March 19, 2019

Nihon Kohden Corporation
% Natalie Kennel
Quality & Regulatory Consultant
NJK & Associates, Inc.
13721 Via Tres Vista
San Diego, California 92129

Re: K183529
Trade/Device Name: AE-120A EEG Head Set
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMC, GXY
Dated: December 17, 2018
Received: December 19, 2018

Dear Natalie 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Patrick Antkowiak -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)*
K183529

Device Name
AE-120A EEG Head Set

Indications for Use *(Describe)*
The AE-120A EEG Head Set is intended to amplify, capture, and wirelessly transmit electrical activity of the brain for review by a trained medical professional using the previously cleared and validated Nihon Kohden electroencephalograph systems (EEG-1200A series and EEG-9100) to assist in the diagnosis of neurological disorders. The AE-120A EEG Head Set and its associated EEG Software do not provide any diagnostic conclusion or automated alerts of an adverse clinical event about a patient's condition.

The device is intended for use by trained medical professionals in a medical facility such as a physician's office, laboratory, or clinic. The device is intended for use on adults (ages 18 and above).

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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K183529
Traditional 510(k) Summary

Submitter	Nihon Kohden Corporation 1-31-4 Nishiochiai, Shinjuku-Ku Tokyo, Japan 161-8560 (949) 680-9048 (Thomas Bento)
Contact Person	Natalie Kennel Consultant NJK & Associates, Inc. 13721 Via Tres Vista San Diego, CA 92129 Phone: (858) 705-0350 Fax: (858) 764-9739 Email: nkennel@njkconsulting.com
Date Prepared	March 19, 2019

Subject Device

Device Name	AE-120A EEG Head Set
Common Name	Electroencephalograph (EEG)
Device Class	Class II
Product Code & Regulation	OMC (Primary); Reduced- Montage Standard Electroencephalograph 21 CFR 882.1400; Class II; Electroencephalograph GXY (Secondary); Cutaneous Electrode 21 CFR 882.1320; Class II; Cutaneous Electrode
Review Panel	Neurology; Diagnostic Devices

Intended Use

The AE-120A EEG Head Set is intended to amplify, capture, and wirelessly transmit electrical activity of the brain for review by a medical professional using the following Nihon Kohden specified electroencephalograph system to assist in the diagnosis of neurological disorders, as the subject device's components, accessories, and software operate as a system with the following devices that have been previously cleared:
K011204 –Neurofax Models EEG-9100
K080546 – EEG-1200A series

The above EEG systems are compatible with the subject device because they have been updated or can be updated to include newly developed EEG Software needed to operate with the subject device headset.

Device Description for the Subject Device: AE-120A EEG Head Set

The Nihon Kohden AE-120A EEG Head Set is a battery powered (2 AA, LR6 alkaline disposable) wireless EEG head set which facilitates the placement of disposable EEG electrodes on the patient's scalp. The AE-120A EEG Head Set with the electrodes is then attached to the patient's head using the head set's chin, top, and rear straps.

With the head set turned on and secured in place, the head set acquires and amplifies electrical activity via EEG electrodes placed in contact with the patient's scalp. The captured waveforms from these signals are transmitted wirelessly via Bluetooth to a Nihon Kohden specified electroencephalograph through the AE-120A EEG Head Set and receiver.

The head set outputs the collected brain electrical activity to the computer component of the electroencephalograph system where a medical professional can review and interpret the information.

The AE-120A EEG Head Set has 8 channels for measurement along with one reference and one Z electrode. The electrodes are fixed into position with the head set to approximate the 10-20 electrode positions.

The AE-120A EEG Head Set is designed to work with the Nihon Kohden EEG-1200A series and EEG-9100, cleared in K080546 and K011204, respectively. The associated system software is used to facilitate the communication and display of the information from the head set.

Indications for Use

The AE-120A EEG Head Set is intended to amplify, capture, and wirelessly transmit electrical activity of the brain for review by a trained medical professional using the previously cleared and validated Nihon Kohden electroencephalograph systems (EEG-1200A series and EEG-9100) to assist in the diagnosis of neurological disorders. The AE-120A EEG Head Set and its associated EEG Software do not provide any diagnostic conclusion or automated alerts of an adverse clinical event about a patient's condition.

The device is intended for use by trained medical professionals in a medical facility such as a physician's office, laboratory, or clinic. The device is intended for use on adults (ages 18 and above). (Rx Only)

Predicate Devices

The AE-120A EEG Head Set is substantially equivalent to the Ceribell Pocket EEG with the Ceribell Instant EEG Headband. Table 1, below, lists the primary predicate device, **K170363 (**headbox, processing unit, basic software needed to display, store, and archive EEG and allow user-only annotation and marking; does NOT include electrodes, more complex software used to

analyze EEG or automatically detect events). The secondary predicate device, **K171459,** is intended to cover the cutaneous electrode component of system, which is necessary to achieve the intended use and does not change the intended use as compared to the primary predicate EEG device, K170363.

Table 1 – List of Predicate Devices to which AE-120A EEG Head Set K183529 Claims Substantial Equivalence; Lower 2 Rows Include Reference Devices for Wireless EEG Data Transmission Characteristics of the Subject Device

Purpose	510(k) Number	Regulation Name	Device Name	Submitter
Reduced Montage Standard EEG (Primary Predicate)	K170363	Reduced- Montage Standard Electroencephalograph	Ceribell Pocket EEG Device	Ceribell, Inc.
Electrode Component (Secondary Predicate)	K171459	Cutaneous Electrode	Ceribell Instant EEG Headband	Ceribell, Inc
Reference Devices (Not Intended as Predicates)	K131944	Reduced- Montage Standard Electroencephalograph	iEEG	Jordan NeuroScience, Inc.
	K082886	Non-Normalizing Quantitative Electroencephalograph Software	BrainScope Z-100	BrainScope Company Inc

Technological Characteristics as Compared to Predicate Devices

Table 2, below, includes a comparison of the AE-120A EEG Head Set and its predicates K170363 Ceribell Pocket EEG & K171459 Ceribell Instant EEG Headband. Where applicable, there is also a comparison to two legally marketed reference devices to support the scientific methodology of wireless transmission of EEG data transfer at decision point 5a of the 510(k) flowchart (*"Are the methods acceptable?"*) to help determine substantial equivalence for the subject device.

Table 2 - Comparison of the AE-120A EEG Head Set to Predicates K170363 & K171459

Characteristic	AE-120A EEG Head Set K183529	Ceribell Pocket EEG Device K170363 and Ceribell Instant EEG Headband K171459	Comment
Intended Use	The AE-120A EEG Head Set is intended to amplify, capture, and wirelessly transmit electrical activity of the brain for review by a trained medical professional using the Nihon Kohden electroencephalograph systems cleared in K080546 and K011204 to assist in the diagnosis of neurological disorders.	K171459: A single-use disposable headpiece with an integrated array of 10 passive cutaneous electrodes, that are applied to the patient's head to record EEG signals when connected to an EEG recording device. K170363: Device intended to record and store EEG signals, and to present EEG signals to medical staff.	Similar intended use. The combination of the 2 Ceribell devices together provide the same intended use. The combination of the subject device and a Nihon Kohden specific EEG system provides the same intended use: assisting in the diagnosis of neurological disorders by amplifying, capturing, and sending electrical activity of the brain and patient data for review by a medical professional.

Characteristic	AE-120A EEG Head Set K183529	Ceribell Pocket EEG Device K170363 and Ceribell Instant EEG Headband K171459		Comment
Indications for Use	The AE-120A EEG Head Set is intended to amplify, capture, and wirelessly transmit electrical activity of the brain for review by a trained medical professional using the previously cleared and validated Nihon Kohden electroencephalograph systems (EEG-1200A series and EEG-9100) to assist in the diagnosis of neurological disorders. The AE-120A EEG Head Set and its associated EEG Software do not provide any diagnostic conclusion or automated alerts of an adverse clinical event about a patient's condition. The device is intended for use by trained medical professionals in a medical facility such as a physician's office, laboratory, or clinic. The device is intended for use on adults (ages 18 and above). (Rx only)	The Ceribell Pocket EEG Device is intended to record and store EEG signals, and to present the EEG signals in visual and audible formats in real time. The visual and audible signals assist trained medical staff to make neurological diagnoses. The Pocket EEG Device does not provide any diagnostic conclusion about the subject's condition and does not provide any automated alerts of an adverse clinical event. The Pocket EEG Device is intended to be used in a professional healthcare facility environment. (Rx only)	The Ceribell Instant EEG Headband is an electroencephalogram (EEG) electrode array intended for single patient use in the recording of EEGs in patients of 6 years and older. The Instant EEG Headband is intended for prescription use in the home, healthcare facility, or clinical research environment. (Rx only)	Similar; The combination of the 2 Ceribell devices provides the same intended use. The combination of the subject device and a Nihon Kohden specific EEG system provides the same intended use: assisting in the diagnosis of neurological disorders by amplifying, capturing, and sending electrical activity of the brain and patient data for review by a medical professional. (Rx only)
Device Class & Regulation	Class II per 21 CFR 882.1400 Electroencephalograph (Head Set) Class II per 21 CFR 882.1320 (for electrodes within headset)	Class II per 21 CFR 882.1400 Electroencephalograph (EEG Device) Class II per 21 CFR 882.1320 (Instant EEG Headband – cutaneous electrodes)		Same
Product Code(s)	Primary Proposed: OMC Secondary Proposed: GXY	K170363 cleared under: OMC K171459 cleared under: GXY		Same
Modalities	EEG	EEG		Same
Type of patient contact	Electrodes and gel contact patient's scalp	Electrodes and gel contact patient's scalp		Same

Characteristic	AE-120A EEG Head Set K183529	Ceribell Pocket EEG Device K170363 and Ceribell Instant EEG Headband K171459	Comment
Electrodes	10 passive Ag/AgCl electrodes	10 passive Ag/AgCl electrodes	Same Subject device EEG disk electrode of Ag cleared in **K171124** but with different length of lead.
Type of use - Electrodes	Single use, non-sterile, disposable	Single use, non-sterile, disposable	Same
Type of use - EEG device	AE-120A EEG Head set is reusable and non-patient contacting. Belts are patient contacting and reusable (they can be cleaned & disinfected but are recommended for single patient use)	Ceribell Pocket EEG Device is reusable and non-patient contacting. Ceribell Instant EEG headband is single use, patient contacting and disposable.	Subject device is reusable whereas predicate is single use disposable. However, this difference does not raise different questions of safety and effectiveness.
EEG channels	8	8	Same
Montage	10/20 System[1]	10/20[2]	Same
Electrical Safety & EMC	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-26	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-26 IEC 62133	Same; Refer to performance testing section of this Summary for details on the standards to which the subject device claims conformance and other performance testing. Note: IEC 62133 does not apply to AE-120A because the subject device is powered by alkaline batteries.

[1] AE-120A EEG Head Set approximates the 10/20 montage but may deviate slightly depending on the patient's head shape

[2] Ceribell Pocket EEG Device and Ceribell Instant EEG Headband also approximates a 10/20 montage

Characteristic	AE-120A EEG Head Set K183529	Ceribell Pocket EEG Device K170363 and Ceribell Instant EEG Headband K171459	Comment
Input dynamic range	1 mVp-p	Unknown (presumed to be same as it meets IEC 60601-2-26)	Similar; AE-120A complies with the requirement of the input dynamic range specified in clause 201.12.1.101.2, IEC 60601-2-26
Input noise	5 µVp-p or less (0.53 to 60 Hz)	Unknown (presumed to be same as it meets IEC 60601-2-26)	Similar AE-120A complies with the requirement of the input noise specified in clause 201.12.1.101.3, IEC 60601-2-26
Transfer of data to EEG	Bluetooth 2.4 GHz	Micro-USB cable	Whereas the subject device transmits the data wirelessly in real time via Bluetooth to the compatible EEG system, the Ceribell Pocket EEG Device transmits the data via a cable after collection. The following two legally marketed reference devices are cited to support this scientific methodology of wireless transmission of EEG data transfer as acceptable for the intended use. The **reference devices** are: iEEG (**K131944**) and BrainScope Z-100 (**K082886**).
Power source	Battery powered	Battery powered	Same
Type of battery	2 AA (LR6) alkaline batteries (not rechargeable)	Lithium ion batteries –rechargeable with 100-240 V AC power adapter (Device does not work when connected to AC to recharge)	Similar; The differences do not raise any different questions of safety or effectiveness
Data format	Nihon Kohden original format	Edf	Similar; Since the AE-120A EEG Head Set provides the data to only Nihon Kohden specified EEG's, this difference does not raise any different questions of safety or effectiveness.

Characteristic	AE-120A EEG Head Set K183529	Ceribell Pocket EEG Device K170363 and Ceribell Instant EEG Headband K171459	Comment
Compatibility	Works only with Nihon Kohden specified EEG's: EEG-1200A series (K080546) EEG-9100 (K011204)	Ceribell Instant EEG Headband works only with Ceribell Pocket EEG Device	Similar; Both subject and predicate device are intended to be connected to external EEG recording devices. The differences in EEG recording compatibility does not raise any different questions of safety or effectiveness
EEG Software	AE-120A EEG Head Set comes with EEG software to be placed on the compatible EEG for interaction with and viewing of EEG data	Ceribell Pocket EEG Device comes with EEG Recording Viewer Software	Similar. Both devices come with software for viewing the EEG data collected with the device. The AE-120A EEG Head Set software for the associated Nihon Kohden EEG allows the user to interact with the head set and review and interpret the data on the EEG.
Connector	Single connector of electrodes to AE-120A Head Set	Integrated single cable connector in Ceribell Instant EEG Headband to connect to EEG recording device	Same
Able to accommodate different patient head sizes	AE-120A EEG Head Set has flexible arms that are adjusted to fit different adult patient head sizes along with adjustments from the belts/ straps (chin)	Ceribell Instant EEG Headband comes in three sizes Small (48.4 – 53.6 cm) Medium (53.3 -56.5 cm) Large (55.5 – 62 cm)	Similar; Both subject and predicate devices can accommodate different patient sizes. AE-120A is limited to adults only to be sure that its flexibility is adequate for the range of head sets
Conductive Electrolyte Material	Conductive electrolyte paste is included in a packet gel reservoir integrated into each electrode. User inserts electrode into the electrode attachment position in Head Set with paste.	Conductive electrolyte gel is included in a packet gel reservoir integrated into each electrode assembly. User is also able to add additional electrolyte gel when needed using a syringe	Same

Characteristic	AE-120A EEG Head Set K183529	Ceribell Pocket EEG Device K170363 and Ceribell Instant EEG Headband K171459	Comment
Biocompatibility	Patient contacting components verified with Cytotoxicity, Sensitization, and Irritation per ISO 10993-5and ISO 10993-10 (or previous clearance or previous use of material/processing for same patient contact and duration). These components include: electrodes, electrode gel, paste	Patient contacting components verified with Cytotoxicity, Sensitization, and Irritation per ISO 10993-5and ISO 10993-10	Similar; All patient contacting components evaluated according to ISO 10993-1 and associated FDA guidance
Additional electrodes	Two additional optional electrode sets can be used (NE-090S1 and NE-091S7)	N/A	The subject device includes two additional electrodes that can be added to the headset's occipital region; these have been tested for performance since they were not previously cleared under 21 CFR 882.1400 like the other electrodes; this difference does not raise different questions of safety or effectiveness; This electrode is the same as NM-317Y3 cleared in K120397 (882.1870 Evoked response electrical stimulator) but is not used for the purpose of evoked stimulation; it is only used for recording.

Table 3 – Comparison to Reference Devices

Characteristic	AE-120A EEG Head Set K183529	Reference Device #1 iEEG K131944	Reference Device #2 BrainScope Z-100 K082886	Comment
Modalities	EEG	EEG	EEG	Same
EEG Channels	8	8	8	Same
Montage	10/20 system	10/20 system	10/20 system	Same
Wireless Output	Bluetooth 2.4 GHz	Bluetooth 2.4 GHz	Bluetooth 2.4 GHz	Same
Sampling Rate	200 Hz	250 Hz	200 Hz	Subject device same as second reference device. Both meet the minimum of 200Hz recommended by ECRI 2017

Characteristic	AE-120A EEG Head Set K183529	Reference Device #1 iEEG K131944	Reference Device #2 BrainScope Z-100 K082886	Comment
ADC Resolution	12 bit	16 bit	16 bit	Subject device is lower than reference devices but 12 bit still provides more than 4000 levels of resolution & meets the minimum of 12 bit according to ECRI 2017 review.
ADC Common Mode Rejection Rate (CMRR)	> 90 dB	> 115 dB	> 100 dB	Substantially equivalent to the predicates. Subject device is slightly lower but complies with the requirement of the input noise specified in clause 201.12.1.101.5, IEC 60601-2-26
Input Impedance	1200 Mohms	10 Mohms	10 Mohms	Subject device is improved compared to the predicates
Electrode impedance check	Yes	Yes	Yes	Same

PERFORMANCE TESTING

Electrode Performance Testing

- ANSI AAMI EC12:2000/(R)2015 Disposable ECG electrodes for **NE-091S7 electrodes**

This study verified the performance of the NE-091S7 electrodes using the standard ANSI/AAMI EC12:2000 because portions of this test protocol are appropriate and suitable for the subject device since they are also disposable electrodes. Only clauses 5.2.2.1 (electrode impedance), 5.2.2.2 (Electrode DC Offset Voltage), and 5.2.2.3 (Combined Offset Instability and Internal Noise) were applicable as this standard is primarily intended for electrodes for Electro-cardiographs (ECG), not EEG. Thus, some aspects of the standard cannot be applied due to the difference in anatomical region and difference in the intended use of the subject device. Twelve (12) electrode pairs were tested. The NE-091S7 met all pre-specified acceptance criteria demonstrating the acceptable performance of the electrodes related to electrode pair impedance characteristics (164.7Ω-188.2Ω), electrode pair voltage (-0.7 mV to 0.1 mV), and offset variation and internal noise (13.1μV to 43.6μV).

NE-118A EEG disk electrodes were previously cleared in K171124, a 510(k) held by the sponsor of the subject device 510(k) and these electrodes identical materials but are of different length lead.

BIOCOMPATIBILITY

The patient-contacting components of the subject device fall within category A – limited (< 24 hours) - according to FDA's Guidance entitled "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," issued on June 16, 2016. Therefore, the biological endpoints included cytotoxicity, sensitization, and irritation.

The evaluation of each patient-contacting accessory and component involved the testing of the finished device testing and where applicable, use in previously cleared devices (e.g., previously cleared electrodes). This biocompatibility evaluation established the biological safety for all patient contacting device components and accessories of the AE-120A EEG Head Set System by applying the pre-specified acceptance criteria to each test article. The test battery included:

- ISO 10993-1:2009/(R)2013 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010/(R)2014 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

SOFTWARE

The software in the AE-120A EEG Head Set System including both the firmware on the physical headset device and the associated application to be used on the EEG computer monitor, separate from the headset, has been verified and validated. Software documentation up to a moderate level of concern (LOC) as required by the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11, 2005 was included in this submission based on the device type, and the totality of software documentation shall be retained for reference.

ELECTRICAL SAFETY & EMC

The AE-120A EEG Head Set was tested and demonstrated to conform to the following electrical safety and electromagnetic compatibility standards. The rationale in choosing the 3rd edition of the non-FDA recognized standards with respect to EMC below is due to the fact that the wireless reference devices and the two predicates claimed conformance to these versions of this standard. The sponsor also performed wireless co-existence testing on the headset in addition to providing a comparison and discussion of the differences between the 4th and 3rd editions of the standard (i.e., FDA-recognized vs. non-FDA-recognized version of the standard) to demonstrate how differences were covered in the 510(k) submission.

Standard Developing Organization and Designation Number & Date	Title of Standard
1. AAMI/ANSI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012, A2:2010/(R)2012-Pt 1 (Ed 3.1)	Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 Ed 3 +AM1:2012Ed 3.1 with US Deviations due to portions that were not applicable due to device design elements)
2. IEC60601-1:2005 + A1:2012	Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance
3. IEC 60601-1-2: 2007	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility – Requirements and tests

Standard Developing Organization and Designation Number & Date	Title of Standard
4. IEC 60601-1-6:2010 + A1:2013	Medical electrical equipment, Part 1-6: General requirements for safety, Collateral Standard – Usability
5. IEC-60601-2-26:2012	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs.
6. CISPR 11:2009 + A1:2010	Industrial, scientific and medical equipment -Radio-frequency disturbance characteristics -Limits and methods of measurement
7. IEC 61000-4-2: 2008	Electromagnetic compatibility – Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
8. IEC 61000-4-3: 2006 + A1:2007 + A2:2010	Electromagnetic compatibility – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test
9. IEC 61000-4-6:2008	Electromagnetic compatibility – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields
10. IEC 61000-4-8:2009	Electromagnetic compatibility – Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test

CONCLUSION

The subject device is substantially equivalent to the predicate based on the technological characteristics, intended use, and conclusions drawn from the nonclinical tests that demonstrate that the device is as safe and effective as the legally marketed predicate devices.