K083271

SECTION 2- 510(K) SUMMARY

DEC 2 4 2008

Name and Address of Applicant
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

Contact:
Jack Coggan
Director, Regulatory Affairs
(949) 580-1555 ex. 3325
Fax: (949) 580-1550

Trade/Device Name: BSM-2300 Series and BSM-6000 Series with CGS-9001A Series Communication Gateway Server Optional Accessory.

Common or usual Name: Bedside Monitor, Patient Monitor, Cardiac Monitor, Vital Signs Monitor, Anesthesia Monitor

Legally Marketed Predicate: Nihon Kohden BSM-2300A Series Bedside Monitor and Accessories per 510(k) K011918, commercial distribution certification dated September 12, 2001 and BSM-6000 Series Bedside Monitor per 510(k) K080342, commercial distribution certification date February 26, 2008.

Intended Use:
This device is intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility. The device is intended to monitor the electrocardiogram and generate visible and/or audible alarms when an arrhythmia exists. The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO_2), noninvasive blood pressure (NIBP), invasive blood pressure (IBP), body temperature, carbon dioxide concentration (CO_2 and $EtCO_2$), and respiratory rate. The device may generate an audible and/or visible alarm when a measured rate falls outside preset limits. The device may also condition and transmit physiological signals via radio frequency. This will be available for use by medical personnel on all patient populations.

A summary of the technological characteristics of the device compared to the predicate device:
The CGS-9001A Series Communication Gateway Server is an Optional Accessory to the BSM-2300A and BSM-6000 Bedside Monitors, it is a software product that allows the Nihon Kohden Patient Monitoring System to transfer alarm event information from the monitoring device to a third party system. The Communication Gateway Server collects alarm information from all networked patient monitors in a Nihon Kohden Patient Monitoring System and forwards it to a commercially available third party Secondary Alarm Notification System. The alarm notification generated by the third party alarm (not marketed by Nihon Kohden America, Inc.) is for Secondary Alarm Notification Only.

Performance Testing

- The device complies with IEC 601-1 sub-clause 56.2(c) implemented by 21 CFR Part 868 Performance Standard for Electrode Lead Wires and Patient Cables. To date, no other special controls or performance standards are known or established for this device.

- The device is not sterile.

- The device does not directly contact patients. Therefore, good laboratory practice studies were not required per 21 CFR Part 58.

- The BSM-2300A and BSM-6000 Bedside Monitors with CGS-9001A Series Communication Gateway Server Optional Accessory is a new device.

- The BSM-2300A and BSM-6000 Bedside Monitors with the CGS-9001A Series Communication Gateway Server Accessory was subjected to safety and performance testing procedures. These tests verified that the device performed within specifications.

- Therefore, Nihon Kohden US Lab believes that the device is substantially equivalent to the Nihon Kohden predicate device as stated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 4 2008

Nihon Kohden America, Inc.
c/o Mr. Jack Coggan
Director of Regulatory Affairs/Quality Assurance
90 Icon Street
Foothill Ranch, California 92610-1601

Re: K083271
Trade Name: BSM-2300A and BSM-6000 Bedside Monitors with CGS-9001A Series Communication Gateway Server Optional Accessory
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class II (two)
Product Code: MHX
Dated: December 10, 2008
Received: December 12, 2008

Dear Mr. Coggan:

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.
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) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 (240) 276-3150 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

G. Indications for Use Statement:

510(k) Number (if known): K083271

Device Name: The BSM-2300A and BSM-6000 Bedside Monitors with the CGS-9001A Series Communication Gateway Server Optional Accessory

Indications for Use:

The device is intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility. The device is intended to monitor the electrocardiogram to generate audible and/or visible alarms when an arrhythmia exists. The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO_2), noninvasive blood pressure (NIBP), invasive blood pressure (IBP), body temperature, carbon dioxide concentration (CO_2 and $EtCO_2$), and respiratory rate. The device may generate an audible and/or visible alarm when a measured rate falls outside preset limits. The device may also condition and transmit physiological signals via radio frequency. This will be available for use by medical personnel on all patient populations.

Prescription Use: X (Part 21 CFR 801 Subpart D) and/or Over the Counter Use: ____ (21 CFR 807 Subpart C)

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

CONCURRANCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083271