DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 4, 2015

Nihon Kohden Corporation
c/o Natalie Kennel
NJK & Associates, Inc
13721 Via Tres Vista
San Diego, CA. 92129

Re: K130238
Trade/Device Name: Nihon Kohden AE-918P Neuro Unit
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMA, OLT, OMC
Dated: February 3, 2015
Received: February 4, 2015

Dear Ms. Kennel:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Felipe Aguel -S

for Carlos Peña, Ph.D., M.S.
Director,
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K130238

Device Name
Nihon Kohden AE-918P Neuro Unit

Indications for Use *(Describe)*
The AE-918P EEG Neuro Unit is an 8 channel EEG measuring unit that connects to a Nihon Kohden patient monitor and is intended to monitor brain function. The unit amplifies and analyzes EEG and displays the EEG waveform and the result of analysis on the patient monitor.

The AE-918P EEG Neuro Unit includes the calculation of a set of quantitative measures intended to monitor and analyze the EEG waveform. These include quantitative EEG functions such as SEF, MDF, PPF, TP, CSA, DSA, %Delta, %Theta, %Alpha, %Beta, %Gamma, Abs Delta, Abs Theta, Abs Alpha, Abs Beta, and Abs Gamma. These quantitative EEG measures should always be interpreted in conjunction with review of the original EEG waveform. The aEEG functionality included in the AE-918P EEG Neuro Unit is intended to monitor the state of the brain.

The device is intended for use by medical personnel in any location within a medical facility, physician's office, laboratory, clinic or nursing home under direct supervision of a medical professional.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Sponsor:	Nihon Kohden Corporation 1-31-4 Nishiochiai Shinjuku-ku, Tokyo 161-8560 Japan
Initial Importer/ Distributor	Nihon Kohden America, Inc. 15353 Barranca Parkway Irvine, CA 92618
Contact Person:	Ms. Natalie J. Kennel Consultant NJK & Associates, Inc. 13721 Via Tres Vista San Diego, CA 92129 USA Phone: (858) 705-0350 Fax: (858) 764-9739 email: NKennel@njkconsulting.com
Date Revised:	March 2, 2015

DEVICE INFORMATION

Proprietary Name:	AE-918P Neuro Unit
Common Name:	Electroencephalograph
Regulation section:	21 CFR 882.1400
Classification:	Class II
Product Code:	OMC
Panel:	Neurological
Predicate Device:	EEG-1200A Series Neurofax K080546 Nihon Kohden

Additional Predicates:

The following additional predicates support specific functionality in this system (Table 1).

Table 1

K#	Product	Manufacturer	Aspect
K051178	MEE-1000	Nihon Kohden	MDF function
K963644	A-1050	Aspect	MDF function
K021185	Nervus Monitor	Nervus	Total Power
K120485	QP-160AK	Nihon Kohden	aEEG
K131789	Celebralogik	Mennen	aEEG

Product Description:

Electroencephalography (EEG) is the recording of electrical activity along the scalp. EEG measures voltage fluctuations resulting from ionic current flows within the neurons of the brain. In clinical contexts, EEG refers to the recording of the brain's spontaneous electrical activity over a period of time, as recorded from multiple electrodes placed on the scalp.

The AE-918P is an 8 channel digital Electroencephalography (EEG) that connects to a Nihon Kohden patient monitor. It receives EEG data from patients and digitizes the signals, the waveforms and analysis are displayed on a Nihon Kohden Patient Monitor.

The AE-918P is contained in a small enclosure that contains the EEG amplifier and digital circuitry. This enclosure is mounted to the bottom of the patient monitor and connects to the patient monitor through the multilink cable.

Indications for Use

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The AE-918P EEG Neuro Unit includes the calculation of a set of quantitative measures intended to monitor and analyze the EEG waveform. These include quantitative EEG functions such as SEF, MDF, PPF, TP, CSA, DSA, %Delta, %Theta, %Alpha, %Beta, %Gamma, Abs Delta, Abs Theta, Abs Alpha, Abs Beta, and Abs Gamma. These quantitative EEG measures should always be interpreted in conjunction with review of the original EEG waveform.

The aEEG functionality included in the AE-918P EEG Neuro Unit is intended to monitor the state of the brain.

The device is intended for use by medical personnel in any location within a medical facility, physician's office, laboratory, clinic or nursing home under direct supervision of a medical professional.

Comparison to Predicate Devices

The following table compares the technological aspects of the new device with its predicate device (see Table 2). The intended use comparison is given in the conclusion section.

Table 2 Technological Comparison to Predicate

Aspect	AE-918P New Device	EEG-1200A (K#080546) Configuration with standard JE-921A Junction Box
Number of Channels	8	32
Input Impedance	15 M ohm at 10Hz	100 M ohm
Calibration Check	Step square 50 uV	Step square or Sine wave 2 to 1000 uV (9 steps)
Impedance Check	All inputs with Screen	All inputs with Screen and Input box readout
Common-Mode Rejection Ratio (CMRR)	110 dB or more (in isolation mode) 60 dB or more (in balance mode)	105 dB or more
Noise Level	< 3 uV p-p (0.53 to 30 Hz)	< 1.5 uV p-p (0.53 to 60 Hz)
Frequency Response	0.08 to 70 Hz	0.08 to 300 Hz
High-pass Filter (Low-cut)	0.08 to 5.3 Hz	0.016 to 159 Hz DC standard
Low-pass Filter (High-cut)	15 to 70 Hz	15 to 300 Hz
AC Filter	50 or 60 Hz (rejection ratio > 1/20)	50 or 60 Hz (rejection ratio > 1/25)
ECG Filter	None	Standard
Sensitivity	OFF, 1 to 200 uV/mm (14 steps)	OFF, 1 to 200 uV/mm (15 steps) DC: OFF, 10 to 200 mV/mm (10 steps)
A-D Conversion	16 bits	16 bits
Sampling	All channels 200 Hz (A-D Conversion: 4 kHz)	All channels 100, 200, 500, 1000 Hz
Display Resolution/Channels	N/A	1600 x 1200 64 + Mark Channel
Communication	Serial interface	Analog Input/Output, Networking, Modem

Aspect	AE-918P New Device	EEG-1200A (K#080546) Configuration with standard JE-921A Junction Box
Power	+12V+/- 5% 500 mA or less +5V+/- 5% 100 mA or less	120 V +/- 10% 50 / 60 Hz 750 VA
Operating Environment	Temperature: 10 to 40 degree C Humidity: 30 to 90 %	Temperature: 10 to 35 degree C Humidity: 30 to 80 %
Trend parameter	DSA	DSA
	aEEG	aEEG
	FFT power	FFT power
	FFT power ratio	FFT power ratio
Number of trends	8	More than 8
Number of trend windows	1	2
Time interval of trends	N/A	1 minute/page to 24 hours /page 1 cm/hour to 60 cm/hour
Annotation list	No	Annotation list
Annotation trend	No	Annotation trend
MDF (Median Frequency)	Yes	No
TP (Total Power Value)	Yes	No
aEEG	Yes	No

Performance Testing

The AE-918P was subjected to safety and performance testing procedures. The AE-918P has undergone validation and verification testing to ensure conformance to all design requirements. Additionally, the system has undergone comparison testing to ensure the substantial equivalence of the calculation and display of EEG trends. These tests verified that the device performed within specifications.

No Clinical testing was required

Testing of the Nihon Kohden AE-918P Neuro Unit was performed in compliance with Nihon Kohden Corporation design control process. Testing to the following standards was done. (See Table 3):

Table 3 Medical Electrical Equipment

IEC 60601-1 Part1: General requirements for safety 1998-12
IEC 60601-1, Amendment 1 Part 1: General Requirements for safety, Amendment 1,

1991-11
IEC 60601-1, Amendment 2 Part 1: General Requirements for safety, Amendment 2, 1995-03
IEC 60601-1-2 2nd edition Part 1-2: General requirements for safety – Collateral standard. Electromagnetic compatibility, 2001-09
IEC 60601-1-2 2nd edition, Part 1-2: General requirements for safety – Collateral Amendment 1 standard. Electromagnetic compatibility. Amendment 1, 2004-09
IEC 60601-2-26 Part 2-26: Particular Requirements for the safety of electroencephalograph 2002-11

Electrodes used as accessories with the device are the same as those of the predicate device and have previously been testing for biocompatibility for a surface contacting device of prolonged duration according to ISO 10993-1 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

Conclusion:

Based on the comparison information in the technical comparison chart above and confirmed by verification/validation testing in compliance with the Design Control requirements, the AE-918P was shown to be equivalent in safety and effectiveness to the main predicate device EEG-1200A.

The intended use of AE-918P Neuro unit is different from the predicate (EEG-1200A, K080546) because it is a simplified version of the EEG-1200A, thus with a subset of the intended use. The AE-918 has only 8 channels of EEG and used mainly for monitoring brain activity on a patient monitor. The EEG-1200 has up to 256 channels of EEG and can also be used for monitoring brain activity but has additional intended uses such as sleep studies. The technology and materials of the AE-918 are the same as used in the EEG-1200A. The other differences are covered by other predicates as shown in Table 1.