K072843

SECTION 2- 510(K) SUMMARY

Date: October 2, 2007

NOV 2 9 2007

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

Contact:
Jack Coggan
Director, Regulatory Affairs
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- **Trade/Device Name:** TG-920P CO_2 Sensor Kit
- **Common or usual Name:** Carbon Dioxide Gas Analyzer
- **Classification Name:** The devices have been classified as Class II by the Division of Anesthesiology Devices and the Anesthesiology Classification Panel under 21 CFR Part 868.1400 Analyzer, gas, carbon dioxide, gaseous-phase as per product code 73 CCK.
- **Legally Marketed Predicate:** Nihon Kohden TG-920P CO_2 Sensor Kit per 510(k) #040875, commercial distribution certification dated October 15, 2004.

Intended Use:

The Nihon Kohden new TG-920P CO_2 Sensor Kit has the same intended use as the predicate Nihon Kohden TG-920P CO_2 Sensor Kit. Both are intended for medical purposes to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilator status. These device are intended to measure the partial pressure of the expired CO_2 of the patient and the respiratory airflow with a cannula tube.

A summary of the technological characteristics of the device compared to the predicate device: The new TG-920P CO_2 Sensor Kit has an airflow cannula where the device can be use for Children patients weighing more than approximately 7kg, where the predicate device TG-920P CO_2 Sensor Kit is for weighing more than 10 kg. The new TG-920P CO_2 Sensor Kit has a pressure tube for breath detection, where the predicate does not and the new device is not sterilized where the predicate device can be sterilized once with ethylene oxide gas before use. The new device is similar to Nihon Kohden predicate device in use with the TG-920P CO_2 sensor kit to measure the partial pressure of the expired CO_2 of the patient for nasal-oral breathing, use frequency, shelf-life, patient contact, storage environment, chemical resistance and safety. See attachment # 5 for comparison of the TG-920P CO_2 Sensor Kit to the predicate device..

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- The device is not sterile.

- The devices comply with the IEC-60601-1 standard and sub-clause 56.3 (c) implemented by 21 CFR Part 868 Performance Standard for Electrode Lead Wires and Patient Cables.

- The devices were subjected to tests including safety, environment, vibration and impact. Refer to the test report for TG-920P CO_2 Sensor Kit (Report No. 1891). Refer to the post qualification test report for TG-920P CO_2 Sensor Kit test report 1891. Safety test was conducted only for display test using the new TG-920P CO_2 Sensor Kit device as a prototype. The test results confirmed that the device performed within specifications.

- Therefore, based on the above, Nihon Kohden believes that the new TG-920P CO_2 Sensor Kit is substantially equivalent to the TG-920P CO_2 Sensor Kit predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2007

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

Re: K072843
Trade/Device Name: TG -920P CO_2 Sensor Kit
Regulation Number: 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: November 8, 2007
Received: November 9, 2007

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 Office of Compliance at (240) 276-0115. 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

G. Indications for Use Statement:

510(K) Number (if known): _____

Device Name: TG-920P CO_2 Sensor Kit

Indications for Use:

The Nihon Kohden TG-920P 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)

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

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