December 10, 2020

Bioserenity SAS
Julien DUPONT
Quality and Regulatory Affairs Director
ICM-iPEPS
47 Boulevard de l'Hopital
75013
Paris, France

Re: K202334
Trade/Device Name: Neuronaute
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, GXY
Dated: July 30, 2020
Received: September 11, 2020

Dear Julien DUPONT:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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)*
K202334

Device Name
Neuronaute

Indications for Use *(Describe)*
Neuronaute is a system intended to acquire, display, store, archive, and periodically transmit EEG signals from the brain using a full montage array to enable review at a physician's office, hospital, or other remote locations. It allows remote access by users via the Neuronaute N-CLOUD which receives EEG signals from Neuronaute Head Module which sends transmissions to the cloud. Neuronaute and its associated software are intended to assist in the diagnosis of neurological disorders. Neuronaute and its components do not provide any diagnostics conclusions or automated alerts of an adverse clinical event about a patient's clinical condition.

The device is for use by trained medical professionals for patients under medical supervision. The device is intended for use on adults (ages 18 and above). Neuronaute is not intended to replace direct communication with healthcare providers. The system data should not be used alone, but should be used along with all other clinical data and exams to come to a diagnosis.

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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K202334 Neuronaute

Traditional 510(k) Summary

Prepared in accordance to the content and format outlined in 21 CFR 807.92

Submitter Information

Submitter's Name:	BioSerenity SAS
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Date of Summary Preparation:	December 09, 2020

Subject Device Information

Trade Name:	Neuronaute
Common Name:	Electroencephalograph (EEG)
Classification Name:	Electroencephalograph
Primary Product Code:	GWQ - Full-montage standard electroencephalograph
Intended Use:	The subject device is intended to acquire, display, store, and archive EEG signals from the brain using a full montage array (i.e., 16 or more electrodes) and user-specified locations in order to assist in the diagnosis of neurological disorders by a physician.
Regulation Number:	21 CFR 882.1400, Electroencephalogram
Device Class:	II

Predicate Device Information

K183529	
Device Name	AE-120A EEG Head Set
Manufacturer	Nihon Kohden Corporation
Primary Product Code	OMC; reduced- montage standard electroencephalograph
Regulation number	21 CFR 882.1400
Device Class	II
Clearance Date	03/19/2019

Subject Device Description

Neuronaute allows up to 24 channels EEG monitoring. It includes the following components:

Neuronaute Head Module
removable recorder composed of an electronic card in a plastic case. It connects to the Neuronaute BioAdapter using snap buttons located on its rear. The data from the Head Module is uploaded to a secure cloud platform. The data acquired during a recording is stored locally on the Head Module recorder.

Neuronaute High Capacity Battery Module
removable and rechargeable electronic device. The battery is recharged using the Neuronaute Battery charger. The Neuronaute High Capacity Battery module connects to the Neuronaute Bio-Adapter using snap buttons located on its rear.

Neuronaute BioAdapter
enables the connection of the Neuronaute Head Module and the Neuronaute High Capacity battery module to the Neuronaute IceCap or a specific set of reusable cup electrodes manufactured with Ag/AgCl discs connected to a lead wire. The wire is insulated and terminates with a touch proof connector (DIN 42802) - equivalent to the reusable cup electrodes from Technomed Europe, FDA cleared under the 510k number K072016 in order to record and transmit data to the cloud platform.

Neuronaute Mobile App
The mobile application associated with the system which enables healthcare professionals to access and manage the prescribed recording sessions. It is compatible with iOS systems.

Neuronaute N-CLOUD

A web-based information system that receives the EEG signals from the recorder through a paired Wi-Fi connection. The cloud platform enables long-term storage and display of the recorded signals. The physician, who prescribes the use of the Neuronaute system, should monitor its use and confirm the proper functioning of signal recording through the Neuronaute Cloud by testing this connection and use as outlined in the user manual.

Neuronaute N-DEO

A camera enabling the visualization of the patient during a recording. The IP camera provides HD resolution video sequence at 1080p, with advanced night mode and WDR technology.

Neuronaute N-WAY

a router module enabling flexible connectivity for remote monitoring and data transmission to the cloud platform.

Neuronaute IceCap

a single-use headset containing 21 electrodes which is connected to the Neuronaute Head Module via the IceAdapter, the DB25 cable, and the Neuronaute BioAdapter.

Target population

The target patient population for the Neuronaute is adult patients, ages 18 and above.

Comparison to Predicate Device

The Neuronaute and the predicate device, AE-120A EEG Head Set, have the same intended use. Both devices use an integrated array of cutaneous electrodes to obtain a recording of EEG signals to aid clinicians in the diagnosis of neurological disorders. The characteristics of the subject device and the predicate device are summarized in the following table and differences in technological characteristics do not raise different questions of safety and effectiveness.

The table below provides a summary of the technological characteristics of the subject device in comparison to those of the predicate device.

Item of Comparison	Subject Device K202334	Predicate Device K183529	Comment
Trade Name	Neuronaute	AE-120A EEG Head Set	
Manufacturer	BioSerenity SAS	Nihon Kohden Corporation	
510(k) Number	K202334	K183529	
Primary Product Code	GWQ; Full montage standard EEG (16 or more electrodes)	OMC; Reduced montage standard EEG (less than < 16 electrodes)	**Similar**; both product codes fall under the same regulation 882.1400
Secondary Product Code	GXY	GXY (cutaneous electrode)	**Same**

Indications for Use	Neuronaute is a system intended to acquire, display, store, archive, and periodically transmit EEG signals from the brain using a full montage array to enable review at a physician's office, hospital, or other remote locations. It allows remote access by users via the Neuronaute N-CLOUD which receives EEG signals from Neuronaute Head Module which sends transmissions to the cloud. Neuronaute and its associated software are intended to assist in the diagnosis of neurological disorders. Neuronaute and its components do not provide any diagnostics conclusions or automated alerts of an adverse clinical event about a patient's clinical condition. The device is for use by trained medical professionals for patients under medical supervision. The device is intended for use on adults (ages 18 and above). Neuronaute is not intended to replace direct communication with	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)	**Similar** Wording differences that include descriptions of the device functions do not change the intended use

Item of Comparison	Subject Device K202334	Predicate Device K183529	Comment
	healthcare providers. The system data should not be used alone but should be used along with all other clinical data and exams to come to a diagnosis.		

Item of Comparison	Subject Device K202334	Predicate Device K183529	Comment
Intended User(s)	Trained healthcare professionals: doctors, polysomnogram technicians, and nurses	Trained medical professionals	**Similar** Both devices are used by trained healthcare users. The subject device has passed the usability tests for the intended users
Type of use	Prescription	Prescription	**Same**
Environment of use	Physician's office, hospital or other remote locations under medical supervision.	Medical facility such as a physician's office, laboratory, or clinic	**Similar** Both devices are intended to be used in an environment that includes medical and trained supervision.

Item of Comparison	Subject Device K202334	Predicate Device K183529	Comment
Video	Optional; The subject device includes a component video camera called N-DEO	No	**Different** The subject device can be used with a camera which is not the case for the predicate device. The subject device has passed the essential performance and usability requirements to account for the introduction of this technological characteristic.
Electrode Components			
Type of patient Contacting components included with the device	Electrodes and gel contact patient's scalp	Electrodes and gel contact patient's scalp	**Same**

Item of Comparison	Subject Device K202334	Predicate Device K183529	Comment
Electrodes	Up to 21 electrodes: • 19 EEG electrodes • 1 FpZ used for ground connection • An Oz electrode is used as a reference for EEG calculation	10 electrodes (8 EEG electrodes, 1 reference electrode, 1 Z electrode)	**Similar** Both devices have sufficient number of electrodes for EEG monitoring. The subject device meets the performance requirements outlined in IEC 60601-2-26 (input noise) to account for this difference.
Material Composition	Silver & polyimide	Ag/AgCl electrodes	**Similar** The subject device meets the biocompatibility requirements outlined in ISO 10993-1 to account for this difference.
Electrodes; single or reusable?	Single use, non-sterile	Single use, non-sterile	**Identical** Both devices are single use, non-sterile and disposable.
Montage	10/20 Sy stem	10/20 System	**Same**

Item of Comparison	Subject Device K202334	Predicate Device K183529	Comment
Able to accommodate different patient head sizes	The material of the Neuronaute IceCap stretches such that it can fits on the patient's head, similar to a sock	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)	**Similar**
Conductive Electrolyte gel	Conductive electrolyte paste put in the central hole of each electrode, cleared in K860210 Elefix.	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.	

Item of Comparison	Subject Device K202334	Predicate Device K183529	Comment
EEG channels	Up to 24 channels	8	**Similar** Both devices have sufficient number of EEG channels for EEG monitoring. CDRH has cleared other EEG systems with 24 Channels under 882.1400: K170441and K010460.
Data format	EDF	Nihon Kohden original format	**Similar** The subject device provides the data in the standard format used by the healthcare. Therefore, this difference does not raise any different questions of safety or effectiveness.

Item of Comparison	Subject Device K202334	Predicate Device K183529	Comment
Sampling Rate	250 or 500 Hz	200 Hz	**Similar** The subject device acquisition frequency is higher than the predicate device. Consequently, the subject device has a better accurate signal. Therefore, this difference does not raise any different questions of safety or effectiveness.
Recorder Component			
Wireless Output	WiFi 2,4GHz Bluetooth 2,4GHz	Bluetooth 2.4 GHz	**Similar** Both devices include wireless communication. The subject device conforms with IEC 60601-1, IEC 60601-2 and FCC PART 15B requirements.

Item of Comparison	Subject Device K202334	Predicate Device K183529	Comment
Input dynamic range and differential offset voltage	±400mV	±500 mV or more	**Similar** The subject device conforms with IEC 60601-2-26 requirements to account for this difference.
ADC Resolution	24 bits	12 bits	**Similar** The subject device has an improved ADC resolution.
ADC Common Mode Rejection Rate (CMRR)	> 105 dB	90 dB or more	**Similar** The subject device conforms with the 60601-2-26 requirements and has a better ADC CMRR to account for this difference.
Input Impedance	> 1Gohm	1200 Mohms	**Similar** The subject device conforms with the 60601-2-26 requirements.

Item of Comparison	Subject Device K202334	Predicate Device K183529	Comment
Input noise	< 6µVp-p over 0.1-50Hz	5 µVp-p or less (0.53 to 60 Hz)	**Similar** The subject device conforms with the 60601-2-26 requirements.
Electrode impedance check	Yes	Yes	**Same**
General System Characteristics			
Power source	Battery		**Same**
Type of battery	Rechargeable LiPo (Lithium Polymer) 3.7-volt, 2.4 Ah	2 AA (LR6) alkaline batteries (not rechargeable)	**Similar** The subject device conforms with FDA-recognized electrical safety standards.
Battery dimensions	Neuronaute High Capacity Battery module: 199,5 x 170,6 x 27,2 mm	56 W × 43 H × 151 D mm	**Similar** The batterie subject device is used with the BioAdapter. The battery dimensions have no impact in the use of device for the patient.

Item of Comparison	Subject Device K202334	Predicate Device K183529	Comment
Weight	• Neuronaute High Capacity Battery module: 147 g	240 g (without the belts, forehead pad and batteries)	**Similar** The batterie subject device is used with the BioAdapter. The battery weight has no impact in the use of device for the patient.

System components	• Neuronaute Head Module • Neuronaute IceCap • Neuronaute IceAdapter • Neuronaute BioAdapter • Neuronaute Battery • Neuronaute N-WAY • Neuronaute N-DEO • Neuronaute® N-CLOUD • Neuronaute® Mobile APP • Standard cup electrodes to be used with the BioAdapter (not	Works only with Nihon Kohden specified EEG's: EEG-1200A series (K080546) EEG-9100 (K011204)	**Similar** Both subject and predicate devices are intended to be connected to external EEG recording devices. The predicate device meets the usability requirements to achieve the intended use.

Item of Comparison	Subject Device K202334	Predicate Device K183529	Comment
	supplied by BioSerenity). BioSerenity recommends the use of FDA cleared EEG cup electrodes only		
EEG Software	The Neuronaute System contains a software which enables collecting and communicating EEG data.	AE-120A EEG Head Set comes with EEG-compatible software for interaction with and viewing of EEG data	**Similar** The subject device has been developed in accordance with the IEC 62304 and usability requirements.
Connectors	• Snap buttons on the Neuronaute Head Module and the battery • Neuronaute IceAdapter • DB25 cable • Touch proofs	Single connector of electrodes to AE-120A Head Set	**Similar**

Item of Comparison	Subject Device K202334	Predicate Device K183529	Comment
Electrical Safety & EMC	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-1-11 • IEC 60601-2-26	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-2-26	**Similar** Both devices conform to the relevant standards. As the subject device can be used at home under supervision of a healthcare professional, IEC 60601-1-11 requirements have been added to allow for use in this environment.
Biocompatibility	Neuronaute IceCap and electrode gel paste (K860210) conform to ISO 10993-5 and ISO 10993-10	Patient contacting components verified with Cytotoxicity, Sensitization, and Irritation per ISO 10993-5 and 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	**Same** The subject device meets the biocompatibility requirements outlined in 10993-1 relevant to the patient contacting type, according to the risk profile of the device.

Performance Testing

Non-clinical Performance Testing

In order to demonstrate the substantial equivalence between Neuronaute and the predicate, bench testing was carried out on the following characteristics:

- Electromagnetic compatibility (EMC)
- Electrical safety testing
- EEG signal quality
- Software verification and validation testing
- Usability testing
- Biocompatibility

Neuronaute was tested and meets the requirements of following:

- 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 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- EC 60601-2-26:2012 Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

In order to demonstrate the signal quality, BioSerenity has compared the Neuronaute device with EEG gold standards.

The firmware in Neuronaute Head Module, Neuronaute mobile application and Neuronaute Cloud have been tested through verification and validation procedures according to the IEC 62304: 2006/A1:2016 standard and as per the FDA Guidance “General Principles for Software Validation”. The results of the verification and validation activities demonstrate that the software meets the requirements for safety, functionnal and intended use.

BioSerenity has carried tests according to the IEC 62366 standard and FDA guidance “Applying Human Factors and Usability Engineering to Medical Devices (2016)”. The objective was to assess the usability within the overall human factors engineering process and to identify any potential risks related to the use of the device. The tests have

demonstrated all the points listed above do not raise any new questions of safety or effectiveness for the Neuronaute intended purposes.

Clinical Performance Testing

No clinical testing was submitted to determine substantial equivalence.

Conclusion

Neuronaute and the predicate device, K183529 AE-120A EEG Head Set, have the same intended use. Differences in technological characteristics do not raise different questions of safety and effectiveness to achieve the intended use and the performance testing submitted to evaluate these differences are acceptable to demonstrate substantial equivalence to the predicate device.