November 9, 2023

BioSerenity SAS
Madubuike Okafor
Director of QMS & Regulatory Affairs for US Medical Devices
47, avenue de l'Hôpital
ICM-iPEPS
Paris, 75013
France

Re: K231366
Trade/Device Name: Neuronaute Plus
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, GXY
Dated: May 9, 2023
Received: May 11, 2023

Dear Madubuike Okafor:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FDA Patrick Antkowiak -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231366

Device Name
Neuronaute Plus

Indications for Use *(Describe)*
The Neuronaute Plus is a system intended to acquire, store, archive, and periodically transmit physiological 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 BioSerenity Cloud.

The Neuronaute Plus and its associated software are intended to assist in the diagnosis of neurological disorders. The Neuronaute Plus and its components do not provide any diagnostic conclusions or automated alerts of an adverse clinical event about a patient's clinical condition.

The Neuronaute Plus is intended to be used by trained healthcare professionals, technicians or patients above 15 years old. In case of a patient below 15 years old, Neuronaute Plus is intended to be used by a care giver.

Adequate training is recommended for proper use of the device.

Neuronaute IceCap 2 electrodes are able to be used on patients weighing at least 10 kg and having a head circumference above 43 cm.

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.

The BioSerenity Cloud allows the display of signals in order to help aid in the diagnosis of physiological disorders through the data collected by recording.

The BioSerenity Cloud should allow the analysis and filtering of data in order to aid doctors in diagnosing neurological disorders.

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.

K231336 Neuronaute Plus

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
Submitter's Address:	47, avenue de l'Hôpital ICE-iPEPS Paris, 75013 France
Telephone:	347-507-6722
Contact Person:	Madubuike OKAFOR
Email:	Madubuike.okafor@bioserenity.com

Subject Device Information

Trade Name:	Neuronaute Plus
Common Name:	Electroencephalograph (EEG)
Classification Name:	Full-Montage Standard Electroencephalograph
Primary Product Code:	GWQ
Intended Use:	The Neuronaute Plus is a system intended to acquire, store, archive, and periodically transmit physiological signals from the brain using a full montage array to enable review at a physician's office, hospital, or other remote locations. The Neuronaute Plus and its associated software are intended to assist in the diagnosis of neurological disorders.
Regulation Number:	21 CFR 882.1400, Electroencephalogram
Device Class:	II
Secondary Product Code:	GXY

Predicate Device Information

K202334	
Device Name	Neuronaute
Manufacturer	BioSerenity SAS
Primary Product Code	GWQ
Regulation number	21 CFR 882.1400
Device Class	II
Clearance Date	12/10/2020

Intended Use/Indications for Use

The Neuronaute Plus is a system intended to acquire, store, archive, and periodically transmit physiological 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 BioSerenity Cloud.

The Neuronaute Plus and its associated software are intended to assist in the diagnosis of neurological disorders. The Neuronaute Plus and its components do not provide any diagnostic conclusions or automated alerts of an adverse clinical event about a patient's clinical condition.

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Adequate training is recommended for proper use of the device.

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The BioSerenity Cloud should allow the analysis and filtering of data in order to aid doctors in diagnosing neurological disorders.

Indications for Use Comparison

Indication for use comparison between Neuronaute Plus and its predicates:

The indication for use is similar. Both devices are intended to assist the diagnosis of neurological disorders by remotely recording EEG signals.

According to the Neuronaute with IceCap 2 and 2 Small, the Neuronaute recorders themselves are intended on patients of all ages.

Age restrictions are still applicable according to the electrodes used for EEG recordings (the IceCap can only be used on adults (age 18 and over), but IceCap 2 can be used on adults and pediatrics patients).

Neuronaute Plus introduces the patient as an intended user of the recorder. This change according to consensus standard does not affect the substantial equivalence of Neuronaute Plus compared to its predicate.

Neuronaute was already compliant to the patient's home use even though it was not stated in its indication for use.

Electrical and EMC safety tests were performed according to the IEC 60601-1-11 (home use) and IEC 60601-1 consensus standards and tests conclude that the Neuronaute Plus and its predicate comply with the standards.

No other risks have been identified linked to its new environment of use.

These differences do not appear to affect the substantial equivalence of Neuronaute Plus compared to its predicate device.

Device Description

The Neuronaute Plus is a non-invasive medical device which enables the acquisition, recording, storage and transmission of electrophysiological signals in order to analyze potential neurological disorders.

The system is composed of the pieces of equipment listed below, and the Neuronaute Plus components are connected through Bluetooth and Wi-Fi.

- Neuronaute Plus (Core module): is a signal acquisition system: an electronical amplifier that records EEG, ECG, EMG, EOG and breathing signals via a connection to EEG caps which transmits the data to the Neuronaute mobile application and Cloud system.

- Neuronaute Plus IceCap extender : is a removable interface to connect the signal acquisition system to the IceCap and IceCap2 & 2 Small.

- Neuronaute Plus DB25 Extender : is a removable interface that can connect the signal acquisition system to any DB25-compatible EEG cap.

- Holding band : is a wearable textile band which allows the patient to place the Neuronaute Plus close around his chest over clothes. the use of the holding band is optional.

- Neuronaute IceCap: is a single use 21 electrode headset that connects to the Neuronaute Head Module via the IceAdapter, the DB25 cable and the Neuronaute BioAdapter, or Neuronaute Plus with its IceCap Extender. Recently, the Neuronaute Touchproof Adapter was developed to connect the IceCap electrode to Neuronaute Head module via a touchproof channel.

- Neuronaute IceCap 2 & 2 Small: recently cleared version of the IceCap dedicated to adults and pediatric patients. It connects similarly to Neuronaute and Neuronaute Plus.

- Neuronaute Mobile APP: is compatible with iOS systems. The mobile application enables the healthcare professionals to access and manage the prescribed recording sessions.

- Bioserenity CLOUD: is 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 this device, should monitor its use and confirm the proper functioning of signal recording through the Neuronaute Cloud.

- VEEG pack: it is composed of the Neuronaute N-DEO and Neuronaute N-WAY. The Neuronaute N- DEO camera enables 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. The Neuronaute N- WAY enables wireless connectivity (4G) for remote monitoring and data transmission to the cloud platform.

Technological Comparison

Technical characteristics difference:

Electrode components:

None. Neuronaute Plus is compatible with both electrodes (IceCap and IceCap 2). Neuronaute Plus remains substantially equivalent to its predicates on electrode characteristics.

Type of recorded signals and channels:

Input signals are similar. From up to 28 unipolar channels including channels for the reference and the ground and 2 bipolar channels for Neuronaute, Neuronaute Plus counts 29 unipolar and 2 bipolar channels. The number of channels as well as their

specific design for Neuronaute Plus (reference and ground channel directly integrated into the extender channels) were tested according to the consensus standards for ensuring the electrical, EMC and usability safety. Validation tests on the complete system with compatible electrodes and EEG viewer software (Neuronaute app mobile and Bioserenity Cloud) were performed to validate the performance of the system according to tests similar to the Neuronaute system, its predicate.
Therefore the difference does not appear to affect the substantial equivalence of Neuronaute Plus compared to the predicate device.

Recorder component:

The wireless outputs are different from the predicate (the Neuronaute Plus includes WIFI 5G). Radioemission safety tests were performed according to the 60601-1, 60601-1-2, CFR 47 Part 15 Subpart B – Radio frequency devices – Unintentional radiators 2021, and ANSI 63.4 of 2014.
The tests successfully passed, therefore the difference does not appear to affect the essential performance of the subject device.

Firmware:

New features implemented to adapt to the design of Neuronaute Plus core module:

- Battery level indicator
- Patient event button
- Data storage up to 72h without WiFi connection (offline mode)

Tests of verification and validation according to consensus standard and "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices and General Principles of Software Validation" were performed to ensure the safety and the effectiveness of new features contained in the firmware of Neuronaute Plus. The tests are similar to those performed for Neuronaute firmware.
Therefore the difference does not appear to affect the substantial equivalence of Neuronaute Plus compared to its predicate.

Battery:

The design of the battery in Neuronaute Plus is different compared to Neuronaute; it has different performance specifications compared to the predicate battery (lighter, more compact but same autonomy), and it is removable from Neuronaute Plus core module. The Neuronaute Plus design with its internal removable battery was tested according to consensus standards for ensuring the electrical, EMC and usability safety. Validation tests covering complete system with compatible electrodes and EEG viewer software (Neuronaute app mobile and Bioserenity Cloud) were performed to validate the performance of the system according to tests that were similar to the Neuronaute system, its predicate. Therefore, the difference does not affect the substantial equivalence of Neuronaute Plus compared to its predicate device.

Accessories to connect Neuronaute Plus to the electrodes:

With Neuronaute Plus, it is possible to plug 2 different extenders to connect to:

- IceCap or the IceCap 2 (via the IceCap Extender)

- Micromed EEG Cap electrodes via DB25 extender

The Neuronaute Plus design with its extenders on channels was tested according to consensus standards for ensuring the electrical, EMC and usability safety. Validation tests on the complete system with compatible electrodes and EEG viewer software (Neuronaute mobile app and Bioserenity Cloud) were performed to validate the performance of the system according to tests similar to the Neuronaute system, its predicate.

The biocompatibility of the holding band (textile) and the Neuronaute Plus casing materials was assessed and shows no biocompatibility risks sufficient to need supplemental tests, allowing to conclude it is a biocompatible device for the patient.

Therefore, the difference does not appear to affect the substantial equivalence of Neuronaute Plus compared to its predicate.

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

Device & Predicate Device(s):	**Subject Device Neuronaute Plus K231366**	**Predicate Device Neuronaute K202334**	**Reference Device Neuronaute with IceCap 2 & 2 Small K223644**
Manufacturer	BioSerenity SAS	BioSerenity SAS	BioSerenity SAS
Product Codes	GWQ (Electroencephalograph) GXY (Cutaneous electrodes)	GWQ (Electroencephalograph) GXY (Cutaneous electrodes)	GWQ (Electroencephalograph) GXY (Cutaneous electrodes)
Software Analysis	It allows remote access for users via the BioSerenity Cloud which receives physiological signals from Neuronaute Plus (which sends transmissions to the cloud).	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.	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.
Video	Optional; The subject device includes a component video camera called N-DEO.	Optional; The subject device includes a component video camera called N-DEO.	Optional; The subject device includes a component video camera called N-DEO.
Types of patient-contacting components	EEG cap electrodes and gel are in contact with patient's scalp. Neuronaute Plus is compatible with both types of electrodes (IceCap and IceCap 2).	EEG cap electrodes and gel are in contact with patient's scalp. **IceCap** - Polyimide substrate - EEG conductive paste	EEG cap electrodes and gel are in contact with patient's scalp. **IceCap 2 & 2 Small:** - Silicone adhesive - Dielectric ink - EEG Conductive pastes
Electrodes	Up to 21 electrodes: - 19 EEG electrodes - 1 electrode (Fpz) used for ground connection - 1 electrode (Oz) used as a reference for EEG calculation	Up to 21 electrodes: - 19 EEG electrodes - 1 electrode (Fpz) used for ground connection - 1 electrode (Oz) used as a reference for EEG calculation	Up to 21 electrodes: - 19 EEG electrodes - 1 electrode (Fpz) used for ground connection - 1 electrode (Oz) used as a reference for EEG calculation
Material Composition	Neuronaute Plus is compatible with both types of electrodes (IceCap and IceCap 2).	**IceCap** - Polyimide - Copper covered with a layer of silver	**IceCap 2 & 2 Small:** - Polyethylene terephthalate (PET) - Silver and Silver/Silver chloride conductive inks - Insulation inks - Stiff PETG film - Skin adhesive - Graphical ink Silicone adhesive

Device & Predicate Device(s):	**Subject Device Neuronaute Plus K231366**	**Predicate Device Neuronaute K202334**	**Reference Device Neuronaute with IceCap 2 & 2 Small K223644**
Single vs Multi-Use	Single use, non-sterile	Single use, non-sterile	Single use, non-sterile
Montage	10/20 System	10/20 System	10/20 System
Able to accommodate different head sizes	Neuronaute Plus is compatible with both types of electrodes (IceCap and IceCap 2).	**IceCap** The material of the Neuronaute IceCap stretches such that it can fits on the patient's head, similar to a sock. The unique cap size fits to at least 90% of the population.	**IceCap 2 & 2 Small:** The material of the Neuronaute with IceCap 2 & IceCap 2 Small stretches to fit the patient's head. It's provided in two sizes depending on the head circumference of the patient: - Head circumferences between 43 and 53 cm: use the IceCap 2 Small - Head circumference between 53 and 60 cm: use the IceCap 2 The IceCap 2 is used when the patient is between 2 sizes.
Conductive Electrolyte Gel	Conductive electrolyte paste put in the central hole of each electrode, cleared in K860210 Elefix.	Conductive electrolyte paste put in the central hole of each electrode, cleared in K860210 Elefix.	Conductive electrolyte paste put in the central hole of each electrode, cleared in K860210 Elefix.
Type of Recorded Signals and Channels	EEG, ECG, EMG, EOG and breathing signals. - 29 unipolar - 2 bipolar channels The ground and the reference are integrated in the extender connection.	EEG, ECG, EMG, EOG and breathing signals. - 28 unipolar channels for EEG including 4 channels for the reference and the ground - 2 bipolar channels	EEG, ECG, EMG, EOG and breathing signals. - 28 unipolar channels for EEG including 4 channels for the reference and the ground - 2 bipolar channels
Data Format	EDF	EDF	EDF
Sampling Rate	250 or 500 Hz	250 or 500 Hz	250 or 500 Hz
Wireless Output	WiFi 2.4 GHz WiFi 5 GHz Bluetooth 2.4GHz - WiFi 2.412 GHz ~ 2.484 GHz (2.4 GHz ISM Band) - WiFi 5.180 GHz ~ 5.7 GHz	WiFi 2.4GHz Bluetooth 2.4GHz - WiFi 2.412 GHz ~ 2.484 GHz (2.4 GHz ISM Band) - BLE 2.402 and 2.480 GHz	WiFi 2.4GHz Bluetooth 2.4GHz - WiFi 2.412 GHz ~ 2.484 GHz (2.4 GHz ISM Band) - BLE 2.402 and 2.480 GHz

Device & Predicate Device(s):	Subject Device Neuronaute Plus K231366	Predicate Device Neuronaute K202334	Reference Device Neuronaute with IceCap 2 & 2 Small K223644
	- BLE 2.402 and 2.480 GHz		
Input dynamic range and differential offset voltage	≤10% at ±150 mV	±400mV	±400mV
ADC Resolution	24 bits	24 bits	24 bits
ADC Common Mode Rejection Rate (CMRR)	≥-80dB at 50hz and 60Hz	> 105 dB	> 105 dB
Input Impedance	> 1Gohm	> 1Gohm	> 1Gohm
Input Noise	< 6µVp-p over 0.1- 50 Hz	< 6µVp-p over 0.1- 50 Hz	< 6µVp-p over 0.1- 50 Hz
Electrode Impedance check	Yes	Yes	Yes
Firmware	New features implemented to adapt to the design of Neuronaute Plus core module: - Battery level indicator - Patient event button - Data storage for more than 24h without WiFi connection (offline mode) - Power backup for seamless battery change - Reference electrode impedance level	Firmware version adapted to Neuronaute Head module	Firmware version adapted to Neuronaute Head module
Power Source	Internal removeable battery	Battery	Battery
Type of battery	Varta Li-ion EasyPack XL 3.7V | 2400mAh | 8.9Wh VKB: 56456 702 099	Rechargeable LiPo (Lithium Polymer) 3.7-volt, 2.4 Ah	Rechargeable LiPo (Lithium Polymer) 3.7-volt, 2.4 Ah
Battery dimensions	Battery size : 90 x 44,2 x 27 mm Autonomy > 24h	Neuronaute High Capacity Battery module: 199.5 x 170.6 x 27.2 mm Autonomy : 24/72h	Neuronaute High Capacity Battery module: 199.5 x 170.6 x 27.2 mm Autonomy : 24/72h
Weight	49 g	Neuronaute High Capacity Battery module: 147 g	Neuronaute High Capacity Battery module: 147 g

Device & Predicate Device(s):	Subject Device Neuronaute Plus K231366	Predicate Device Neuronaute K202334	Reference Device Neuronaute with IceCap 2 & 2 Small K223644
Accessories to connect Neuronaute Plus to the electrodes	Possibility of plugging 2 different extenders to connect to: - IceCap and IceCap 2/ 2 Small via IceCap Extender - Micromed EEG and Cap electrodes via DB25 extender	Neuronaute BioAdapter	Neuronaute BioAdapter

Performance Testing

Non-Clinical and/or Clinical Tests Summary

Verification and validation

Electrical safety:

The electrical safety tests were performed by EMITECH for Neuronaute Plus according to :

- IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
- IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020 for use in conjunction with IEC 60601-1:2005, IEC 60601- 1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
- IEC 80601-2-26:2019 for use in conjunction with IEC 60601-1:2005, AMD1:2012, AMD2: 2020

All tests done for electrical safety tests are in passed status. We conclude that Neuronaute Plus appear to demonstrate substantially equivalent electrical safety to its predicate Neuronaute.

EMC tests:

The testing has been performed according to the following standard IEC 60601-1-2: 2014 + A1 (2020). According to the final report of the laboratory, the product fulfills the requirements of the standard like its predicate Neuronaute. All tests done by the laboratory are passed. The system used for EMC tests is substantially equivalent to Neuronaute system and demonstrates EMC substantial equivalence to the of Neuronaute Plus.

Wireless safety and likelihood of wireless coexistence:

These tests ensure radio-emission safety of Neuronaute Plus due to the implementation in its core module of WiFi (4G) and BLE modules like its predicate Neuronaute Head module. But additionally, those tests ensure the safety of Neuronaute Plus according to this main design change that consists of the WiFi 5G integration and the ability of the

patient to wear Neuronaute Core Module by the patient within 20 centimeters of their body through the use of the Neuronaute Plus Holding Band.

All the tests on radio-emission safety are passed.

Therefore the adding of WiFi 5G module in the Neuronaute Plus core module do not appear to affect the safety or performance of Neuronaute Plus and remains substantially equivalent to Neuronaute.

Concerning the wireless functions (BLE and WiFi) of Neuronaute Plus, a safety risk analysis and likelihood of wireless coexistence tests allow us to conclude that Neuronaute Plus has demonstrated substantial equivalence to its predicate.

Programmable Electrical Medical System (PEMS):

The PEMS requirements have been implemented and tested for ensuring safety and electrical performance of Neuronaute Plus according to the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601- 1:2005/AMD2:2020 and IEC 62304:2007/A1: 2015 standard.

All tests addressing the electrical safety of the Neuronaute Plus firmware have been performed and are in PASSED status.

Because the firmware includes new features like data storage for more 24h, battery level checking, patient event button, etc. more tests have been performed to ensure its safety.

The difference in the number of tests between Neuronaute Plus and Neuronaute ensures an increased coverage of Firmware functionality safety compared to the predicate. Testing demonstrates substantial equivalence between the predicate and Neuronaute Plus.

Cybersecurity

According to the risk management file and cybersecurity FDA guidance, the design process allows to demonstrate the safety and the performance of the cybersecurity aspect for NEURONAUTE PLUS. To manage future unknown threats that would appear in all life cycle of NEURONAUTE PLUS, a cybersecurity post-market surveillance plan is implemented.

Biocompatibility

Based on the analysis of literature which covers raw materials, OEKO-TEX certificates that ensures the safety of used textiles taking into account manufacturing adjuvants, and the standard ISO 10993-1, no further testing is required for the evaluation of Neuronaute Plus biocompatibility. The risks associated with the product are considered very low in regard to its components, its use by the patient and the limited skin contact duration. Regarding the type and duration of skin contact, Neuronaute Plus and its accessories satisfy the requirements of ISO 10993-1 and FDA and can therefore be classified as a biocompatible device.

This confirms that Neuronaute Plus biocompatibility is substantially equivalent to the predicate Neuronaute even including the new accessory, the holding band. This confirms the substantial equivalence between Neuronaute Plus and its predicate.

Usability

Human factors studies have been performed according to the IEC 62366-1 standard and FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices (2016)" for Neuronaute Plus. The objective is to assess the usability within the overall human factors engineering process and to identify any potential risks related to the use of the Neuronaute Plus and prove that it is substantially equivalent to Neuronaute.

Usability tests were performed on two user groups:

- User group 1: Health care professionals (Physicians, nurses, technicians) => n=9
- User group 2: Patients (15-30 years; 31-50 years; >50 years) => n=15

Two configurations of the device system were tested: the entire Neuronaute Plus system associated with IceCap 2 electrodes and its corresponding extender, or the entire Neuronaute Plus with Micromed Cap electrodes associated with its DB25 extender.

The protocol was conducted in four main steps: a training, a study and session presentation (Oral information provided by the test personnel about the purpose of the evaluation), the usability tests, and a debriefing step.

The results of this evaluation have shown that the validation criteria are met with no use errors leading to critical or major risks that may lead to harm occurred during this evaluation, and the pre assessment of tested risks that did not result in new critical or major risks.

The usability testing conducted supports substantial equivalence of the Neuronaute Plus compared to its predicate.

Battery

The battery included in the Neuronaute Plus core module is compliant by design to the IEC 62133 ed. 2.

In addition to this compliance, electrical safety tests on the system itself (including the battery and, for specific requirements, on the battery alone on its charger) were performed for Neuronaute Plus according to:

- IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
- IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020
- IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020 for use in conjunction with IEC 60601-1:2005, IEC 60601- 1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020

All tests done for electrical safety tests on battery are in "passed" status.

We conclude that Neuronaute Plus appears to demonstrate substantially equivalent electrical safety to its predicate, Neuronaute.

Clinical tests

No clinical data was needed for demonstrating substantial equivalence of the Neuronaute Plus.

Conclusion

All main concerns of new risks following the development of Neuronaute Plus compared to Neuronaute and Neuronaute with IceCap 2 & 2 Small was assessed in this

document. According to these results described above, we have demonstrated substantial equivalence of Neuronaute Plus with its predicate.