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SECTION 2 - 510(K) SUMMARY

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

The device has been classified as Class II under 21 CFR Part 890.1375 "Diagnostic Electromyograph" per IKN; 21 CFR Part 882.1400 "Electroencephalograph" per GWQ; 21 CFR Part 882.1550 "Nerve Conduction Velocity Measurement Device" per JXE; 21 CFR 882.1540 "Galvanic Skin Response Measurement Device" PER GZO; 21 CFR 882.1870 "Evoked Response Electrical Stimulator" per GWF; 21 CFR 882.1890 "Evoked Response Photic Stimulator" per GWE; and 21 CFR 882.1990 "Evoked Response Auditory Stimulator" per GWJ.

Common names for the MEB-2200A device include Evoked Response, Evoked Potential (EP) and Electromyograph (EMG).

The predicate marketed device is the Nihon Kohden MEB-5500A Neuropack Sigma per 510(k) #K950208, commercial distribution certification dated May 10, 1995.

Nihon Kohden's, model number MEB-2200A is intended for medical purposes to monitor, record and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor, record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular disease (EMG). The device is also intended to measure and display nerve conduction time by applying a stimulus to a patient's nerve (NCV). The device may use electrical stimulus, visual stimulus, or sound stimulus for use in evoked response measurements (EP). The device may be used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin. The device may also measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head (EEG).

The device is intended for use by medical personnel within a hospital, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording. The device is available for use on any patient as determined by the medical professional including adults and children.

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 device is in compliance with the following voluntary industrial standards: IEC 60601-1 (1988-12), Amendment 1 (1991-11), Amendment 2 (1995-03); IEC 60601-1-1 (1992-06), Amendment 1 (1995-10); IEC 60601-2-10 (1987-12); EN 60601-1-2 (1993-05); CAN/CSA-C22.2 No. 601.1-M90 (19990-11) and CAN/CSA-C22.2 No. 601.2.10-92 (1992-08)

The device is not intended to be sterile. No GLP studies were required for this device.

The MEB-2200A was subjected to electromagnetic, environmental, safety and performance testing procedures. Software validation tested the operation of the software of the device. The results confirmed that the device performed within specifications.

Therefore based on the above, Nihon Kohden believes that the MEB-2200A Neuropack Evoked Potential and EMG Measuring System is substantially equivalent to the predicate MEB-5500A Neuropack Sigma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Bonnie Bishop
Regulatory Affairs Manager
Nihon Kohden America, Inc.
2601 Campus Drive
Irvine, California 92612

Re: K991899
Trade Name: MEB-2200A Neuropack Evoked Potential and EMG Measuring System
Regulatory Class: II
Product Code: GWF, IKN, GWQ, and GZO
Dated: June 3, 1999
Received: June 4, 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,

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): K 991899

Device Name: MEB-2200A Neuropack Evoked Potiential and EMG Measuring System

Indications for Use:

The MEB-2200A Neuropack Evoked Potential and EMG Measuring System is intended to monitor, record and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor, record and display the electrical activity produced by nerves to aid the clinician in the diagnosis and prognosis of neuromuscular disease (EMG). The device is also intended to measure and display nerve conduction time by applying a stimulus to a patient's nerve (NCV). The device may use electrical stimulus, visual stimulus, or sound stimulus for use in evoked response measurements (EP). The device may be used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin. The device may also measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head (EEG).

The device is intended for use by medical personnel within a hospital, laboratory, clinic or nursing home setting or outside of a medical facility under direct supervision of a medical professional. The device may also be placed in the intensive care unit or operating room for continuous recording.

The device is available for use on any patient as determined by the medical professional including adults and children.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 991899