K073491

SECTION 2- 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

Contact:
Jack Coggan
Director, Regulatory Affairs
(949) 580-1555 ex. 3325
Fax: (949) 580-1550

Trade/Device Name:
EEG-1100A Switch Boxes

Common or Usual Name:
Electroencephalograph (EEG)

JAN 11 2008

Classification Name:
The device has been classified as Class 2 by the Neurology Device Classification Panel under 21 CFR Part 882.1400 Electroencephalograph per GWQ and under 21 CFR Part 882.1890 Evoked Response Photic Stimulator per GWE.

Legally Marketed Predicate Device:
Nihon Kohden EEG-1100A and Accessories per 510(k) 992742 commercial distribution certification dated October 14, 1999.

Intended Use:
The EEG-1100A Switch Boxes product is connected between the multi-channel electrode junction boxes, JE-207A/209A/212A and a mini electrode junction box and switches the signal line of electrodes to EEG or stimulation unit. It corresponds to 65 to 128 channels and 129 to 192 channels.

A summary of the technological characteristics of the device compared to the predicate device: The new EEG-1100A Switch Boxes device has two switch boxes, the AAA-15919 switch box which is designed for the JE-207A, JE-209A, JE-212A electrode Junction Boxes and JE-208A, JE-210A, JE-213A, JE-214A, JE-2156A, JE-216A, JE-217A Mini Junction Boxes and the AAA-16060 192 channel Switch Box which is designed for the JE-212A Electrode Junction Box and JE-213A, JE-214A, JE-217A Mini Junction Boxes. The EEG-1100 predicate device did not previously control the electrical stimulation signals through a switch box. The electrical stimulation signals from an electrical stimulation unit can be applied to each electrode through the switch box. The AAA-6060 192 channel switching is available by connecting to the AAA-15919 128 channel Switch Box.

510(k) Summary:

- The device is not sterile.

- The device does not directly contact patients. Accessories that contact patients, such as electrodes, are the same accessories as used with the predicate or are comprised of the same component material with the same design and manufacturing processes as the predicate accessories. The device may also use commercially available electrode and sensor products. Therefore, good laboratory practice studies were not required per 21 CFR Part 58.

- The EEG-1100A Switch Boxes was subjected to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. Software validation tested the operation of the software functions or acquiring, processing, displaying and recording of all 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

JAN 11 2008

Nihon Kohden America, Inc.
% Mr. Jack Coggan
Director, Regulatory Affairs
90 Icon Street
Foothill Ranch, CA 92610

Re: K073491
Trade/Device Name: EEG-1100A Switch Boxes
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ, GWE
Dated: December 12, 2007
Received: December 12, 2007

Dear Mr. Coggan:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
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: EEG-1100A Switch Boxes

Indication of Use:

The EEG-1100A is intended to record, measure and display cerebral and extracerebral activity for EEG and Sleep Studies. These data may be used by the clinician in Sleep Disorder, Epilepsies and other related disorders as an aid in diagnosis.

The device is intended for use by medical personnel in any location within a medical facility, laboratory, clinic or nursing home or outside or a medical facility under direct supervision of a medical professional.

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

510(k) Number K073491

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)