SECTION 2 - 510(K) SUMMARY

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

Date: June 28, 2006

DEC 27 2006

Contact:
Serrah Namini,
Regulatory Affairs Assoc. Director
(949) 580-1555 Ext. 4401
Fax: (949) 580-1550

- **Device Name**: OLG-2800A series
- **Trade or proprietary name:** OLG-2800A
- **The common or usual name:** Breathing Frequency Monitor, Carbon Dioxide Gas Analyzer
- **The classification name:** Monitor, breathing frequency
- **Legally Marketed Predicate:** Nihon Kohden BMS-5130A Series Bedside Monitor per 510(k)# K030105.

Description and Intended Use: The OLG-2800A is a portable monitor that monitors respiration status of patients at a medical facility setting. The device is used with commercially available sensors for intubated and non-intubated patients. The device is a monitor, which displays waveforms and numeric data, such as: , $EtCO_2$, and respiratory rate, as well as trendgraphs. The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits. Alarms are indicated by sound, blinking LED (numeric display) and messages on the LCD.

The device LED displays $EtCO_2$ value and respiration rate and the LCD indicates CO_2 waveforms, and alarm settings and trendgraphs. The device is AC and/or battery operated. This device will be available for use by medical personnel at medical facility setting, including ER, OR, ICU, CCU, clinic and doctor's office on all patient populations, depending on the accessories (CO_2 sensors) used with the device. These accessories have been cleared and are available with other Nihon Kohden monitors.

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

Performance Testing

- To date, no 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 (1988-12), Amendment 1 (1991-11), Amendment 2 (1995-03), IEC 60601-1-2 (2001), IEC 60601-1-1 (2000)
- The device is not sterile.

- The device does not directly contact patients. Accessories that contact patients, such breathing adapters, are the same accessories used with other legally marketed products.

- The device was subject to environmental testing including temperature/humidity stress testing, electromagnetic interference / electromagnetic compatibility testing and safety standards testing and performance testing procedures. Test criteria were established before testing based on product specifications and applicable standards. The completed testing showed that the device met its product specifications and verified conformance to safety, reliability, and recognized standards as applicable. Software verification and validation verified and confirmed the operation of the software and hardware functions of the device.

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. Therefore, Nihon Kohden believes that the new OLG-2800A series, is substantially equivalent to the predicate BSM-5130A Series Bedside Monitor with having fewer indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Serrah Namini
Regulatory Affairs Associate Director
Nihon Kohden America, Incorporated
90 Icon Street
Foothill Ranch, California 92610-1601

DEC 27 2006

Re: K062115
Trade/Device Name: Carbon Dioxide Monitor, Model OLG-2800A
Regulation Number: 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: November 27, 2006
Received: November 28, 2006

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.

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

- **Indications for Use**

510(k) Number (if known):

Device Name: OLG-2800A

Indications For Use:

The OLG-2800A is a portable monitor that measures respiration status of patients at a medical facility setting. The device is used with commercially available sensors for intubated and non-intubated patients. The device displays waveforms and numeric data of monitored parameters, such as: CO_2 , $EtCO_2$, respiratory rate, and trendgraphs. The device may generate an audible and/or visual alarm when a measured parameter falls outside preset limits.

The device LED display shows $ETCO_2$ value and respiration rate and the LCD display shows CO_2 waveforms, and alarm settings. The device is AC and/or battery operated. This device will be available for use by medical personnel on all patient populations depending on the CO_2 sensor kit.

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)

Neil C. Ogden for A.A.G.
(Div...)
...of Anesthesiology, General Hosp..., Page 1 of _____
...n Control, Dental Devices
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