OCT 14 1999

K992742

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
2601 Campus Drive
Irvine, California 92612-1601
Phone: (949) 250-3959
Fax: (949) 250-3210

Primary Contact:
Bonnie Bishop, Regulatory Affairs Manager
(949) 250-3959 ext. 4401

Alternate Contact:
Gary Reasoner, Director of Product Operations
(949) 250-3959 ext. 3387

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

Common names for the EEG-1100A device include Electroencephalograph (EEG) and Polysomnograph (PSG).

The predicate marketed device is the Nihon Kohden EEG-2100 per 510(k) # K944678, commercial distribution certification dated 5/22/98.

Nihon Kohden's, model number EEG-1100A intended to record, measure and display the physiological data required for EEG and sleep studies (Polysomnography or PSG). These data, may be used by the clinician in Sleep Disorders, Epilepsies and other disorders as an aid in diagnosis. This device is intended for use by medical personnel. The device will be available for use within a medical facility, laboratory, clinic or nursing home or outside of a medical facility under direct supervision of a medical professional.

The device complies with IEC 601-1 subclause 56.3(c) as implemented by 21 CFR Part 898 Performance Standard for Electrode Lead Wires and Patient Cables. No other special controls or performance standards are known or established for this device.

The EEG-1100A 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 materials 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 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 of acquiring, processing, displaying and recording of all functions of the device. The results confirmed that the device performed within specifications.

SECTION 3 - PROPOSED LABELING

A. Intended Use
The EEG-1100A is intended for medical purposes to record, measure and display 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 an aid in diagnosis.

B. Device/Package Labels
The proposed product labels for the device is located in Attachment 1.

C. Proposed Packaging
Packaging for the EEG-1100A is depicted in Attachment 2.

D. Instructions for Use
The proposed instructions for use are provided with each packaged device and are presented in Attachment 9.

E. Advertisement/Promotional Literature
To date no advertisement or promotional literature has been created for the EEG-1100A for distribution in the United States.

F. Contraindications, Precautions & Warnings
Warnings and cautions are listed in the Operator's Manual as shown in Attachment 3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 1999

Ms. Bonnie Bishop
Regulatory Affairs Manager
NIHON KOHDEN AMERICA, INC.
2601 Campus Drive
Irvine, California 92612

Re: K992742
Trade Name: Neurofax Model EG-1100A Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: August 13, 1999
Received: August 16, 1999

Dear Ms. Bishop:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

G. Indications for Use Statement

510(k) Number (if known): K992742

Device Name: EEG-1100A

Indications for 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 Disorders, 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 Devices
510(k) Number K992742

Prescription Use X
(Per 21 CFR 801.109)