DEC 1 1998

K 983072

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
Attn: Regulatory Affairs
2601 Campus Drive
Irvine, California 92612-1601
(949) 250-3959

The device has been classified as Class II by the Division of Cardiovascular, Respiratory, and Neurological Devices and the Neurology Device Classification Panel under 21 CFR Part 882.1400 Electroencephalograph per 84 GWQ, by the Anesthesiology Device Classification Panel under 21 CFR Part 868.2375 Ventilatory Effort Recorder per 73 MNR, and by the Cardiovascular Device Classification Panel under 21 CFR Part 870.2700 Oximeter per 74 DQA.

Common names for the SSR3201 device include Electroencephalograph, Ambulatory EEG Recorder and Ambulatory Sleep Recorder.

The predicate devices are Bio-logic Systems Corporation's Sleepscan Traveler per 510(k) #K962103, commercial distribution certification dated August 22, 1996 and Oxford Instruments Medilog MR95 per 510(k) #K961642, commercial distribution certification dated January 17, 1997.

The SSR3201 is intended for medical purposes to record electrical activity of the brain (EEG) and other bio-potential signals and to record physiological data required for sleep studies (Polysomnography or PSG) including EEG, eye movement (EOG), respiratory signals such as air flow or air pressure and thoraco-abdominal movement, chin and arm/leg movement (EMG), body position, EKG and blood oxygen saturation. The device does not provide alarms and can not be used as an automated apnea monitor.

This device is intended to record up to 24 hours of continuous patient data for freely moving or sleeping patients both inside and outside of a medical facility. The SSR3201 is intended to record patient data for later review by a medical professional using a legally marketed digital EEG/PSG system.

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 SSR3201 device is not intended to be sterile.

The device material components were determined to be non-contacting. Therefore, good laboratory practice studies were not required per 21 CFR part 58.

The SSR3201 is subjected to environmental, safety and performance testing procedures. Software validation is performed for the device software. These tests verify the operation and confirm that the device performs within specifications.

The SSR3201 is a battery-powered device with no voltage inside the unit greater than 9 volts DC. An isolated junction box connects electrodes and/or sensors to the patient. Because of the low voltage and isolated design, no failure modes of the device can cause serious patient injury.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1998

Mr. Gary Reasoner
Director of Product Operations
Nihon Kohden America, Inc.
2601 Campus Drive
Irvine, California 92612-1601

Re: K983072
Trade Name: SSR3201 Ambulatory EEG/Sleep Recorder
Regulatory Class: II
Product Code: GWQ
Dated: September 1, 1998
Received: September 2, 1998

Dear Mr. Reasoner:

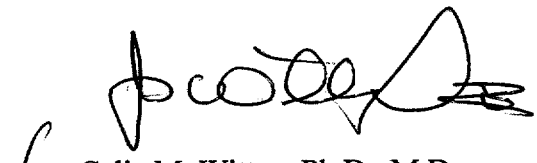
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4595. 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.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983072

Device Name: SSR3201 Ambulatory EEG/Sleep Recorder

Indications For Use:

The SSR3201 Ambulatory EEG/Sleep Recorder is intended for medical purposes to record electrical activity of the brain (EEG) and to record physiological data required for sleep studies (Polysomnography or PSG). These studies including EEG, eye movement (EOG), respiratory signals such as air flow or air pressure and thoraco-abdominal movement, chin and arm/leg movement (EMG), body position, EKG and blood oxygen saturation. The device does not provide alarms and can not be used as an automated apnea monitor.

This device is intended to record up to 24 hours of continuous patient data for freely-moving or sleeping patients both inside and outside of a medical facility. The SSR3201 is intended to record patient data for later review by a medical professional using a legally marketed digital EEG/PSG system to assist in diagnosing EEG related conditions such as epilepsy and sleep related conditions such as sleep related breathing disorders.

(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 General Restorative Devices
510(k) Number K983072

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)