K040875

## SECTION 2 - 510(K) SUMMARY

OCT 15 2004

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

Name and address of Manufacturer:
Nihon Kohden Corporation
1-31-4 Nishiochiai,
Shinjuku-ku, Tokyo, 161-8560 Japan

The TG-920P $CO_2$ Sensor Kit is classified as Class II by the Division of Anesthesiology Devices and the Anesthesiology Device Classification Panel under 21 CFR Part 868.1400 "Analyzer, Gas, Carbon dioxide, Gaseous-phase" as per part 73 CCK.

Common names for the TG-920P $CO_2$ Sensor Kit include $CO_2$ Analyzer and $CO_2$ Indicator.

The predicate marketed device is the Nihon Kohden TG-901T $CO_2$ Sensor Kit as per 510(k): K990063, commercial distribution certification dated June 1999.

The Nihon Kohden $CO_2$ Sensor Kit, model number TG-920P, 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 mouth/nose piece airway adapter, Nasal Adapter, is a Single-Patient-Use and hence, disposable.

The device is intended as an indicator of patient carbon dioxide concentration during expiration, for non-intubated patients. This device is intended for use with patients of ages three (3) years and older. This device is not recommended for patients with low tidal volume such as patients younger than three (3) years of age or weighing less than 22 pounds or patients with a respiration rate greater than or equal to 150 breaths per minute.

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. The device is not sterile.

Therefore, based on the above, Nihon Kohden believes that the TG-920P $CO_2$ Sensor Kit is substantially equivalent to Nihon Kohden's TG-901T $CO_2$ Sensor Kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2004

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

Re: K040875
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: October 7, 2004
Received: October 8, 2004

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.

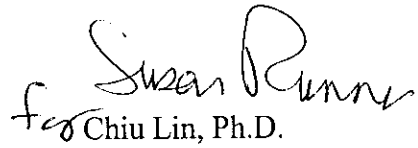
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), 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/dsma/dsmamain.html

Sincerely yours,



for 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): K040875

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 Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K040875