K973918

JAN 13 1998

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

These devices have been classified as Class II by the Division of Cardiovascular, Respiratory, and Neurological Devices and the Cardiovascular Device Classification Panel under 21 CFR Part 870.2300 Cardiac Monitor (including cardiotachometer and rate alarms) per 74 DRT, 870.2700 Oximeter per 74 DQA, 870.1130 Noninvasive Blood Pressure Measurement System per 74 DXN, and 870.2910 Radio Frequency Physiological Signal Transmitter per 74 DRG

Common names for the BSM-1101 and BSM-1102 include Patient Monitor, Portable Monitor, Transport Monitor, Cardiac Monitor and Bedside Monitor.

The predicate device is the Nihon Kohden BSM-2101A Patient Monitor per 510(k) #K914092, commercial distribution certification dated May 28, 1992.

Nihon Kohden's BSM-1101 and BSM-1102 Patient Monitors are intended for medical purposes to measure the heart rate from a signal produced by an electrocardiograph. These devices sound an alarm when the heart rate falls outside preset upper and lower limits. The devices include an oximeter used to transmit radiation at a known wavelength through blood and to measure the blood oxygen saturation based on the amount of reflected or scattered radiation. These devices include a noninvasive blood pressure measurement system that provides a signal from which systolic, diastolic, and mean pressures can be derived through the use of pressure cuffs placed on the arm, leg or finger. The devices may be used as a radio frequency physiological signal transmitter to condition physiological signals so that they can be transmitted via radio frequency from one location to another, e.g. a central monitoring station. These devices will be available for use by medical personnel on all patient populations within a medical facility.

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

The BSM-1101 and BSM-1102 are not intended to be sterile.

The BSM-1101 and BSM-1102 Patient Monitors were determined to be non-contacting per the Tripartite Guidance. Therefore, good laboratory practice studies were not required per 21 CFR part 58. Accessories manufactured by Nihon Kohden that may contact the patient include TL-101T, TL-120T, TL-121T, TL-051S, TL-052S, TL-061S and TL-062S SpO_2 probes. The TL-101T, TL-120T and TL-121T SpO_2 probes are new accessories submitted for review in a separate 510(k) submission. The TL-051S, TL-052S, TL-061S and TL-062S SpO_2 probes were previously submitted as accessories to the ZB-831PA Telemetry Transmitter, per 510(k) #K946175, commercial distribution certification dated November 22, 1995.

The BSM-1101 and BSM-1102 Patient Monitors are subjected to electromagnetic, environmental, safety and performance testing procedures to verify the operation of the device. Software validation tests the operation of the software functions of acquiring, processing, displaying and recording of all functions of the device.

Based on the above, Nihon Kohden believes that the BSM-1101 and BSM-1102 Patient Monitors are substantially equivalent to the Nihon Kohden BSM-2101A Patient Monitor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

JAN 13 1998

Mr. Gary Reasoner
Director of Product Operations
Nihon Kohden America, Inc.
2601 Campus Drive
Irvine, CA 92715

Re: K973918
Trade Name: Nihon Kohden BSM-1101 and BSM-1102 Patient Monitor
Regulatory Class: II (two)
Product Code: 74 DRT
Dated: October 14, 1997
Received: October 15, 1997

Dear Mr. Reasoner:

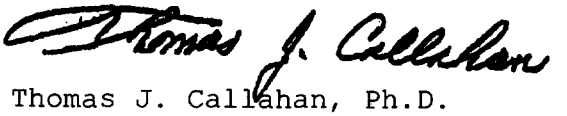
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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): _____

Device Name: BSM-1101 and BSM-1102 Patient Monitor

Indications for Use:

The BSM-1101 and BSM-1102 Patient Monitors are intended for medical purposes to measure the heart rate from a signal produced by an electrocardiograph. The devices sound an alarm when the heart rate falls outside preset upper and lower limits. The devices include an oximeter used to transmit radiation at a known wavelength through blood and to measure the blood oxygen saturation based on the amount of reflected or scattered radiation. The devices include a noninvasive blood pressure measurement system that provides a signal from which systolic, diastolic, and mean pressures can be derived through the use of pressure cuffs placed on the arm, leg or finger. The devices may be used as a radio frequency physiological signal transmitter to condition physiological signals so that they can be transmitted via radio frequency from one location to another, e.g. a central monitoring station.

The BSM-1101 and BSM-1102 Patient Monitors will be available for use by medical personnel on all patient populations within a medical facility.

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973918