking and data collection capabilities. No clinical trials were performed in support of this submission.

**Conclusion**

All verification and validation testing conducted demonstrate that this release of the LifeBed Network Patient Vigilance System is substantially equivalent to the prior release (K092037).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR 1 5 2010

Hoana Medical, Inc.
c/o Ms. Cindy Green
Regulatory Affairs/Quality Assurance Consultant
North West Regulatory Support, LLC
21031 SE 202nd Street
Renton, WA 98058

Re: K100745
LifeBed Network Patient Vigilance System
Regulatory Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: II (two)
Product Code: 74 DRT
Dated: March 3, 2010
Received: March 16, 2010

Dear Ms. Green:

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.

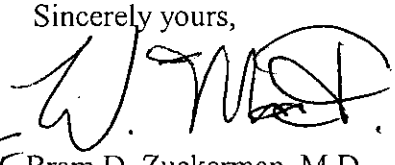
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

K100745

# Indications for Use

510(k) Number (if known):

Device Name: LifeBed Network Patient Vigilance System

Indications For Use:

The LifeBed Network Patient Vigilance System is intended for use with adult patients by health care professionals in the continuous measurement of heart rate, respiratory rate, and as an integral part of fall prevention protocols.

Prescription Use x AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100745

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