

NIHON KOHDEN AMERICA, INC.
September 1, 1998

510(k) NOTIFICATION
SSR3201 Ambulatory EEG/Sleep Recorder

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 *OLV, GWB*

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.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -W066-G609
Silver Spring, MD 20993-0002

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

APR - 9 2012

Re: K983072

Trade/Device Name: SSR3201 Ambulatory EEG/Sleep Recorder
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV, GWQ
Dated (Date on orig SE ltr): September 1, 1998
Received (Date on orig SE ltr): September 2, 1998

Dear Mr. Reasoner:

This letter corrects our substantially equivalent letter of December 1, 1998.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for
Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat 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
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____