SECTION 2- 510(K) SUMMARY

AUG 29 2008

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-1200A Series Neurofax

Common or Usual Name:
Electroencephalograph (EEG)

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, OLT, OLV

Legally Marketed Predicate Device:
Nihon Kohden EEG-1100A Series and Accessories per 510(k) K992742 commercial distribution certification dated October 14, 1999.

Intended Use:
The EEG-1200A Series Neurofax 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.

A summary of the technological characteristics of the device compared to the predicate device: The new EEG-1200A Series Neurofax technological characteristics differences compared to the predicate device are:

Comparison	New Device	Predicate Device
Number of channels	32	40
Noise Level	< 1.5uV p-p(0.53 to 60 Hz)	< 3 uV p-p (0.53 to 60 Hz)
Frequency Response	0.08 to 300 Hz	0.016 to 300 Hz
High-pass Filter (Low-cut)	DC Standard	DC Option
Power	120 V +/- 10% 50/60 Hz 750 VA	117 V +/- 10% 50/60 Hz 550 VA

All other characteristics are of the device are the same.

510(k) Summary:

- The device is not sterile.

- The EEG-1200A Electroencephalograph is the instrument to provide the information for intervention to utilize derivation, recording, analysis, or each combination of the brain's action potential. The instrument can measure the vital signal (including ECG waveform, EMG waveform, respiration waveform, ocular motility, SpO_2 and CO_2) in relation to EEG examination and display the waveform on the screen changing the montage and amplifier conditions. In addition, measurement data is available to file into the electric media. Changing the montage and amplifier conditions, then record to the printer, previews the measured data filed into the electric media. EEG data analysis is also executed to use the analysis software.

- 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-1200A Series 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 for 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Nihon Kohden America
% Mr. Jack Coggan
Director of Regulatory Affairs/Quality Assurance
90 Icon Street
Foothill Ranch, California 92610

APR - 9 2012

Re: K080546
Trade/Device Name: EEG-1200A Series Neurofax
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLT, OLV, GWQ
Dated (Date on orig SE ltr): July 29, 2008
Received: (Date on orig SE ltr): July 30, 2008

Dear Mr. Coggan:

This letter corrects our substantially equivalent letter of August 29, 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 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

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,

Kesia Alexander

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): K080546

Device Name: EEG-1200A Series Neurofax

Indication of Use:

The EEG-1200A Series Neurofax 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.

Mark N Millerson

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

510(k) Number K080546

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)