OCT - 2 2009

Section 5 – 510(k) Summary

Submitted By:	Hoana Medical, Inc. 828 Fort Street Mall, Suite 620 Honolulu, HI 96813 Phone: (808) 294-6934 (808) 523-0745 Fax: (808) 523-5480
Contact:	Dr. Larry Burgess Chief Medical Officer
Date Summary Prepared:	June 24, 2009
Trade Name:	LifeGurney™ Network Patient Vigilance System
Common/Classification Name	Monitor, Cardiac 74DRT, 870.2300
Substantially Equivalent Devices	LifeBed Network Patient Vigilance System (K083534)

Device Description

The Vigilance Display is a modification of the LifeBed Display previously submitted and cleared as K083534. The Vigilance Display differs from the Lifebed Display in that it has additional enclosures attached which contain batteries, a battery controller, an auxiliary nurse call system, and a wireless adapter. The battery and controller are attached to the back of the Display, the auxiliary nurse call system and wireless adapter are attached to the top.

User interaction is the same as on the LifeBed Display – the front panel keypad (hidden behind a door in the above photos) is used to change settings and mark events in the log. The large button on the front of the Display is used to acknowledge events. The software for the system is the same as in the predicate system. The nurse call connector and the Display power switch are located under a hatch on the right side of the Display (as viewed from the front). The Display power switch controls the power from the batteries to the Display.

The AC power connection is on the side of the battery and controller enclosure. Above the AC power connection is the main power switch. This switch controls the AC power to the battery controller. When the switch is on and an AC power source is connected the batteries are charging. When the switch is off or no AC power source is connected, then power is drawn from the batteries. On the opposite side are the slots for the removable batteries. These batteries are typically installed in pairs, but only one is required to operate the system (with reduced run time).

An optional external battery charger and spare batteries are available, enabling the operation of the system in areas where AC power is not available or is difficult to use.

The coverlet is the component that provides the interface between the patient and the Vigilance Display unit. It contains the sensors, wiring, and electronics necessary to measure the patient's heart rate, respiration rate, and bed presence and transmit signals to the Vigilance Display.

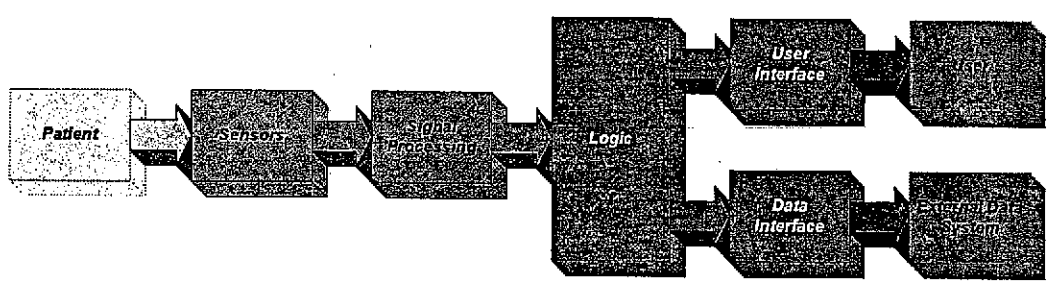
The LifeGurney Network Patient Vigilance System is compatible with and uses the same series of coverlets as the LifeBed Network Patient Vigilance System. Gurney specific coverlets will be sized to fit specific gurney mattresses.

The coverlet contains the sensing elements and interface electronics for connecting the coverlet to the Display with a coverlet cable. The sensing elements and electronics are separated from the patient by a layer of coated fabric; there is no contact between the patient and the sensors. Additional separation of the sensors is provided by the bed sheets, pads, and the patients' garments. The coverlet encases the existing mattress. The coverlet contains all necessary conductors to carry sensor signals within the coverlet.

Indications for Use

The LifeGurney 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.

Principles of Operation



The LifeGurney Network Patient Vigilance System has 5 functional blocks: Sensors, Signal Processing, Logic, User Interface, and the Data Interface. The Sensors provide an interface to the patient, the User Interface to the User, and the Data Interface to an External Data System.

There are two classes of sensors, one for heart and respiration rate and one for detecting the presence of a patient. The sensors translate the motion of the heart beating and lungs breathing to electronic signals which are transmitted to the Signal Processing Block.

The Signal Processing block transforms the signals from the sensors into a set of three numbers; a heart rate, a respiratory rate, and a patient presence indication.

These numbers are then used by the Logic block to detect the conditions which are being monitored (e.g. rate violations, patient presence). The heart rate and respiratory rate are handled independently of

each other. The patient presence indication is calculated independently also, and this is fed back to the heart rate and respiratory alert state machines, When a monitored condition is detected, the Logic block will communicate this to the User and Data Interfaces. Additionally the data received by the Logic block from the Signal Processing block is passed on to these interfaces.

The User Interface block is responsible for presenting the data to the User via the LCD display. The User Interface also allows the user to control parameters and acknowledge alerts.

The Data Interface block is similar in function to the User Interface block except that it interacts with an External Data System over a network connection. The External Data System may represent a variety of entities such as an Electronic Medical Record System or a server supporting remote users.

Summary of Technological Characteristics

Measurement Limits	Heart rate from 35 - 200 BPM Respiration rate from 4 -70 BPM
Operating Limitations	Environment: 10-40° C, 20-80% Relative Humidity
Power	100 -240 VAC, 50 -60 Hz, 1.75A @ 100V
Available settings	Patient Select Heart Rate High/Low Limits Respiration Rate High/Low Limits Bed Exit Monitoring TCP/IP Network Settings Auxiliary Alert Enable LCD Display Contrast/Brightness
Functional Limitations	The LifeGurney Network Patient Vigilance System is solely responsible for establishing the notification parameters for patients on the system. Parameters other than heart rate, respiratory rate, and bed exit are not monitored. The system is not intended for use with patients under the age of 18 years or patients who weigh less than 45 kg (99 lbs) or more than 227 kg (499 lbs). The system is not intended for use while the patient is experiencing excessive motion due to seizure, therapeutic equipment, or transport.
Performance Limitations	Mattress overlays, "toppers", or anything placed between the patient and coverlet may decrease performance of the system. More than one person in the bed may interfere with monitoring.

Electrical, Mechanical and EMC Testing for the LifeGurney Patient Vigilance System, patient vicinity components:

Testing has been completed and results meet applicable standards.

Electrical, Mechanical and EMC Testing for the LifeGurney Patient Vigilance System, non-patient vicinity components:

Testing has been completed and results meet applicable standards.

Conclusion

All verification and validation testing conducted demonstrate that the LifeGurney Network Patient Vigilance System is substantially equivalent to the LifeBed Network Patient Vigilance System.

	Lifebed Network Patient Vigilance System (K083534)	LifeGurney Network Patient Vigilance System	Same/Different
System Components	Sensing unit, control unit, software	Sensing unit, control unit, software	Same
Technological Characteristics	Piezo-electric sensing	Piezo-electric sensing	Same
Mode of Operation	Contact-less monitoring	Contact-less monitoring	Same
	Sensor in mattress coverlet	Sensor in mattress coverlet	Same
Performance Characteristics	Measures heart rate and respiration rate	Measures heart rate and respiration rate	Same
	Detects bed exit	Detects bed exit	Same
	Notifies nurse or caregiver of change in condition (e.g., heart rate or respiration rate exceeds set limits)	Notifies nurse or caregiver of change in condition (e.g., heart rate or respiration rate exceeds set limits)	Same
	Notifies nurse or caregiver of bed exit	Notifies nurse or caregiver of bed exit	Same
	Control unit receives the electric signals, processes them, and calculates, logs, displays the patient's parameters and generates alerts as per set thresholds, when needed.	Control unit receives the electric signals, processes them, and calculates, logs, displays the patient's parameters and generates alerts as per set thresholds, when needed.	Same

	Lifebed Network Patient Vigilance System (K083534)	LifeGurney Network Patient Vigilance System	Same/Different
Intended Use	Lifebed Network Patient Vigilance System is intended to measure heart rate, respiratory rate, and bed exit in adult patients for use by health care professionals.	The LifeGurney 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.	Same (Wording changes to improve readability and understandability)

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

Hoana Medical, Inc
c/o Ms. Cindy Green
NorthWest Regulatory Support, LLC
21031 SE 202nd Street
Renton, WA 98058

OCT - 2 2009

Re: K092037
Trade/Device Name: LifeGurney Network Patient Vigilance System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor
Regulatory Class: Class II (two)
Dated: June 24, 2009
Received: July 6, 2009

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.

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

Indications for Use

510(k) Number (if known): K092037

Device Name: **LifeGurney™ Network Patient Vigilance System**

Indications for Use:

The LifeGurney™ 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092037 16/1864