SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
Attn: Regulatory Affairs
2601 Campus Drive
Irvine, California 92612-1601

Phone: (949) 250-3959
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The device has been classified as Class II by the Cardiovascular Device Classification Panel under 21 CFR Part 870.2700 "Oximeter" per 74 DQA and by the Anesthesiology Classification Panel under 21 CFR Part 868.1400 Analyzer, Gas, Carbon dioxide, Gaseous-phase" per 73 CCK.

The common name for the OGS-2001A device is SpO_2/CO_2 monitor.

The predicate devices are the OLG-1100A PocketCap CO_2 Monitor per 510(k) #K964305 commercial distribution certification dated 02/19/1997and the BSM-1101 Life Scope EC Patient Monitor per 510(k) #K973918, commercial distribution certification dated 01/13/1998.

Nihon Kohden's model number OGS-2001A is intended for medical use to measure the blood oxygen saturation (SpO_2) and to measure the concentration of carbon dioxide in a gas mixture (CO_2) to aid in determining the patient's ventilatory status. This product will be available for use by medical personnel within a medical facility or in a remote environment. This device is not intended to be the sole basis of diagnosis.

The CO_2 function of the device is intended for patients three (3) years and above and is not recommended for patients with low tidal volume such as patients weighing less than 22 pounds or patients with a respiratory rate greater than 60 breaths per minute. The CO_2 function will be available for all other patient populations.

The device complies with IEC 601-1 subclause 56.3(c) implemented by 21 CFR Part 868 Performance Standard for Electrode Lead Wires and Patient Cables. To date, no other special controls or performance standards are known or established for this device.

The OGS-2001A device is not sterile. The airway adapter is for single patient use only. Reusable or single patient use SpO_2 probes are available.

The device material components have been determined to be non-contacting per the guidance provided by BS EN 30993: 1994 / ISO 10993: 1993 which replaces the Tripartite Guidance. The reusable SpO_2 probe surface is silicone, known to be biocompatible by over 30 years of various medical device uses per the open literature. The disposable, SpO_2 probes are the same probes as used with the predicate device BSM-1101 (K973918). Therefore, good laboratory practice studies were not required per 21 CFR 58.

The OGS-2001A PocketCare was subjected to electromagnetic, environmental, safety and performance testing procedures per Nihon Kohden design control requirements. These tests verified the operation of the device. Software validation tested the operation of the software functions of acquiring, processing, displaying and recording all functions of the device. The results confirmed that the device performed within specifications.

Therefore based on the above, Nihon Kohden believes that the OGS-2001A PocketCare is substantially equivalent to the combination of the predicate devices.

SECTION 3 - PROPOSED LABELING

A. Intended Use

The OGS-2001A PocketCare is intended for medical purposes to transmit radiation at a known wavelength through blood and measure the blood oxygen saturation based on the amount of reflected or scattered radiation and is intended to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory status.

B. Device/Package Labels

Drawings of the device and the proposed product labels are provided in attachment 1.

C. Proposed Packaging

Packaging for the OGS-2001A PocketCare is depicted in Attachment 2.

D. Instructions for Use

The proposed instructions for use are provided with each packaged device and are presented in Attachment 8.

E. Advertisement/Promotional Literature

To date no advertisement or promotional literature has been created for the OGS-2001A PocketCare device for distribution in the United States.

F. Contraindications, Precautions & Warnings

Warnings and cautions are listed in the Operator's Manual as shown in Attachment 3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2000

Mr. Bonnie Bishop
Nihon Kohden America, Inc.
2601 Campus Drive
Irvine, CA 92612

Re: K992455
Nihon Kohden OGS-2001A PocketCare
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: November 5, 1999
Received: November 8, 1999

Dear Mr. Bishop:

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 (Premarket 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"(21 CFR 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,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

G. Indications for Use Statement

510(k) Number (if known): _____

Device Name: OGS-2001A PocketCare

Indications for Use:

Nihon Kohden's model number OGS-2001A is intended for medical use to measure the blood oxygen saturation (SpO_2) and to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory status (CO_2).

This product will be available for use by medical personnel within a medical facility or in a remote environment including transport. This device is not intended to be the sole basis of diagnosis.

The CO_2 function of the device is intended for patients three (3) years and above and is not recommended for patients with low tidal volume such as patients weighing less than 22 pounds or patients with a respiratory rate greater than 60 breaths per minute. The CO_2 function will be available for all other patient populations.

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K992455

PRESCRIPTION USE X

OVER-THE-COUNTER USE _____