

K073491

NIHON KOHDEN AMERICA, INC.

SPECIAL 510(k) NOTIFICATION
EEG-1100A Switch Boxes

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, DLV

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.



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

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

Re: K073491

APR - 9 2012

Trade/Device Name: EEG-1100A Switch Boxes
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV, GWQ
Dated (Date on orig SE ltr): December 12, 2007
Received (Date on orig SE ltr): December 12, 2007

Dear Mr. Coggan:

This letter corrects our substantially equivalent letter of January 11, 2008.

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 (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.

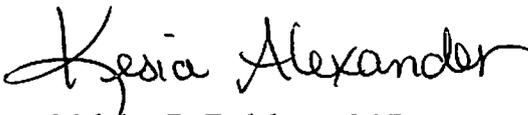
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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


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

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 of 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
(Part 21 CFR 801 Subpart D)

AND/OR

Over The Counter Use _____
(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)