DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 25, 2017

Nihon Kohden Corporation
% Tom Bento
Sr. Vice President, Quality and Regulatory
Nihon Kohden America, Inc.
15353 Barranca Parkway
Irvine, California 92618

Re: K171124
Trade/Device Name: Nihon Kohden Wireless Input Unit WEE-1200
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, OLV
Dated: July 31, 2017
Received: August 1, 2017

Dear Mr. Bento:

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 (DICE) 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" (21 CFR 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 (DICE) 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171124

Device Name
Nihon Kohden Wireless Input Unit WEE-1200

Indications for Use *(Describe)*
The WEE-1200 Wireless Input Unit is intended to acquire, store, record, and transmit the cerebral and extracerebral activity for EEG and sleep studies. The device should be used together with Nihon Kohden specified electroencephalograph via wired or wireless communication to display EEG on the electroencephalograph screen. These data may be used by the clinician in sleep disorder, epilepsies and other related disorders as an aid in diagnosis. The WEE-1200 Wireless Input Unit is designed for use by qualified medical personnel in a medical facility such as a hospital or clinic on all patient populations including adult, neonate, infant, child and adolescent subgroups.

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

Nihon Kohden Wireless Input Unit WEE-1200

Submitter:	Nihon Kohden Corporation
Address:	1-31-4 Nishiochiai, Shinjuku-Ku Tokyo, Japan 161-8560
Phone number:	81-3-5996-8020
Contact person:	Tom Bento
Phone number:	(949) 680-9048
Fax number:	(913) 273-0732

Date prepared:	April 14, 2017
Device name:	Nihon Kohden Wireless Input Unit WEE-1200
Common name:	Electroencephalograph (EEG)
Primary product codes:	GWQ, OLV
Regulation numbers:	21 CFR 882.1400

Substantial equivalence claimed to:	Nihon Kohden Wireless Input Unit WEE-1000A (K033475) Nihon Kohden EEG-1200A with JE-120A Multi Channel Electrode Junction Box (K113117)

Description:

The WEE-1200 Wireless Input Unit is a system that can be used in routine EEG testing, epilepsy monitoring, or PSG testing to send the measured EEG waves, ECG waves, EMG waves, EOG waves, and respiration waves from the electrodes to the electroencephalograph by wired or wireless LAN. The electrodes are connected to a mini junction box which is connected to the telemetry unit that is worn by patient or placed near patient.

The measured data can also be stored in the telemetry unit of the WEE-1200 Wireless Input Unit.

Additionally, by connecting a SpO_2 sensor and SpO_2 adapter to the telemetry unit, SpO_2 value and waveform can be measured and displayed on both the electroencephalograph screen and the telemetry unit LCD display.

Indications for Use:

The WEE-1200 Wireless Input Unit is intended to acquire, store, record, and transmit the cerebral and extracerebral activity for EEG and sleep studies. The device should be used together with Nihon Kohden specified electroencephalograph via wired or wireless communication to display EEG on the electroencephalograph screen. These data may be used by the clinician in sleep disorder, epilepsies and other related disorders as an aid in diagnosis. The WEE-1200 Wireless Input Unit is designed for use by qualified medical personnel in a medical facility such as a hospital or clinic on all patient populations including adult, neonate, infant, child and adolescent subgroups.

Technological Characteristics – Substantial Equivalence Discussion

The WEE-1200, just like its predicate WEE-1000A (K033475), is a device intended to be used together with Nihon Kohden electroencephalographs such as EEG-1200A (K080546) to transmit the measured data via wireless or wired LAN. The WEE-1200 has same measuring parameters as the predicates.

The new SpO_2 adapter, JL-570T, that can be used with the subject device for SpO_2 measurement is substantially equivalent to the previously cleared SpO_2 adapter, JL-550T1 (K113117, EEG-1200A with JE-120A), with only a few minor differences that do not raise any new safety and effectiveness issues.

When compared with the WEE-1000A (K033475), the subject device has an enhanced transmission performance: the maximum transmission throughput is increased and dual-band operation (IEEE802.11 a/b/g/n) is available on the subject device. The wireless LAN security adopted on the predicate device was Nihon Kohden original protocol while the subject device utilizes 802.11i WPA/WPA2. The wireless transmission performance of the subject device is validated according to the FDA guidance “Radio Frequency Wireless Technology in Medical Devices” for its co-existence features and network performance.

Device comparison:

	EEG-1200A with JE-120A Junction Box **Predicate Device (K113117)**	**WEE-1000A Wireless Input Unit** **Predicate Device (K033475)**	**WEE-1200 Wireless Input Unit** **New Device**
Indications for Use			
	EEG-1200 series Neurofax is intended to record, measure and display cerebral and extraccrebral activity for EEG and Sleep Studies. These data may be used by the clinician in sleep disorder, epilepsies and other related disorders as an aid in diagnosis. The device is intended for use by medical personnel in any location within a	The device is intended to acquire, store, and transfer biophysical parameters to EEG machines for the purpose of assisting the diagnosis of neurological and sleep disorders, measurement and display of cerebral and extracerebral activity for EEG and sleep studies. These data may be used by clinician in	The WEE-1200 Wireless Input Unit is intended to acquire, store, record, and transmit the cerebral and extracerebral activity for EEG and sleep studies. The device should be used together with Nihon Kohden specified electroencephalograph via wired or wireless communication to display EEG on the electroencephalograph screen. These data may be

	EEG-1200A with JE-120A Junction Box Predicate Device (K113117)	WEE-1000A Wireless Input Unit Predicate Device (K033475)	WEE-1200 Wireless Input Unit New Device
	medical facility, laboratory, clinic or nursing home or outside of a medical facility under direct supervision of a medical professional.	sleep disorders, epilepsies and other related disorders as a diagnostic tool. The device is intended for use by medical personnel in any location within a medical facility, physician's office, laboratory, clinic or nursing home or outside of a medical facility under supervision of a medical professional. The device will be available in all populations, including pediatrics.	used by the clinician in sleep disorder, epilepsies and other related disorders as an aid in diagnosis. The WEE-1200 Wireless Input Unit is designed for use by qualified medical personnel in a medical facility such as a hospital or clinic on all patient populations including adult, neonate, infant, child and adolescent subgroups.
Product used with	Nihon Kohden EEG-1200A (K080546)	Nihon Kohden EEG-1200A (K080546)	Nihon Kohden EEG-1200A (K080546)
Measurement Parameters	EEG, ECG, EMG, EOG, SpO_2 and CO_2	EEG, ECG, EMG, EOG, Respiration, and SpO_2	EEG, ECG, EMG, EOG respiration, and SpO_2
Telemetry Unit			
Telemetry Unit Model	N/A	ZB-101AA or ZB-102AA	ZB-120A
Wireless LAN	N/A	IEEE 802.11 b/g	IEEE 802.11a/b/g/n
Frequency band	N/A	2.4GHz	2.4 GHz or 5 GHz
Number of channels	N/A	2.4 GHz: 11 channels (1 to 11ch)	2.4 GHz: 11 channels (1 to 11ch) 5 GHz: 24 channels (36, 40, 44, 48, 52, 56, 60, 64, 100, 104, 108, 112, 116, 120, 124, 128, 132, 136, 140, 149, 153, 157, 161, 165 ch)
Modulation	N/A	DSSS (BPSK/QPSK): 1 & 2 Mbps DSSS (CCK): 5 & 11 Mbps	Auto (DSSS (BPSK/QPSK/ CCK)): 802.11b OFDM (BPSK/QPSK/ 16QAM/64QAM): 802.11a/g/n (6/9/12/18/24/36/48/54 Mbps, MCS0/1/2/3/4/5/6 7)
Transmission power	N/A	< 5mW/MHz	2.4GHz < 10mW/MHz 5GHz < 10mW/MHz
Wireless LAN security	N/A	NK Original	WEP, WPA, WPA2
Battery operation time	N/A	18 hours (Using 10s Intermittent transfer mode)	10 hours (using internal battery only) 30 hours (using internal Battery and Extension unit)

	EEG-1200A with JE-120A Junction Box Predicate Device (K113117)	WEE-1000A Wireless Input Unit Predicate Device (K033475)	WEE-1200 Wireless Input Unit New Device
Applied wireless transmission standards and guidance	N/A	FCC 47CFR Part 15 Subpart B FCC 47CFR Part 15 Subpart C	FCC 47CFR Part 15 Subpart C FCC 47CFR Part 15 Subpart E （FCC ID：PVH0941） FCC 47CFR Part 2 1093 （FCC ID：B6B0941）
Electrode Junction Box			
Junction Box Model	・Amplification unit JE-120A ・Mini Junction Box JE-125AK or JE-225AK And JE-226AK/227AK/ 228AK	・Amplification unit ZB-101AA/102AA ・Mini Junction Box JE-011A or JE-012A or JE-013A	・Amplification unit ZB-120A ・Mini Junction Box JE-125AK or JE-225AK or JE-922A
Electrode jacks	Up to 64 for EEG Up to 4 for bipolar input Z electrode COM	Up to 62 for EEG Z electrode	Up to 64 for EEG Up to 4 for bipolar input Z electrode COM
Reference electrode	A5 and A6 (C3 and C4) or COM	A5 and A6 (C3 and C4)	A5 and A6 (C3 and C4) or COM
Input impedance	200M ohm	200M ohm	200M ohm
Noise	Less than 1.5 micro Vp-p	Less than 3.0 micro Vp-p	Less than 2.0 micro Vp-p
Rejection ratio	More than 110dB	More than 105dB	More than 105 dB
Low cut filter	0.016Hz (TC 10 seconds) or 0.08Hz (TC 2 seconds)	0.08Hz (TC 2 seconds)	0.08Hz (TC 2 seconds)
High cut filter	3000Hz (-18dB/oct)	60Hz (-18dB/oct)	1200Hz (-18dB/oct)
Electrode impedance check	Yes	Yes	Yes
A/D resolution	16 bit (97nV/LSB) or 16 bit (388nV/LSB)	16 bit (97nV/LSB)	16 bit (97nV/LSB) or 16 bit (388nV/LSB)
Maximum Sampling frequency	10000 Hz	200Hz	・4000Hz (Wired mode：Without any condition Wireless mode: limit of storage of 40ch electrode) ・2000Hz (without any condition)
Main Unit			
Interface with EEG	100Base-TX LAN (On the QI-123AK)	100Base-TX LAN (On the ZR-101AK)	100Base-TX LAN

Comparison of SpO2 adapters:

	JL-550T1 (K113117)	JL-570T (New)
Measurement Parameters	Saturated oxygen (SpO_2), Pulse rate (PR)	
SpO2 measuring specification		
Measuring method	Two wavelength light absorption method	
Measuring Range	0 to 100%SpO_2	
Measuring accuracy (rms)	±2 %SpO_2 (80 %SpO_2 ≤ SpO_2 ≤ 100 %SpO_2) ±3 %SpO_2 (70 %SpO_2 ≤ SpO_2 < 80 %SpO_2) SpO_2 accuracy is guaranteed at surrounding temperature of 18 to 40°C (64.4 to 104°F).	
Pulse rate measuring specification		
Measuring Range	30 to 300 beats/min	
Measuring accuracy (rms)	±3% ± 1 1/min (30 to 300 beats/min)	
Dimensions and Weight	Width 34±10mm × Height 18±10mm × Depth 117±10mm	
	2500±100mm	600mm±100mm
	95g±10%	55±10g
Degrees of protection provided by enclosure	IPX1	
Temperature (Operating)	10～40℃	
Temperature (Storage/Transportation)	-20～65℃	
Humidity (Operating)	30～85%RH	
Humidity (Storage/Transportation)	10～95%RH	
Voltage input	5V±5%	3.3V±5%
Power consumption	250mWTyp.	30mWTyp.
Hardware specification of SpO_2 measurement board		
1) LED driver	Peak current 0 to 60 mA	Peak current 0 to 40 mA
2) I/V converter	Transform current from the photodiode to voltage	
3) Filter	Band pass filter	
4) Amplifier	Variable DC amplifier	
5) Demodulation	Demodulate R signal and IR signal separately with low pass filter	
6) A/D converter	Convert analog DC signals to digital ΔΣ-A/D 24 bit	
7) CPU	ARM 7	

Test Summary:

i) Non-Clinical Testing

The software verification and validation testing for the WEE-1200 includes the following tests –

- Software Unit Test: Code inspection and static analysis
- Software Integration Test: transfer of data and control across a program's internal and external interfaces

- System Test: Comprehensive testing of all required functionality of the device (hardware and software)

The following tests on wireless technology performance of the device were performed following FDA Guidance, “Radio Frequency Wireless Technology in Medical Device”.

- Wireless Coexistence Test: Performance validation in the presence of wireless emitters in the intended use environment (hardware and software)
- Wireless Network Test: Verify and validate the ability to securely operate in a mixed client enterprise 802.11a/b/g/n network, and to demonstrate the correct quality of service (hardware and software)
- Wireless Operation Test: Verify and validate the Wi-Fi operation of the device (hardware and software)

Standards compliance testing on the device includes:

- AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2: General requirements for safety and essential performance collateral standard: Electromagnetic compatibility – requirements and tests
- IEC 60601-2-26:2012 Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
- ISO 80601-2-61:2011 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

ii) Clinical Testing

No clinical testing on the subject device was necessary to show substantial equivalence to the predicate.

Conclusion:

Device comparison and the results of the above listed performance testing indicate that the Nihon Kohden Wireless Input Unit WEE-1200 is substantially equivalent to the predicate devices, the Nihon Kohden Wireless Input Unit WEE-1000A (K033475) and Nihon Kohden EEG-1200A with JE-120A Multi Channel Electrode Junction Box (K113117), and raises no safety or effectiveness issues.