K050833

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

APR 2 9 2005

Device Name and Classification: Electrode Junction Box and accessories. 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). The internal CO_2 input addition will enable the junction box to transfer the CO_2 data to the EEG monitor. The CO_2 module has been classified as Class II by the Division of Anesthesiology Devices and the Anesthesiology Classification Panel under 21 CFR Part 868.1400 "Analyzer, gas, carbon dioxide, gaseous-phase" as per part 73 CCK.

Legally Marketed Predicate: Nihon Kohden JE-912AK, cleared per 510(k): K022121, is in commercial distribution certification dated 7/29/2002. The CO_2 module, in commercial distribution, has been previously cleared under 510K submission, K040875, dated 10/15/2004.

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

Indications For Use:
The device is intended to acquire, store, and transfer biophysical parameters to EEG machines for the purpose of assisting the diagnosis of neurological and sleep disorders, measurement and display of cerebral and extracerebral activity for EEG and Sleep Studies. These data, may be used by the clinician in Sleep Disorders, Epilepsies and other related disorders as a diagnostic tool. As with the predicate, the information transferred to EEG will be stored, interpreted and printed with commercially software programs available with Nihon Kohden marketed products.

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 supervision of a medical professional. The device will be available on all patient populations, including pediatrics.

Description: The device is intended to record, measure and display the physiological data required for EEG and sleep studies (Polysmonography 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.

The availability of new option, CO_2 Sensor and accessory provides the physician the ease of connecting the CO_2 adapter directly to the amplifier instead of separately connecting to a monitor. The product design and function is equivalent to the predicate in acquisition and data development. The same sensor design is utilized in both devices. The processing unit housed within the CO_2 adapter, processes data, to continously monitor non-intubated pateint's CO_2. The status of real time CO_2 pressure, $ETCO_2$, expiration, and the suction point, can be transferred by the electrode junction box to a Nihon Kohden's EEG monitor.

Performance Testing

- The device complies with IEC 60601-1 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, such as: 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), IEC 60601-1-2 (second edition: 2001-09), IEC 60601-2-26 (1994), IEC 60601-2-26 (second edition: 2002-11)

- The device is not sterile.

- The device does not directly contact patients. Accessories that contact patients, such as the EEG electrodes, CO_2 adapters and SPO_2 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 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2005

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

Re: K050833
Trade/Device Name: Electrode Junction Box, JE-921A Series
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: March 31, 2005
Received: April 1, 2005

Dear Ms. Namini:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

G. Indications for Use

510(k) Number (if known): K050833

Device Name: Electrode Junction Box, JE-921A series

Indications For Use:

The device is intended to acquire, store, and transfer biophysical parameters to EEG machines for the purpose of assisting the diagnosis of neurological and sleep disorders, measurement and display of cerebral and extracerebral activity for EEG and Sleep Studies. These data, may be used by the clinician in Sleep Disorders, Epilepsies and other related disorders as a diagnostic tool. As with the predicate, the information transferred to EEG will be stored, interpreted and printed with commercially software programs available with Nihon Kohden marketed products.

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 supervision of a medical professional. The device will be available on all patient populations, including pediatrics.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

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

510(k) Number K050833