January 12, 2023

Bioserenity
Madubuike Okafor
Director of QMS & Regulatory Affairs for US Medical Devices
47 Boulevard De L Hopital ICM-IPEPS -
Hopital Pitie Salpetriere - CS 21414
Paris, Ile-De-France 75013
France

Re: K223644
Trade/Device Name: Neuronaute with IceCap 2 & IceCap 2 Small
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, GXY
Dated: July 25, 2022
Received: December 6, 2022

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 (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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K223644

Device Name
Neuronaute with IceCap 2 & IceCap 2 Small

Indications for Use *(Describe)*
Neuronaute with IceCap 2 & IceCap 2 Small 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 and pediatrics. 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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Special 510(k):

Neuronaute with IceCap 2 & IceCap 2 Small

510(k) Summary

From 21 CFR Part 807.92:

(a) (1) - (3)

Device Common Name: Full-Montage Standard Electroencephalograph

Device Proprietary Name: Neuronaute with IceCap 2 & IceCap 2 Small

Establishment Registration Number: 3014027738

Submitter:

BIOSERENITY
47 BOULEVARD DE L HOPITAL
ICM-IPEPS - HOPITAL PITIE SALPETRIERE - CS 21414
PARIS CEDEX 13 Ile-De-France, FR 75013

Owner/Operator Number: 10057285

Contact: Madubuike Okafor
madubuike.okafor@bioserenity.com

Date Prepared: January, 11 2023

Classification Regulation: 21 CFR Part 882.1400

Class: Class II

Panel: Neurology

Product Code: GWQ
Subsequent Product Code: GXY

Predicate Device: K202334 - Neuronaute

(4) BioSerenity owns the 510(k) for the predicate: Neuronaute (K202334). The Neuronaute with IceCap 2 & IceCap 2 Small (current submission) only contains the next generation of IceCap electrodes. These new "IceCap 2" electrodes come in two different sizes, regular for adult patients (IceCap 2), and small for pediatric patients above 5 years old (IceCap 2 small). The rest of the components of the Neuronaute system remain unchanged.
The function of the system and the connection of the different elements remain the same. The IceCap 2 / 2 small replaces the IceCap to be connected to the head module, battery, and Bioadapter with the IceAdapter.
The necessary information related to the records are available in the mobile app and the cloud. The video system composed by N-way and N-Deo is optional.

As the description of all the components is provided in the previous 510(k) submission for the Neuronaute system (K202334), the focus in the current submission is only on the description of the new generation of IceCap, namely IceCap 2 & IceCap 2 Small.
IceCap 2/ IceCap 2 Small Description:

IceCap 2 and IceCap 2 Small are medical devices composed of a single-piece flexible printed circuit headset compatible with the Neuronaute Head Module (CE marked and FDA 510(k) cleared. It includes 21 EEG sensors (19 EEG channels, 1 reference and 1 ground), 4 skin adhesive areas and 2 connectors (Figure 1). IceCap 2 is a modification of the Neuronaute IceCap headset from which it differs in material and electrode types. It enables the analysis of potential neurological disorders via the recording of EEG signals.
The IceCap 2 and IceCap 2 Small electrodes are made of Ag/AgCl sensors connected via conductive silver ink and insulated with dielectric ink. The center hole of each electrode (diameter of 4.3 mm) allows the application of several marketed EEG conductive pastes (such as the Elefix paste) before positioning the device on the head. These conductive and adhesive pastes are CE marked and FDA 510(k) cleared; they are not produced by BioSerenity and they are to be bought separately as consumable material to facilitate good performance of the medical device.

The conductive electrolyte paste put in the central hole of each electrode, was cleared in K860210 Elefix.

The size chart for the IceCap 2 is:
- Horizontal: 209 mm

- Vertical: 292mm

The size chart for the IceCap 2 small is:
- Horizontal: 209 mm
- Vertical: 246 mm

The packaging size for both IceCap 2 and IceCap 2 small is:
- Horizontal: 246 mm
- Vertical: 350 mm

IceCap 2 and IceCap 2 Small electrodes are medical devices for patient above 5 years old, used as EEG electrodes. They are used by Healthcare Professionals for the diagnosis of neurological disorders using long-term EEG records (up to 72h). When connected to a compatible EEG system, they are designed to continuously measure multiple-lead EEG signals to enable review at a physician's office, hospital or other remote locations.

The IceCap 2 and IceCap 2 Small are intended to be used in the following environments:
- Hospital
- Doctor's practice
- Private hospital
- Research environment
- Home
- Temperature between 5° and 40°C with relative humidity between 5% and 95% and Atmospheric pressure between 700 hPa ~ 1060 hPa.

(5) Intended use

Neuronaute including IceCap 2 / 2 Small enables the acquisition, recording, storage, transmission, and display of an electroencephalogram (EEG) in order to assist neurological disorders diagnosis.

Indication for use

Neuronaute with IceCap 2 & IceCap 2 Small 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 and pediatrics. 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.

Comparison with the predicate device intended use statement

The intended use statement is the same between the subject device and its predicate, although, in the indication for use, the targeted population is expanded (to target both adult and pediatric patients) compared to the initial indication for use of the Neuronaute submitted in prior 510(k). The change presented here (introduction of IceCap 2 & IceCap 2 Small) supports the expansion of the targeted population of the actual Neuronaute to improve the size fit of IceCap electrode range to a larger pediatric population.

The IceCap 2 electrodes have been adapted by design to be able to transmit EEG signals for children and adults as it is provided in two different sizes:

- IceCap 2
- IceCap 2 Small

Each size is adapted to a range of head size circumferences to cover the population from children (at least 5 years old) to adults.

Therefore, the Neuronaute with IceCap 2 & IceCap 2 Small is demonstrated to be substantially equivalent to the Neuronaute, as it supports the safety and effectiveness of the Neuronaute system in the expanded targeted population.

(6) **Comparison of the predicate's device technical characteristics**

The only change in technical characteristics consists of the materials composition of the electrodes. For IceCap, polyimide is in direct contact with the patient skin. It is superseded by polyethylene terephthalate (PET) for the IceCap 2 & IceCap 2 Small, but this component for IceCap 2 & IceCap 2 Small is no longer in direct contact with the patient's skin. Silicone adhesive and dielectric ink are in direct contact with the patient skin for the IceCap 2 & IceCap 2 Small. EEG pastes remain the same for both generations of IceCap.

The duration of use for the initial IceCap was limited to 12 and half hours due to copper migration across the silver layer when EEG paste was applied on the electrodes. For the IceCap 2 & IceCap 2 Small, the polyimide is superseded by PET (polyethylene terephthalate), widely used in the medical field. With this technology, the IceCap 2 & IceCap 2 Small can be used for several days recording (up to 72h). The previous IceCap electrodes were made of copper covered with a layer of silver, whereas the IceCap 2 & IceCap 2 Small are made of Ag/AgCl , which are widely used in medical industry for several days of recording.

The Neuronaute with IceCap 2 & IceCap 2 Small electrodes' material have been assessed by consensus standard for biocompatibility testing, as previously done with its predicate Neuronaute. Therefore, the Neuronaute with IceCap 2 & IceCap 2 Small is demonstrated to be substantially equivalent to the Neuronaute, as all tests done supports the effectiveness and the safety of the Neuronaute with IceCap 2 & IceCap 2 Small system.

Substantial Equivalence Comparison Table:

Substantial Equivalence Topic	Neuronaute with IceCap 2 & IceCap 2 Small	Neuronaute	Significant Differences
Relationship	**Subject device**	**Predicate device**	**N/A**
510(k) #	**TBD**	**K202334**	**N/A**
Establishment Name	BioSerenity SAS	BioSerenity SAS	N/A
Owner/Operator	10057285	10057285	N/A
Device Classification Name	Full-Montage Standard Electroencephalograph	Full-Montage Standard Electroencephalograph	None
Review Panel	Neurology	Neurology	None
Regulation Number	882.1400	882.1400	None
Product Codes	GWQ, GXY	GWQ, GXY	None
Device Class	II	II	None
Indications For Use	Neuronaute with IceCap 2 & IceCap 2 Small 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	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	The targeted population is expanded compared to the initial indication for use of the Neuronaute to target both adult and pediatric patients. However this change was already implemented by a change that did not need a 510(k) submission to demonstrate the conformity of the Neuronaute acquisition system (Recorder, BioAdapter, Battery) to medical guidelines for EEG recordings on children.

Substantial Equivalence Topic	Neuronaute with IceCap 2 & IceCap 2 Small	Neuronaute	Significant Differences
Relationship	**Subject device**	**Predicate device**	**N/A**
510(k) #	**TBD**	**K202334**	**N/A**
	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 and pediatrics. 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.	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.	The change presented here (introduction of IceCap 2 & IceCap 2 Small) supports the expansion of the targeted population of the actual Neuronaute to improve the size fit of IceCap electrode range to a larger pediatric population. The IceCap 2 electrodes have been adapted by design to be able to transmit EEG signals for children and adults as it is provided in two different sizes: • IceCap 2 • IceCap 2 Small Each size is adapted to a range of head size circumferences to cover the population from children (at least 5 years old) to adults. However, the Neuronaute IceCap 2 & IceCap 2 Small is demonstrated to be substantially equivalent to the Neuronaute.

Substantial Equivalence Topic	Neuronaute with IceCap 2 & IceCap 2 Small	Neuronaute	Significant Differences
Relationship	**Subject device**	**Predicate device**	**N/A**
510(k) #	**TBD**	**K202334**	**N/A**
Prescription or OTC Use	Prescription	Prescription	None
Intended User(s)	Trained healthcare professionals: doctors, polysomnogram technicians, and nurses	Trained healthcare professionals: doctors, polysomnogram technicians, and nurses	None
Intend patient population demographics	Adult and pediatric patients 5 years of age and older.	Adult patients ages 18 years of age and older.	The patient demographic has been expanded to include pediatric patients.
Environment of use	Physician's office, hospital or other remote locations under medical supervision.	Physician's office, hospital or other remote locations under medical supervision.	None
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	None
Electrode Components			
Type of components in contact with the patient	- Silicone adhesive - Dielectric ink - EEG Conductive pastes	- Polyimide substrate - EEG conductive paste	For IceCap, polyimide is in direct contact with the patient skin. It is superseded by polyethylene terephthalate (PET) for the IceCap 2 / 2 Small, but this component for IceCap

Substantial Equivalence Topic	Neuronaute with IceCap 2 & IceCap 2 Small	Neuronaute	Significant Differences
Relationship	**Subject device**	**Predicate device**	**N/A**
510(k) #	**TBD**	**K202334**	**N/A**
			2 / 2 Small is no longer in direct contact with the patient skin. Silicone adhesive and dielectric ink are in direct contact with the patient skin for the IceCap 2 / 2 small. EEG pastes remain the same for both generations of IceCap. IceCap 2 / 2 Small electrodes material has been assessed by consensus standard for biocompatibility testing, as previously done with its predicate Neuronaute including IceCap.
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 • 1electrode (Oz) is used as a reference for EEG Calculation	None

Substantial Equivalence Topic	Neuronaute with IceCap 2 & IceCap 2 Small	Neuronaute	Significant Differences
Relationship	**Subject device**	**Predicate device**	**N/A**
510(k) #	**TBD**	**K202334**	**N/A**
Material Composition	- Polyethylene terephthalate (PET) - Silver and Silver/Silver chloride conductive inks - Insulation inks - Stiff PETG film - Skin adhesive - Graphical ink - Silicone adhesive	- Polyimide - Copper covered with a layer of silver	The duration of use for the initial IceCap was limited to 12 and half hours due to copper migration across the silver layer when EEG paste was applied on the electrodes. For the IceCap 2 / 2 Small, the polyimide is superseded by PET (polyethylene terephthalate), widely used in the medical field Due to this technology, the IceCap 2/ 2 Small can be used for several days recording (up to 72h) The previous IceCap electrodes were made of copper covered with a layer of silver, whereas IceCap 2 / 2 small are made of Ag/AgCl , which are widely used in medical industry for several days of recording. The Neuronaute with IceCap 2 & IceCap 2 Small electrodes' material have been assessed by consensus

Substantial Equivalence Topic	Neuronaute with IceCap 2 & IceCap 2 Small	Neuronaute	Significant Differences
Relationship	**Subject device**	**Predicate device**	**N/A**
510(k) #	**TBD**	**K202334**	**N/A**
			standard for biocompatibility testing, as previously done with its predicate Neuronaute including IceCap.
Electrodes; single or reusable?	Single use, non-sterile	Single use, non-sterile	None
Montage	10/20 System	10/20 System	None
Able to accommodate different patient head sizes	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.	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	The device has been improved from a single size to an extended use in a pediatric population by including the IceCap 2 Small and defining the head circumferences for each use (adults and children). IceCap 2 electrodes have implemented a new size range for pediatrics although materials and technical specifications are similar between IceCap 2 and IceCap 2 Small. However, the Neuronaute IceCap 2 & IceCap 2 Small is demonstrated to be substantially equivalent to the Neuronaute.
Conductive	Conductive electrolyte paste put	Conductive electrolyte paste put	None

Substantial Equivalence Topic	Neuronaute with IceCap 2 & IceCap 2 Small	Neuronaute	Significant Differences
Relationship	**Subject device**	**Predicate device**	**N/A**
510(k) #	**TBD**	**K202334**	**N/A**
Electrolyte gel	in the central hole of each electrode, cleared in K860210 Elefix.	in the central hole of each electrode, cleared in K860210 Elefix.	
EEG channels	Up to 24 channels	Up to 24 channels	None
Data format	EDF	EDF	None
Sampling Rate	250 or 500 Hz	250 or 500 Hz	None
Component dimensions	IceCap2 - Height: 11.50 inches (292 mm) - Width: 8.23 inches (209 mm) - Sensor area: 0.11 inches ^2 (74.7 mm^2) IceCap2 Small - Height: 9.69inches (246 mm) - Width: 8.23 inches (209 mm) - Sensor area: 0.11 inches^2 (74.7 mm^2)	- Height: 14.96 inches (379 mm) - Width: 8.07 inches (205 mm) - Sensor area: 0.24 inches ^2 (152 mm^2)	Height: IceCap 2 and IceCap 2 Small are shorter in height to ease their storage. Width: equivalent Sensor area: sensor areas on IceCap 2 and IceCap 2 Small are shorter due to the change on component material (from Copper to Silver/Silver Chloride)
Recorder Component			
Wireless Output	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	None

Substantial Equivalence Topic	Neuronaute with IceCap 2 & IceCap 2 Small	Neuronaute	Significant Differences
Relationship	**Subject device**	**Predicate device**	**N/A**
510(k) #	**TBD**	**K202334**	**N/A**
Input dynamic range and differential offset voltage	±400mV	±400mV	None
ADC Resolution	24 bits	24 bits	None
ADC Common Mode Rejection Rate (CMRR)	> 105 dB	> 105 dB	None
Input Impedance	> 1Gohm	> 1Gohm	None
Input noise	< 6µVp-p over 0.1-50Hz	< 6µVp-p over 0.1- 50 Hz	None
Electrode impedance check	Yes	Yes	None
General System Characteristics			
Power source	Battery	Battery	None
Type of battery	Rechargeable LiPo (Lithium Polymer) 3.7-volt, 2.4 Ah	Rechargeable LiPo (Lithium Polymer) 3.7-volt, 2.4 Ah	None
Battery dimensions	Neuronaute High Capacity Battery module: 199.5 x 170.6 x 27.2 mm	Neuronaute High Capacity Battery module: 199.5 x 170.6 x 27.2 mm	None

Substantial Equivalence Topic	Neuronaute with IceCap 2 & IceCap 2 Small	Neuronaute	Significant Differences
Relationship	**Subject device**	**Predicate device**	**N/A**
510(k) #	**TBD**	**K202334**	**N/A**
Weight	Neuronaute High Capacity Battery module: 147 g	Neuronaute High Capacity Battery module: 147 g	None

Figure 1. Substantial equivalence table

(b) (1) In order to demonstrate the substantial equivalent of Neuronaute, biocompatibility validation, performance, and electrical safety were conducted in order to ensure that it safely and effectively performs as intended.

(2) N/A Clinical Testing was not required

(3) The conclusion drawn from the nonclinical tests demonstrate that Neuronaute with IceCap 2 & IceCap 2 Small is a safe, as effective, and performs as well as the legally marketed predicate device. The verification and validation tests were all evaluated thoroughly, and passed successfully.