K071969

SECTION 2 – 510(K) SUMMARY OCT 0 6 2008

- **Name and Address of Applicant**

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

Telephone: (949) 580-1555 Ext. 3325
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Attn: Jack Coggan, Director of Regulatory Affairs

Date: June 29, 2007

- **Name of the Device:** Evoked Response Electrical Stimulator

- **Trade or proprietary name:** SEN-4100 Electric Stimulator

- **The common or usual Name:** Evoked Response Electrical Stimulator
- **The Classification:** The device has been classified as 21 CFR Part 882.1870 "Evoked Response Electrical Stimulator" per GWF.

- **The legally marketed equivalence:** The predicate-marketed device is the Digitimer D185 Multipulse Cortical Stimulator, K020400, commercial distribution certification dated August 23, 2002.

- **A description of the device:** The SEN-4100A is the stimulator to output electrostimulation pulses. It conducts the constant voltage stimulation that is necessary for MEP (Motor Evoked Potential) measurement, from an electrophysiological viewpoint, diagnosing and analyzing the neuromuscular action potential for a patient provided with anesthesia care in an operating room.

- **A summary of the technological characteristics of the device compared to the predicate device:** The new device is equivalent to the Digitimer D185 Multipulse Cortical Stimulator in that the stimulator will output electrostimulation pulses. It conducts the constant voltage stimulation that is necessary for MEP (Motor Evoked Potential) measurements from an electrophysiological viewpoint while diagnosing and analyzing the neuromuscular action potential for a patient provided anesthesia care in an operating room.

  Nihon Kohden Sen-4100 Electric Stimulator is used for the intraoperative diagnosis of acute dysfunction in corticospinal tract axonal conduction brought about by mechanical trauma (traction, shearing, laceration, or compression) or vascular insufficiency.

  The device performs as an electrostimulation part under IEC 60601-1-2-40 for ME system when it is used with the clinical device for neurological function (or EMG/Stimulator for evoked reaction). The device is in compliance with the following voluntary industrial standards: IEC 60601-1: 1988; IEC 60601-1 Amendment 1:1991; IEC 60601-1 Amendment 2: 1995; IEC 60601-1-1 2nd edition: 2000; IEC 60601-1-2 2nd edition: 2001; EN 60601-1:1990; EN 60601-1 Amendment 1: 1993; EN 60601-1 Amendment 2:1995; EN 60601-1-1:2001; EN 60601-1-2:2001; CAN/CSA-C22.0 No. 601.1-M90; CAN/CSA-C22.2 No. 601.1S1-94; CAN/CSA-C22.2 No. 601.1B-90 (R2002); CAN/CSA-C22.2 No. 60601-1-1-02; CAN/CSA-C22.2 No. 60601-1-1-02.

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

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

Therefore base on the above, Nihon Kohden believes that the SEN-4100 Electric Stimulator measuring system is substantially equivalent to the predicate device, Digitimer D185 Multipulse Cortical Stimulator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 6 2008

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

Re: K071969
Trade/Device Name: SEN-4100 Electric Stimulator
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked Response Electrical Stimulator
Regulatory Class: Class II
Product Code: GWF
Dated: July 7, 2008
Received: July 08, 2008

Dear Mr. Coggan:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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: SEN-4100 Electric Stimulator

Indications for Use:

Nihon Kohden Sen-4100 Electric Stimulator is used for the intraoperative diagnosis of acute dysfunction in corticospinal tract axonal conduction brought about by mechanical trauma (traction, shearing, laceration, or compression) or vascular insufficiency.

Prescription use: ___x___ AND/OR Over - the – Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for MN

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

510(k) Number K071969