SECTION 2 - 510(K) SUMMARY

K083456

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

Contact:
Jack Coggan
Director, Regulatory Affairs
(949) 580-1555 ex. 3325
Fax: (949) 580-1550

MAR - 2 2009

Trade/Device Name:
Nihon Kohden TG-970P Series CO_2 Sensor Kit

Common or Usual Name:
Capnometer, Carbon Dioxide (CO_2) Analyzer, Carbon Dioxide (CO_2) Indicator

Classification Name:
The device has been classified as Class II by the Division of Anesthesiology Devices and Anesthesiology Classification Panel under 21 CFR Part 868.1400 "Analyzer, Gas, Carbon dioxide, Gaseous-phase" as per part 73 CCK.

Legally Marketed Predicate Device:
Nihon Kohden TG-920P CO_2 Sensor Kit as per 510(k) K040875 commercial distribution certification dated October 15, 2004.

Intended Use:
The Nihon Kohden TG-970P Series CO_2 Sensor Kit is intended for medical purposes to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory status. Along with other methods indicated by the physician for medical diagnosis, this device is intended as an indicator of patient carbon dioxide concentration during expiration.

A summary of the technological characteristics of the device:
The Nihon Kohden CO_2 Sensor Kit, model number TG-970P Series, is intended for medical purposes to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory (end tidal CO_2) status. The device measuring technique is through absorption of infrared radiation. The airway adapter is a Single Patient Use disposable product.
The device is intended as an indicator of patient carbon dioxide concentration during expiration for intubated patients. The device is intended for use with patients weighing 7kg or more. The device is not recommended for patients with low tidal volume such as patients weighing less than 7kg or patients with a respiration rate greater than 150 breaths per minute.

510(k) Summary:

- The device is not sterile.

- The device performance and specifications are consistent with all requirements for this device type. To date, no performance standards or special controls are known or established for this type of device. The device was subject to electromagnetic, environmental, safety and performance testing procedures. These tests verified the safety and efficacy of the device under intended operation for this device.

- Therefore, Nihon Kohden believes that the TG-970P Series CO_2 Sensor Kit device is substantially equivalent to Nihon Kohden's predicate device TG-920P CO_2 Sensor Kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 2009

Mr. Jack Coggan
Director of Regulatory Affairs/Quality Assurance
Nihon Kohden America, Incorporated
90 Icon Street
Foothill Ranch, California 92610-1601

Re: K083456
Trade/Device Name: TG-970P Series CO_2 Sensor Kit
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: January 29, 2009
Received: February 2, 2009

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Ginette Y. Michaud, M.D.
Acting 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): _____

Device Name: TG-970P Series CO_2 Sensor Kit

Indications of Use:

The Nihon Kohden TG-970P Series CO_2 Sensor Kit is intended for medical purposes to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory status. Along with other methods indicated by the physician for medical diagnosis, this device is intended as an indicator of patient carbon dioxide concentration during expiration.

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)

Sally Y. Mahmoud M.D.
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083456