

MAR 04 2003

**SECTION 2 - 510(K) SUMMARY**

**Name and Address of Applicant**

Nihon Kohden America, Inc.  
Attn: Regulatory Affairs  
90 Icon St.  
Foothill Ranch, Ca 92610

Phone: (949) 580-1555  
Fax: (949) 580-1550

**Indications for Use:**

The device is intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring as well as gas monitoring. 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<sub>2</sub>), noninvasive blood pressure (NIBP), invasive blood pressure (IBP), body temperature, Cardiac Output (CO), oxygen concentration (FiO<sub>2</sub>), CO<sub>2</sub> and EtCO<sub>2</sub>, respiratory rate and inspired and expired anesthetic agents and gases including N<sub>2</sub>O, 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 all patient populations within a medical facility.

The device complies with IEC 601-1 sub-clause 56.3(c) implemented by 21 CFR Part 898 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 BSM-5130A series devices are 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 BSM-5130A series Bedside Monitor was subjected to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. Software validation tested the operation of the software functions of the device. The results confirmed that the device performed within specifications.

Therefore, Nihon Kohden believes that the device is substantially equivalent to the combination of two Nihon Kohden predicate devices as stated.

Common names for the BSM-5130A device include Bedside Monitor, Patient Monitor, Cardiac Monitor and Vital Signs Monitor and Anesthesia monitor. The device has been classified as Class III per 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 and the General Hospital and Personal Use Classification Panel as follows: under 21 CFR 870.2300, "Cardiac Monitor (including cardiometer and rate alarms)" per DRT; under 21 CFR 870.2700, "Oximeter" per DQA; under 21 CFR 870.1130, "Noninvasive Blood Pressure Measurement System" per DXN; under 21 CFR 870.1110 and 21 CFR 870.1100, "Blood Pressure Computer and Alarm" per DSK and DSJ; under 21 CFR 880.2910, "Thermometer, Electronic, Clinical" per FLL; under 21 CFR 868.2375, "Breathing Frequency Monitor" per BZQ; under 21 CFR 868.1720, "Oxygen Gas Analyzer" per CCL; under 21 CFR 868.1400, "Carbon Dioxide Gas Analyzer" per CCK; under 21 CFR 870.2910, "Radio Frequency Physiological Signal Transmitter" per DRG.

The predicate devices are the Nihon Kohden BSM-4100A Monitor per 510(k) #K001693, commercial distribution certification dated October 24, 2000 and the Nihon Kohden Multigas Unit, Ag-920RA per 510(k) #K020046, commercial distribution certification dated July 25, 2002. The new device is a combination of the two devices. The predicate device, marketed by other companies, include: Anesthesia Monitor by Datex-Ohmeda, 510k #K022485, which is similar in intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 04 2003

Nihon Kohden America, Inc.  
c/o Mr. Serrah Namini  
Regulatory Affairs Associate Director  
90 Icon Street  
Foothill Ranch, CA 92610

Re: K030105  
Trade Name: BSM-5130A Series Bedside Monitors  
Regulation Number: 21 CFR 870.1025  
Regulation Name: Arrhythmia Detector and Alarm  
Regulatory Class: Class III (three)  
Product Code: MHX  
Dated: January 12, 2003  
Received: January 13, 2003

Dear Mr. Namini:

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.

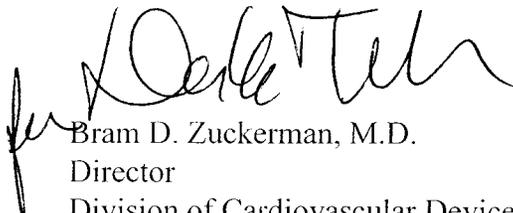
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style with a large initial "B" and "Z".

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

NIHON KOHDEN AMERICA, INC.

510(k) NOTIFICATION  
BSM-5130A Series Bedside Monitor

G. Indications for Use Statement

510(k) Number (if known): K030105

Device Name: BSM-5130A Series Bedside Monitors

Indications for Use:

The series of device are 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<sub>2</sub>) noninvasive blood pressure (NIBP) invasive blood pressure (IBP), body temperature, Cardiac Output (CO ), oxygen concentration (FiO<sub>2</sub>), carbon dioxide concentration (CO<sub>2</sub> and EtCO<sub>2</sub>), and respiratory rate, CO<sub>2</sub> and EtCO<sub>2</sub>, respiratory rate and inspired and expired anesthetic agents and anesthetic gases including N<sub>2</sub>O, 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 including adults, children and infants.

The ECAPS 12 interpretive ECG software program of the device is limited for use with patients age 3 years to adult. The interpretation is intended to provide an assessment of ECG waveform rhythm and morphology to assist the physician in diagnosis and is not intended as the sole basis for diagnosis. All assessments provided by the interpretation program are recommended for review by qualified physicians trained in electrocardiography.

**Prescription Use Only**

  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K030105