

K022121

Special 510(K) Notification
PSG Input Box

JUL 29 2002

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant

Nihon Kohden America, Inc.
Attn: Regulatory Affairs
90 Icon Street
Foothill Ranch, California 92610
Phone: (949) 580-1555
Fax: (949) 580-1550

Device Name and Classification: PSG amplifier and accessories. The device classification is unchanged. The device is classified by the Neurology Panel under 21 CFR Part 882.1400 "Electroencephalograph" per GWQ. Common names for the device include Electroencephalograph (EEG) and Polysomnograph (PSG).

Legally Marketed Predicate: Nihon Kohden EEG 9100, cleared under 510K, K011204

There are no significant changes in function, biocompatibility, performance or manufacturability compared to the predicate device that would affect the safety and effectiveness of the device as intended for use. Therefore, Nihon Kohden believes that the new PSG amplifier is substantially equivalent to the predicate EEG device. The device has the same intended use and indications for use as the existing marketed device and uses the same fundamental scientific technology.

Description and Intended Use: The device is intended to record the physiological data required for EEG and sleep studies (Polysomnography or PSG). These data, may be used by clinicians in Sleep Disorders, Epilepsies and other disorders as a diagnostic aid. This device is intended for use by medical personnel and will be available for use within a medical facility or outside of a medical facility under direct supervision of a medical professional on all patient populations.

Performance Testing

- The device complies with IEC 601-1 sub-clause 56.3(c) implemented by 21 CFR Part 898 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 device is designed to comply with the following voluntary industrial standards: IEC 60601-1 (1988-12), Amendment 1 (1991-11), Amendment 2 (1995-03), IEC 60601-1-1 (1992-06), Amendment 1 (1995-10), IEC 60601-1-2 (1993-05), CISPR11 Group 1, Class B, IEC 60601-2-26 (1994)
- The PSG unit is not sterile.
- The device does not directly contact patients. Accessories that contact patients, such as the EEG electrodes and SP02 probes are the same as current available component materials and accessories legally cleared and marketed in the USA (see accessories list). Therefore, good laboratory practice studies were not required per 21 CFR, part 58.
- The device was developed in accordance with design controls and operation of the device was appropriately verified and validated using test methods as with all other existing devices. The device was subjected to environmental testing including temperature/humidity stress testing, electromagnetic interference / electromagnetic compatibility testing and safety standards testing

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and performance testing procedures. Test criteria are established prior to testing based upon product specifications and applicable standards. The completed testing showed that the device met its product specifications and verified conformance to safety, reliability, and applicable standards. Software verification and validation tested the operation of the software functions of the device. The results confirmed that the device performed within specifications (see Attachment # 6).



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

Ms. Serrah Namini
Regulatory Affairs Associate Director
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, California 92610

APR - 9 2012

Re: K022121

Trade/Device Name: PSG Input Box, Model JE-912AK
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV, GWQ
Dated (Date on orig SE ltr): June 28, 2002
Received (Date on orig SE ltr): July 1, 2002

Dear Ms. Namini:

This letter corrects our substantially equivalent letter of July 29, 2002.

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" (21 CFR 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,



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

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G. Indications for Use Statement

510(k) Number (if known): K022121

Device Name: PSG input Box

Indications for Use:

The device is intended to record cerebral, extracerebral and other bio-potential activities for EEG and Sleep Studies via legally marketed PSG reading software. These data may be used by clinicians in sleep disorders, Epilepsies and other related disorders as a diagnostic aid.

The device is intended for use by medical personnel in any location within a medical facility, physician's office, laboratory, clinic or nursing home or outside of a medical facility under direct supervision of a medical professional. The device will be available on all patient populations (including adults and children) as determined by a trained professional.

for Mark A. Melburn

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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