K110410

510(k) Summary

Company Name: Nihon Kohden Corporation
90 Icon Street
Foothill Ranch, CA 92610

AUG - 4 2011

Device Name: Nihon Kohden MS-120BK Electric Stimulator (Extension Unit)

510(k) Sponsor, Contact: Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

Steve Geerdes
Director Quality Assurance and Regulatory Affairs
Phone: (949) 580-1555 Ext. 3325
Fax: (949) 580-1550

Summary Date: 7/25/2011

Common Name: MS-120BK Electric Stimulator (Extension Unit)

Classification Names:

Evoked Response Electrical Stimulator	882.1870	GWF
Cortical Electrode	882.1310	GYC Class II

Predicate Device(s):

Nicolet Cortical Stimulator	K072964
Ojemann Cortical Stimulator	K924226
Digitimer D185 Multipulse Cortical Stimulator	K020400
Axon Eclipse Neurological workstation	K050798
Nihon Kohden SEN-4100 Electric Stimulator	K071969

1.0 Description of Device

The Nihon Kohden MS-120BK is a dual (high & low) output constant current stimulator. The high and low setting, stimulation current and frequency of stimulation is selected by the user. The Nihon Kohden MS-120BK is connected to the MEE 1000A through the JB-116BK or JB-132BK amplifier.

In the Low output setting the Nihon Kohden MS-120BK applies cortical stimulation energy through the Nihon Kohden stimulation pod (JS-102B) which is connected to commercially available cortical electrodes (strip and grid electrodes).

In the High output setting, the MS-120BK outputs electrostimulation pulse through the Nihon Kohden extension cord (BM-121B) which is connected to commercially available stimulation electrode(s).

2.0 Intended Use of Device

When the Low output is selected the MS-120BK is used as a nerve stimulator for surgical procedures and brain mapping during treatment of patients with seizure disorders.

When High output is selected the MS-120BK is used for the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction brought about by mechanical trauma (traction, shearing, laceration, or compression) or vascular insufficiency.

The system is intended for use by qualified medical personnel within a hospital or clinical environment. The stimulator is available for use on any patients as determined by the qualified medical personnel.

3.0 Technical Characteristics

The technical characteristics of the MS-120BK are equivalent to those of the predicate devices. The following tables summarizes equivalence.

Stimulator Comparison	Predicate Device Nihon Kohden SEN-4100A (K#071969)	Digitimer D185	New Device Nihon Kohden MS-120BK
Stimulator Output			
Voltage	1000V	1000V	350V
Current	1A (1k Ω load)	1A (1k Ω load)	200mA (1k Ω load)
Maximum Stimulation Energy	50mJ	50mJ	40mJ
Output Impedance	less than 120 Ω	less than 120 Ω	50 Ω
Stimulation Mode	Constant Voltage	Constant Voltage	Constant Current
Stimulation Parameters			

Pulse Duration Output Frequency Range Number of Pulse Trains Interpulse Interval	50 µs 1 Hz 1-9 1.0-9.9ms	50 µs 1 Hz 1-9 1.0-9.9ms	50-1000 µs 0.1-1Hz 1-9 1.0-1000ms
Limitation of Voltage / Current and Pulses	1000V: 3 Pulses 510V: 6 Pulses 350V: 9 Pulses	1000V: 3 Pulses 510V: 6 Pulses 350V: 9 Pulses	200mA: 3 Pulses *1 142mA: 6 Pulses *1 115mA: 9 Pulses *1
Polarity Change	OK	OK	OK
Monophasic	OK	OK	OK
Biphasic	NO	NO	OK
Alternate	NO	NO	OK
Maximum Charge	50 micro-Coulomb	50 micro-Coulomb	200 micro-Coulomb
Pulse Shape	Rectangular	Rectangular	Rectangular
Maximum Energy Per Pulse	50mJ	50mJ	40mJ
Maximum Energy Per Second	150mJ	150mJ	40mJ
Electrode Minimum Size	0.5cm2	0.5cm2	0.5cm2
Maximum Charge Density	100 Micro-C/cm2	100 Micro-C/cm2	400 Micro-C/cm2
Interface Control From EP/EMG Machine Trigger Input Trigger Output Foot Switch Control	 MEE-1000A OK OK OK	 NO OK OK OK	 Only MEE-1000A OK *2 OK *2 OK *2

*1: The pulse width in the case of 1ms

*2: Depends on interface of MEE-1000A

Stimulator Comparison	Predicate Device Nicolet Cortical Stimulator (K#072964)	Ojemann Cortical Stimulator (K#924226)	New Device Nihon Kohden MS-120BK
Constant Current Stimulator	Yes	Yes	Yes
Maximum Stimulation Charge	15 micro-Coulomb	20 micro-Coulomb	4.5 micro-Coulomb
Current Stimulation Range	0.1 to 15mA (peak)	0 to 10mA (peak)	0 to 15mA (peak)
Stimulation Frequency	1 to 100Hz	5, 10, 20, 50, 75, 100Hz	0.1 to 50Hz
Stimulation Pulse Width Duration	0.1 to 1.0 msec Per Phase	0.1 to 2.0 msec Per Phase	0.05 to 0.3 msec Per Phase
Pulse Shape	Rectangular	Rectangular	Rectangular
Electrode Minimum Size	0.04cm2	0.5cm2	0.04cm2
Maximum Charge Density	375 micro-C/cm2	40 micro-C/cm2	113 micro-C/cm2
Maximum RMS Current Density Per Pulse	119 mA RMS/cm2	8.9 mA RMS/cm2	46 mA RMS/cm2

4.0 Data Summary

Testing of the Nihon Kohden System with the MS-120BK was performed in compliance with the Nihon Kohden Corporation design control process. Testing included:

Software and hardware verification and validation, and the device is in compliance with the following voluntary industrial standards:

Medical Electrical Equipment
IEC 60601-1 Par1: General requirements for safety 1988
IEC 60601-1, Amendment 1 Part 1: General Requirements for safety, Amendment 1, 1991
IEC 60601-1, Amendment 2 Part 1: General Requirements for safety, Amendment 2, 1995
IEC 60601-1-2-40 * Part 2-40: Particular Requirements for the safety of electromyographs and evoked response equipment, 1998
IEC 60601-1-1 2nd edition: Part 1-1: General requirements for safety – Collateral standard
Safety requirements for medical electrical systems, 2000
IEC 60601-1-2 2nd edition: Medical electrical equipment- Part 1: General requirements for safety – 2. Collateral standard: Electromagnetic compatibility, 2001
EN 60601-1: 1990 Equivalent to IEC 60601-1: 1998*
EN 60601-1 Amendment 1 Medical equipment general requirements for safety, 1993
EN 60601-1 Amendment 2 Medical equipment general requirements for safety, 1995
EN 60601-1-1: 2001 Equivalent to IEC 60601-1:2001
EN 60601-1-2:2001 Electromagnetic compatibility requirement test
CAN/CSA-C22.2 No. 601.1-M90 Medical electrical equipment, Part 1: General requirements for safety.
CAN/CSA-C22.2 No. 601.1S1-94 Supplement No. 1-94 to CAN/CSA-C22.2 No. 601-1-M90 Medical Equipment- Part 1:General requirements for safety.
CAN/CSA-C22.2 No. 60601-1-1-02 Medical electrical equipment, Part 1-1: General requirements for safety- Collateral: Safety requirements for medical electrical systems, 2006
CAN/CSA-C22.2 No. 60601-2-40-01 Medical electrical equipment, Part 2-40: Particular requirements for safety of electromyographs and evoked response equipment (adopted 60601-2-40: 1998
CAN/CSA-C22.2 No. 601.1B-90 Amendment 2 to CAN/CSA-C22.2 No. 601.1-M90 Medical equipment Part 1: General requirements for safety: 2002

5.0 Conclusions

Substantial equivalence of the Nihon Kohden MS-120BK was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the Nihon Kohden MS-120BK is equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

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

Mr. Steve Geerdes
Director Regulatory Affairs and Quality Assurance
Nihon Kohden America, Inc.
90 Icon St.
Foothill Ranch, CA 92610

AUG - 4 2011

Re: K110410
Trade/Device Name: Nihon Kohden MS-120BK Electric Stimulator (Extension Unit)
Regulation Number: 21 CFR 882.1310
Regulation Name: Cortical Electrode
Regulatory Class: Class II
Product Code: GYC and GWF
Dated: June 27, 2011
Received: June 28, 2011

Dear Mr. Geerdes:

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 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

Indications for Use Form

510(k) Number (if known): _____K110410_____

Device Name: ___ MS-120BK Electric Stimulator (Extension Unit)___

Indications for Use:

When the Low output is selected the MS-120BK is used as a nerve stimulator for surgical procedures and brain mapping during treatment of patients with seizure disorders.

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The system is intended for use by qualified medical personnel within a hospital or clinical environment. The stimulator is available for use on any patients as determined by the qualified medical personnel.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kristen Bowsher
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K110410