K113117

MAR 2 2 2012

510(k) Summary

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

Device Name: Nihon Kohden JE-120A Electrode Junction Box for EEG-1200A

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: 9/26/2011

Common Name: Electroencephalograph amplifier (EEG Amplifier)

Classification Names:

Electroencephalograph	882.1400	GWQ

Predicate Device(s):

Nihon Kohden EEG-1200A	K080546

1.0 Description of Device

The EEG-1200A with JE-120A is a digital EEG based on a minimum of a 32-bit computer with a filing function. The device uses Windows Graphic User Interface, receives physiological signals (up to 256 channels with JE-120 electrode junction box) from patients and digitizes the signals, the application of the software reproduces the waveforms, **The EEG-1200A with JE-120A** consists of a main unit, electrode junction box (head box), PC Unit, Isolation Unit and System Programs. The electrode junction box, monitor, keyboard and mouse connect to the computer. The computer and control panel connect to the main unit. Components requiring AC power plug into the main unit's isolated power supply. The main unit plugs into a hospital grade AC power

source. All components fit onto a portable cart. A stand is also available for the electrode junction box. Patient data is stored to hard drive or other commercially available digital storage media. Inputs for Sp02 and EtC02 are available.

2.0 Intended Use of Device

The EEG-1200A series Nerurofax is intended to record, measure and display cerebral and extracerebral activity for EEG and Sleep Studies. This 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.

3.0 Technical Characteristics

The new JE-120A Multi Channel Electrode Junction Box is the successor of the previous JE-212A, cleared with EEG-1200A, The JE-120A allows amplifying and digitizing the EEG signal up to 256 channels, while the predicate JE-212A has up to 192 channels. The EEG-1200A with JE-120A also has inputs for SpO2 and EtCo2 which is the same as the technology found in Nihon Kohden's JE-921A

The product is controlled by the software installed on the EEG-1200 A series electroencephalograph (EEG).

	Predicate Device Electrode Junction Box JE-212A+JE-225AK/226AK/227AK+QI-122A	Predicate Device Electrode Junction Box JE-921A (K#050833)	New Device Electrode Junction Box JE-120A+JE-125AK(JE-225AK)/226AK/ 227AK/228AK+QI-123A
Product used with	Electroencephalograph EEG-1200A K#080546	Electroencephalograph EEG-1200A K#080546	Electroencephalograph EEG-1200A K#080546
Intended Use	Electrode junction box for EEG	Electrode junction box for EEG/PSG	Electrode junction box for EEG/PSG
Measurement parameters	EEG	EEG, ECG, EMG, EOG, respiration, SpO_2 and CO_2	EEG, ECG, EMG, EOG, SpO_2 and CO_2
Specification			

Number of input terminals EEG input terminals Multi-purpose input terminals Bipolar input terminals Respiration input terminals DC input terminals Input impedance Noise Rejection ratio Low cut filter High cut filter Electrode impedance check A/D resolution Maximum Sampling frequency	192 0 0 0 16 200M ohm Less than 1.5 micro Vp-p More than 110dB 0.016Hz(TC 10 seconds) or 0.08Hz (TC 2 seconds) 3000Hz (-18dB/oct.) Yes 16 bits (97nV/LSB) 10000Hz	25 4 14 3 4 100M ohm Less than 1.5 micro Vp-p More than 105dB 0.08Hz (TC 2 seconds) 300Hz (-18dB/oct) Yes 16 bit (97nV/LSB) 1000Hz	256 0 4 (JE-125AK) 0 16 200M ohm Less than 1.5 micro Vp-p More than 110dB 0.016Hz(TC 10 seconds) or 0.08Hz (TC 2 seconds) 3000Hz (-18dB/oct) Yes 16 bit (97nV/LSB) or 16 bit (388nV/LSB) 10000Hz
SpO_2 input	None	SpO_2 adapter is connected to this unit directly.	SpO_2 adapter is connected to this unit directly.
EtCo2 input	None	EtCo2 adaptor is connected to this unit directly.	EtCo2 adaptor is connected to this unit directly.
Body position sensor	None	DC input terminals	None
Mini electrode junction box	Option	Option	Option
Interface with EEG	Ethernet	USB	Ethernet
Safety	Type of protection against electrical shock: Class I Degree of protection against electric shock: Type BF	Type of protection against electrical shock: Class I Degree of protection against electric shock: Type BF	Type of protection against electrical shock: Class I Degree of protection against electric shock: Type BF

4.0 Data Summary

Testing of the Nihon Kohden EEG-1200ASystem with The JE-120A was performed in compliance with Nihon Kohden Corporation design control process. Testing included:

1. User needs/Functional	Accepted	Report # A100-000336B
2. Chassis	Accepted	Report # A152-005167
3. Labeling	Accepted	Report # A152-005167
4. Operating environment, temperature and humidity, EMC and EMI	Accepted	Report # A152-005138
5. Storage environment	Accepted	Report # A152-005138
6. Condition for transport	Accepted	Report # A152-005138
7. Risk analysis (including preliminary review and validation for improvement)	Accepted	Risk Analysis Table: 0704-905679B
Software unit test (JE-120A Software)	Accepted	Report # A275-000544
Software unit test (QI-123A/124A Software)	Accepted	Report # A275-000546
Software unit test (EEG-1200 Input module)	Accepted	Report # A275-000546
Software integration test (JE-120A Software)	Accepted	Report # A276-001026

Software integration test (QI-123A/124A Software)	Accepted	Report # A276-001028
Software integration test (EEG-1200 Input module)	Accepted	A Report # 276-001030

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

The substantial equivalence of the Nihon Kohden EEG-1200A with JE-120A 256 channel amplifier was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the Nihon Kohden EEG-1200A with JE-120A 256 channel amplifier is equivalent to the predicate device Nihon Kohden EEG-1200A cleared with JE-212A 196 channel amplifier. The JE-212 with optional accessories JE-215A, JE-216A, and JE-217A mini electrode junction boxes allow up to 192 channels of amplification in 64 channel increments. The JE-120A with optional accessories JE-225A, JE226A, JE-227A, and JE-228A mini electrode junction boxes allow up to 256 channels of amplification in 64 channel increments. The JE-225, 226, and 227, Are the same technology as JE-215,216, and 217, the only difference is the input connector is a slightly different configuration. The addition of the JE-228 is what allows the JE-120A to have up to 256 channels. The EEG-1200A with JE-120A also has inputs for SpO2 and EtCo2 which is the same as the technology found in Nihon Kohden's JE-921A. Validation was performed to ensure 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

MAR 2 2 2012

Nihon Kohden America, Inc.
c/o Mr. Steve Geerdes
Director of Regulatory Affairs and Quality Assurance
90 Icon Street
Foothill Ranch, CA 92610

Re: K113117
Trade/Device Name: Nihon Kohden JE-120A Multi Electrode Junction Box for EEG-1200A
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Dated: February 14, 2012
Received: February 22, 2012

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,

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): K113117

Device Name: ____ Nihon Kohden EEG-1200A with JE-120A 256 channel amplifier__

Indications for Use:

The EEG-1200A series Nerurofax is intended to record, measure and display cerebral and extracerebral activity for EEG and Sleep Studies. This 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.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

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