K051178

SECTION 2 - 510(K) SUMMARY

AUG 17 2005

- **Name and Address of Applicant**

Nihon Kohden America, Inc.
90 Icon St.
Foothill Ranch, Ca 92610

Phone: (949) 580-1555 Ext. 4401
Fax: (949) 580-1550
Attn: Serrah Namini, Regulatory Affairs Assoc. Dir.

Date: 05/3/05

- **Name of the device:** Neural Function Measuring System
- **Trade or proprietary name:** MEE 1000A Neuromaster
- **The common or usual name:** Common names for the device include Evoked Response, Evoked Potential (EP) and Electromyograph (EMG)
- **The classification name:** The device has been classified as Class II under 21 CFR Part 890.1375 "Diagnostic Electromyograph" per IKN; 21 CFR part 874.1820 "Surgical Nerve Stimulator/locator" per ETN; 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 882.1900 "Evoked Response Auditory Stimulator" per GWJ.
- **The legally marketed equivalence:** The predicate marketed device is the Nihon Kohden MEB-2200A Neuropack per 510(k) #K991899, commercial distribution certification dated 9/1/1999.
- **A description of the device:** The Neuromaster, MEE-1000A, Neural Function Measuring System measures and displays electric/auditory/visual evoked potential, and provides EEG and EMG data during surgical and diagnostic procedures. For evoked potential measurement, continuous and periodic measurements are available. The acquired waveforms and data can be displayed on the trendgraph with waveforms annotations (events). The acquired waveforms with the measurement data can be saved in a storage media and printed via any commercially available printer.
- **A summary of the technological characteristics of the device compared to the predicate device:** Similar to the predicate device, the new device allows monitoring EMG, EEG and evoked potential responses of patients in the same settings as well as under Intensive Care Units. The data is displayed to continuously monitor the patient's conditions. The Main menu allows examinations, managing and storing measurement files. The product is available with more channels; 16/32 channel amp unit acquires waveforms from 16 or 32 channel amplifiers with the 2 or 3 breakout boxes (electrode junction box). The new device is available with more compact junction boxes. Measured waveforms and data can be saved on various types of durable media, such as a CD or a

hard drive, similar to the predicate. Saved waveforms and data can be either printed or reviewed on the screen, similar to the predicate.

The device is intended for use by medical personnel within a hospital, clinic or nursing home setting as well as 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. Similar to the predicate, the device is available for use on adults and children as determined by the medical professional.

The device complies with IEC 60601-1 sub-clause 56.3 as implemented by 21 CFR Part 898 Performance Standard for Electrode Lead Wires and Patient Cables. The device is in compliance with the following voluntary industrial standards: IEC 60601-1: 1988-12; IEC 60601-1 Amendment 1: 1991-11, IEC 60601-1 Amendment 2: 1995-03, IEC 60601-1-1 Second edition: 2000-12, IEC 60601-2-10: 1987-12, IEC 60601-2-40: 1998-02, and IEC-60601-1-2 Second edition: 2001-09

The device is not sterile. Design validation confirmed the operation of the software and hardware of the device according to the design specifications.

The device was subject to electromagnetic, environmental, safety and performance testing procedures. These tests verified the proper operation of the device.

Therefore based on the above, Nihon Kohden believes that the MEE-1000A Neuromaster, Neural Function Measuring System, is substantially equivalent to the predicate device, MEB-2200A Neuropack.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2005

Ms. Serrah Namini
Regulatory Affairs, Associate Director
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, California 92610

Re: K051178
Trade/Device Name: Neuromaster: MEE-100A series
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: II
Product Code: GWF
Dated: July 21, 2005
Received: July 22, 2005

Dear Ms. Namini:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Mark N. Melkerson
Acting 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: Neuromaster ; MEE-1000A series

Indications for Use: Nihon Kohden's model number MEE-1000 is intended for medical purposes to measure, monitor, record and display the bioelectric signals produced by muscles (EMG), to stimulate peripheral nerves and to monitor, record and display the electrical activities produced by nerves to aid clinicians in the diagnosis and prognosis of neuromuscular disease. The device monitors electric/auditory/visual evoked potential, EEG and EMG. The device is also intended to measure and display nerve conduction time by applying a stimulus to a patient's peripheral nerve. This device includes the stimulator and the electronic processing equipment for measuring and displaying the nerve conduction time.

The device may use electrical stimulus, visual stimulus, or sound stimulus for use in evoked response measurements (EP). Continuous and/or periodic measurements of evoked potential activities are displayed and stored. The device applies an electrical stimulus to a patient thru commercially available skin electrodes for the purpose of measuring the evoked response. The photic stimulator is used to generate and display a shifting pattern or to apply a brief light stimulus to a patient's eye and the auditory stimulator produces a sound stimulus for use in evoked response measurements or electroencephalogram activation. 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 activities of the patient's brain obtained by placing two or more electrodes on the head (EEG).

The acquired waveforms are displayed in cascaded format and measurement data may be displayed on the trendgraph with waveforms annotations (events). The acquired waveforms with the measurement data can be saved in a large capacity storage media.

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

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)

Barbara Michels for Mellerson

(Division Sign-Off)

Division of General, Restorative.

K051178