K 974292

JUN - 8 1998

NIHON KOHDEN AMERICA, INC.
November 13, 1997

510(k) NOTIFICATION
TL-101T, TL-1210T and TL-121T SpO2 Probes

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
Attn: Regulatory Affairs
2601 Campus Drive
Irvine, California 92612-1601
(714) 250-3959

The TL-101T, TL-120T and TL-121T SpO2 Probes are accessories for use with Nihon Kohden patient monitoring devices and are not individually classified. Common names for the devices include SpO2 probe, SpO2 sensor, pulse oximeter probe, pulse oximeter sensor, probe and sensor.

The TL-101T, TL-120T and TL-121T SpO2 Probes are new optional accessories for use with the following Nihon Kohden devices: AL-800PA SpO2 Module per 510(k) #K884536, dated February 6, 1989; BSM-2101A and BSM-2102A Patent Monitors, per 510(k) #K914092, dated May 28, 1992; and ZB-831PA Telemetry Transmitter, per 510(k) #K946175, dated November 22, 1995

The predicate marketed devices are the Nihon Kohden TL-101S, TL-120S and TL-121S SpO2 Probes, which are accessories for the AL-800PA SpO2 Module, per 510(k) #K884536, dated February 6, 1989, used with the BSM-8800A Bedside Monitor per 510(k) #K920154, dated December 18, 1992.

Nihon Kohden's TL-101T, TL-120T and TL-121T SpO2 Probes are used with Nihon Kohden patient monitoring devices to measure the blood oxygen saturation of a patient based upon the amount of reflected or scattered light.

The TL-101T is a finger probe intended for use on adult patients heavier than 20 kg. The TL-120T is a multi-site probe intended for use on adults and infants heavier than 3 kg. The TL-121T is a foot probe intended for use on infants and neonates lighter than 3 kg.

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 TL-101T, TL-120T and TL-121T devices are not intended to be sterile.

Biocompatibility testing was performed in accordance with the guidelines of the International Organization for Standardization Part 10: Tests for Irritation and Sensitization. Primary skin irritation studies calculated the Cumulative Irritation Index of 0.00.with no irritation observed on the skin of the rabbits. Sensitization studies showed no evidence of delayed dermal contact sensitization in the guinea pig. Cytotoxicity studies showed no evidence of causing cell lysis or toxicity greater than a USP grade of 2 (mild reactivity). The test articles passed these ISO studies.

The TL-101T, TL-120T and TL-121T SpO2 Probes were subjected to safety and performance testing procedures. These tests verified that the device performed within specifications.

Therefore based on the above, Nihon Kohden believes that the TL-101T, TL-120T and TL-121T SpO2 Probes are substantially equivalent to the TL-101S, TL-120S and TL-121S SpO2 Probes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN -8 1998

Mr. Gary Reasoner
Nihon Kohden America, Inc.
2601 Campus Drive
Irvine, CA 92612

Re: K974292
Nihon Kohden TL-101T, TL-120T and TL-121T SpO2 Probes
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: March 10, 1998
Received: March 12, 1998

Dear Mr. Reasoner:

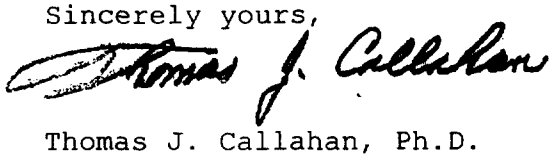
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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/dsmamain.html".

Sincerely yours,



Thomas J. Callahan, Ph.D.
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): K974292

Device Name: TL-101T, TL-120T and TL-121T SpO2 Probes

Indications for Use:

The TL-101T, TL-120T and TL-121T SpO2 Probes are intended for use with Nihon Kohden patient monitoring devices to measure the blood oxygen saturation of a patient based upon the amount of reflected or scattered light.

The TL-101T is a finger probe intended for use on adult patients heavier than 20 kg. The TL-120T is a multi-site probe intended for use on adults and infants heavier than 3 kg. The TL-121T is a foot probe intended for use on infants and neonates lighter than 3 kg.

Prescription

Lark Mada 6-5-98
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K974292