K 020046

JUL 2 5 2002

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
Attn: Regulatory Affairs
90 Icon Street
Foothill Ranch, California 92610

Phone: (949) 580-1555
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Common names for the device include Bedside Monitor, Patient Monitor, Cardiac Monitor and Vital Signs Monitor. The functions of the device added by the AG-920RA option are classified as Class II per the Anesthesiology Device Classification Panel per 21 CFR 868.1500, "Analyzer, Gas, Enflurane, Gaseous-Phase", CBQ; 21 CFR 868.1620, "Analyzer, Gas, Halothane, Gaseous-Phase", CBS; and 21 CFR 868.1700, "Analyzer, Gas, Nitrous-Oxide, Gaseous-Phase", CBR.

The AG-920PA module is equivalent to the 90518 Multi-gas Analyzer per K954962 and the SC9000/SC9015 Multi-gas Module per K965062.

The device currently marketed per K001693 is intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring including arrhythmia detection and alarms within a medical facility. With the new AG-920PA option, the device will measure and display Carbon dioxide (CO_2), nitrous oxide (N_2O), oxygen (O_2), and any of five anesthetic agents (Halothane, Isoflurane, Enflurane, Sevoflurane, and Desflurane).

The device complies with IEC 601-1 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 not sterile.

The device does not directly contact patients, therefore, good laboratory practice studies were not required per 21 CFR part 58.

The device 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 device software. The results confirmed that the device performed within specifications.

The device is designed to comply with the following voluntary industrial standards: IEC 60601-1 (1988-12), Amendment 1 (1991-11), Amendment 2 (1995-03), IEC 60601-1-2 (1993-05) and CISPR11 Group 1, Class A

Therefore, Nihon Kohden believes that the device is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 5 2002

Ms. Serrah Namini
Regulatory Affairs Manager
Nihon Kohden America, Incorporated
90 Icon Street
Foothill Ranch, California 92610

Re: K020046
Trade/Device Name: Multigas Unit, Model AG-920RA
Regulation Number: 868.1400; 868.1720; 868.1700; 868.1500; 868.1620
Regulation Name: Carbon dioxide gas analyzer; Oxygen gas analyzer; Nitrous oxide gas analyzer; Enflurane gas analyzer; Halothane gas analyzer
Regulatory Class: II
Product Code: CCK; CCL; CBR; CBQ, NHO, NHP, NHQ; CBS
Dated: May 2, 2002
Received: May 2, 2002

Dear Ms. 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.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

G. Indications for Use Statement

510(k) Number (if known): K020046

Device Name: BSM-4100A Bedside Monitor with AG-920RA Option

The device currently marketed per K001693 is intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring including arrhythmia detection and is available for use by medical personnel on patients within a medical facility including adults, children and infants.

The optional AG-920RA module will measure carbon dioxide (CO_2), nitrous oxide (N_2O), oxygen (O_2), and any of five anesthetic agents (Halothane, Isoflurane, Enflurane, Sevoflurane, and Desflurane) of a patient undergoing anesthesia and display the results on a bedside monitor.

Prescription Use ✓

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020046