SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant

Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

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

Device Name: OPV Series Bedside Monitor. Common names for the device include Bedside Monitor, Patient Monitor, Cardiac Monitor and Vital Signs Monitor.

Legally Marketed Predicate: Nihon Kohden BMS-2300A Series Bedside Monitor per 510(k)# K011918.

Description and Intended Use: The device is a multi-parameter monitor consisting of a color LCD screen to display waveforms and numerics of monitored parameters. Options include a built-in thermal array recorder. The device is software driven. Both the device and the predicate have the same intended use 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. The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO_2), noninvasive blood pressure (NIBP), and respiratory rate. The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits. This device may also condition and transmit physiological signals via radio frequency. This device will be available for use by medical personnel on all patient populations.

There are no significant changes in function, biocompatibility, performance or manufacturability compared to the predicate device that would affect the safety and effectiveness of the device as intended for use. The new device is a simplified version of BSM-2300 as well as BSM-4100 and does not include arrhythmia detection. Therefore, Nihon Kohden believes that the new OPV Series, is substantially equivalent to the predicate BSM-2300A Series Bedside Monitor.

Performance Testing

- The device complies with IEC 60601-1 subclause 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 device is designed to comply with the following voluntary industrial standards: IEC 60601-1 (1988), Amendment 1 (1991), Amendment 2 (1995), IEC 60601-1-1 Amendment 1 (1995), IEC 60601-1-2 (1993-05), IEC 60601-2-27 (1994), IEC 60601-2-30 (1995)
- The device is not sterile.
- The device does not directly contact patients. Accessories that contact patients, such as ECG leads, SpO_2 probes and NIBP cuffs, are the same accessories as used with other legally marketed products or are comprised of the same component materials as the predicate accessories.
- The device was subjected to environmental testing including temperature/humidity stress testing, electromagnetic interference / electromagnetic compatibility testing and safety standards testing and performance testing procedures. Test criteria is established prior to testing based upon product specifications and applicable standards. The completed testing showed that the device met its product specifications and verified conformance to safety, reliability, and applicable standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 6 2003

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

Re: K032749
Trade Name: OPV Series Bedside Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac monitor (including cardiotachometer and rate alarm).
Regulatory Class: Class II (two)
Product Code: MWI
Dated: August 31, 2003
Received: September 5, 2003

Dear Ms. Namimi:

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 (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,

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): K032749

Device Name: OPV 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 monitor ECG. The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO_2) noninvasive blood pressure (NIBP) and respiratory rate. The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits. The device may also condition and transmit physiological signals via radio frequency. Waveforms, numeric data, trendgraphs, and vital signs lists can be recorded manually or automatically on the optional recorder unit. Waveforms and parameter data from the monitor can be sent to a Cardiac Telemetry System, or to a Central Monitor via a Multiple Patient Receiver and transmitter. The device will be available for use by medical personnel on all patient populations.

Prescription Use Only

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032749