

JUN 9 1999

12990063

NIHON KOHDEN
January 7, 1999

510(k) NOTIFICATION
TG-901T CO₂ Sensor Kit

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant

Nihon Kohden America, Inc.
Attn: Regulatory Affairs
2601 Campus Drive
Irvine, California 92612-1601

Nihon Kohden Corporation
31-4 Nishiochiai, 1-Chome
Shinjuku-ku, Tokyo, 161 Japan

The TG-901T CO₂ 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-901T CO₂ Sensor Kit include CO₂ Analyzer and CO₂ Indicator.

The predicate device is the OLG-1100A PocketCap CO₂ Monitor per 510(k) # K964305, commercial distribution certification dated February 19, 1997.

The Nihon Kohden CO₂ Sensor Kit, model number TG-901T, 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. The device is intended as an indicator of patient carbon dioxide concentration during expiration and is not intended as the sole basis for medical diagnosis. 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 22 pounds or patients with a respiration rate greater than or equal to 60 breaths per minute.

To date, no performance standards or special controls are known or established for this device as required by Section 514 of the Food, Drug and Cosmetic Act and implemented by 21 CFR Part 861.

The TG-901T is not intended to be sterile.

The TG-901T was subject to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device.

Therefore, based on the above, Nihon Kohden believes that the TG-901T CO₂ Sensor Kit is substantially equivalent to the OLG-1100A Pocket CO₂ Monitor.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Gary Reasoner
Director of Program Operations
Nihon Kohden
2601 Campus Drive
Irvine, CA 92612

Re: K990063/S1
Nihon Kohden TG-901T CO₂ Sensor Kit With Accessories
Regulatory Class: II (two)
Product Code: CCK
Dated: April 19, 1999
Received: April 20, 1999

Dear Mr. Reasoner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

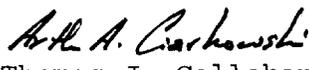
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and

Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 
Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT J: Indications for Use Statement

510(k) Number (if known): K990063

Device Name: TG-901T CO₂ Sensor

Indications for Use:

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This device is intended for use with patients three (3) years of age 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 22 pounds or patients with a respiration rate greater than or equal to 60 breaths per minute.

Alh. A. Carlowski

(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K990063

Prescription Use X
(Per 21 CFR 801.109)