

KDS 2446

SECTION 5 – 510(k) Summary

FEB 2 2006

Submitted By: Hoana Medical Inc.
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Contact: Matt Gleis
Vice President of Research and
Development and Regulatory Affairs

Date Summary Prepared: September 2, 2005

Trade Name: LG¹ Intelligent Medical Vigilance System

Common/Classification Name: Monitor, Cardiac
74DRT, 870.2300

Substantially Equivalent Devices: Escort 100/300 Series B Patient Monitor
(K992413)
Hill-Rom Advanta-Bed, Class I Exempt

Description of the LG¹ Intelligent Medical Vigilance System:

The LG¹™ technology analyzes basic heart and respiratory rates without direct patient contact, eliminating the use of electrodes, wires and leads. The technology integrates proprietary signal processing algorithms with patented data collection devices that produce an electrical signal in response to physiological stimuli. The Bedside Unit passively extracts patient information as the patient lies upon this "sensor array," providing accurate measurements even through clothing, gowns or sheets.

The LG¹ system consists of two main components: the Bedside Unit, and the Passive Sensor Array™ (PSA™). The Bedside Unit houses the digital signal processing algorithms (LG¹ algorithms, version 1.0.0.36) that calculate heart and respiratory rates and bed exit status (in-bed sensor) in real time, and displays the data as part of the integrated graphical user interface. The Bedside Unit also houses the alarm logic, and interfaces to the existing nurse call system found in the hospital. The PSA is comprised of a mattress ticking ("coverlet" that zips over the entire mattress) that houses an array of sensors, which connect to the Bedside Unit via a cable with an integrated "quick disconnect" safety feature.

Intended Use

The LG¹™ Intelligent Medical Vigilance System is intended to measure heart rate and respiratory rate in adult patients, in bed, in a general care hospital environment. The system will also monitor bed exit.

Principles of Operation

The LG¹ Intelligent Medical Vigilance System operates in the following manner. The bed on a general care floor is fitted with the sensor array built into a sleep surface coverlet. Each bed is then fitted with a normal sheet and bedding above the coverlet.

The device measures heart rate and respiration rate and monitors those against preset limits. If the bedside unit senses the heart rate or respiration rate is outside the desired limits for a period of time, it will signal the nurse with an alarm indicator using the existing nurse call system. If the patient has been evaluated as at risk to fall, the bed exit alarm can also be enabled. When the unit senses the patient is attempting to get out of bed, it will use the nurse call system to signal the nurse.

The system will trend and display graphics or a table of heart rate and respiration rate in 10 minute, 2, 4, 8, and 12 hour views of the data.

Electrical, Mechanical and EMC Testing

Electrical, Mechanical and EMC Testing per IEC 60601 was performed and the LG¹ Intelligent Medical Vigilance System passed all tests.

Biocompatibility Testing

Biocompatibility testing was conducted according to the requirements of ISO 10993, *Biological Evaluation of Medical Devices, Table 1 – Initial Evaluation Tests for Consideration* for a surface device in contact with skin for less than 24 hrs. All test article materials passed.

Clinical Testing

The results of the clinical testing demonstrate that the LG¹ Intelligent Medical Vigilance System meets the performance requirements.

Conclusion

All test results demonstrate that the LG¹ Intelligent Medical Vigilance System is safe, effective and performs as well as the predicate devices, the Escort 100/300 Series B Patient Monitor and the Hill-Rom Advanta-Bed Patient Position Monitor.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2006

Hoana Medical, Inc.
c/o Mr. Matthew S. Glei
Vice President, Research and Development and Regulatory Affairs
1001 Bishop Street
American Savings Bank Tower, Suite 228
Honolulu, HI 96813

Re: K052446
Trade Name: LG¹™ Intelligent Vigilance System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: DRT
Dated: January 3, 2006
Received: January 5, 2006

Dear Mr. Glei:

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.

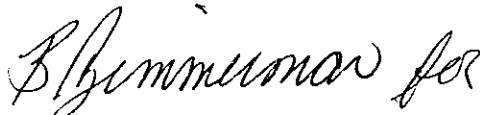
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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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); 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. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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): K052446Device Name: LG¹™ INTELLIGENT MEDICAL VIGILANCE SYSTEM

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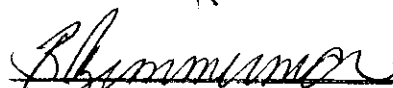
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K052446

(Posted November 13, 2003)