SECTION 2- 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
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FEB 26 2008

- **Trade/Device Name:** BSM-6000 Series Bedside Monitor

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

- **Classification Name:** The device has been classified as Class II by the Cardiovascular Device Classification Panel under 21 CFR Part 870.1025, Physiological patient Monitor with Arrhythmia Detection and Alarms as MHX and under 21 CFR 870.2340, ECG Analysis System as LOS. Functions of the device have also been classified as Class II by the Anesthesiology Device Classification Panel.

  Legally Marketed Predicate: Nihon Kohden BSM-5130A Beside Monitor per 510(k) K030105, commercial distribution certification dated March 4, 2003 and Nihon Kohden ORG-9700 Multiple Patient Receiver as per 510(k) K071058, commercial distribution certification dated June 29, 2007.

A Description of the Device:

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 produce a visual record of the electrical signals produced by the heart and monitor the electrocardiogram to 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), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), body temperature, Cardiac Output (CO), oxygen concentration (FiO_2), CO_2 and $EtCO_2$, respiratory rate, BIS and inspired and expired anesthetic agents and gases including CO_2, O_2, N_2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane. Anesthetic agents and gases are detected using the cleared AG-920RA Anesthetic Agent Detection System. The device can interface to external equipment to display numerical and waveform data and alarms from the external devices. Supported external devices include AG-920RA Anesthetic Agent Detection System, Ventilators, CO_2 Monitors, TOF Monitors, BIS Monitors, CCO/SvO_2 Monitors and continuous NIBP Monitors. The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits. This device may also be used to condition and transmit physiological signals via radio frequency.

A summary of the technological characteristics of the device compared to the predicate device:

Similarities:

- The indications of use are identical.
- The fundamental technology has not changed, in that the Beside Monitor technology remains the same.
- The alarm display, electrosurgery interface filter, heart rate counting method, VPC counting range remain the same.
- The Arrhythmia graphic trend, arrhythmia alarm and arrhythmia recall remains the same.
- SpO_2 display range, declared range remains the same.
- The NIBP non-invasive blood pressure methods, display measuring range and alarm limits remain the same.
- Invasive Pressure (IBP) measuring method, range accuracy, alarm limits, pulse sync tone, pulse rate count range and counting accuracy remain the same.
- Cardiac Output (CO) measuring method, range, accuracy and alarm limits remain the same.
- External communication, user interface, recorder, transmitter, ECG acquisition and analysis and environmental conditions are the same.

Minor Differences:

- Arrhythmia Detection recalls files have 100 files for the predicate and 24 hours for the new devices.
- SpO_2, there is a slight difference in pulse rate count range, predicate: 0, 30-300 bpm and 0, 20-250 bpm. The new devices have 0, 30-300 bpm, 0, 20-300 bpm and 0, 25-240 bpm.
- Invasive pressure (IBP) number of channels, there are up to 5 channels for the predicate and up to 7 channels for the new devices.
- External Communication has the following differences:
  - Predicate Central Station Communications is optional and new device is standard.
  - External Display Connector is a standard item for the predicate and optional for the new devices.
  - User Interface full disclosure storage, is 30 hours 5 waves as standard and 24 hours all waves and standard for the new device.
  - Dimensions and weight, the predicate device's dimensions are 339 x 315 x 250 and the weight is 10kg, the new devices dimensions are (BSM-6501A) 342 x 353 x 183 and weighs 8.3 kg and the BSM-6701A dimensions are 415 x 392 x 191 and weights 10.3 kg.

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- The device is not sterile.
  - The device does not directly contact patients. Accessories that contact patients, such as probes and thermistors, are the same accessories as used with other legally marketed products or are comprised of the same component materials as the predicate accessories. Therefore, good laboratory practice studies were not required per 21 CFR Part 58.

- The device complies with the IEC-60601-1 standard and sub-clause 56.3 (c) implemented by 21 CFR Part 868 Performance Standard for Electrode Lead Wires and Patient Cables.

- The BSM-6000 Series device was subjected to tests to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. The software validation tested the operation of the software function of the device. The results confirmed that the device performed within specifications.

- Therefore, Nihon Kohden believes that the devices are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 26 2008

Nihon Kohden America, Inc.
c/o Mr. Jack Coggan
Director, Regulatory Systems
90 Icon Street
Foothill Ranch, CA 92610

Re: K080342
BSM-6000 Series Bedside Monitors
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: February 06, 2008
Received: February 08, 2007

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,

B Zuckerman for

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): _____

Device Name: BSM-6000 Series Bedside Monitors

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 produce a visual record of the electrical signals produced by the heart and 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), non-invasive blood pressure (NIBP), continuous non-invasive blood pressure (CNIBP), invasive blood pressure (IBP), body temperature, BIS, Cardiac Output (CO), oxygen concentration (FiO_2), carbon dioxide concentration (CO_2) and $EtCO_2$, respiratory rate and inspired and expired anesthetic agents and anesthetic gases including N_2O, Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane. The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits. This device may also be used to condition and transmit physiological signals via radio frequency.

The device will be available for use by medical personnel on patients within a medical facility on all patient populations.

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080342

Prescription Use ___X_____ AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)