December 26, 2017

Bioserenity
% Esin Yesilalan
Senior Regulatory Scientist
Voisin Consulting Inc. Life Sciences
222 Third Street
Suite 3121
Cambridge, Massachusetts 02142

Re: K170138
Trade/Device Name: Neuronaute
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ, GXY
Dated: June 20, 2017
Received: June 23, 2017

Dear Ms. Yesilalan,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

William J. Heetderks -S
2017.12.26 09:58:05 -05'00'

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)*
K170138

Device Name
Neuronaute

Indications for Use *(Describe)*
The Neuronaute is a medical, wireless and mobile equipment, which allows acquisition, record, storage, transmission and displaying of electroencephalogram (EEG) from adult patients.

It can be used with patients in health care facility (data acquisition and reporting) or clinical research environment.

The Neuronaute requires operation by a trained healthcare professional.

The Neuronaute only acquires and displays physiological signals, no claims are being made for analysis of the acquired signals with respect to the accuracy, precision and reliability.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510 (k) Summary

5.1 Submitter Information

Company Name:	**BioSerenity**
Company Address:	47 boulevard de l'Hôpital 75013 Paris, France
Company Phone:	+33 157 274 456
Company Fax:	+33 186 953 093
Contact Person:	Mr. Quang TRAN
Date the summary was prepared:	January 6, 2017

5.2 Device Identification

Trade Name: Neuronaute

Common Name: Neuronaute

Classification Name:	Electroencephalograph
Product Code:	GWQ, GXY
Regulation Number:	882.1400, 882.1320

Device Class: II

5.3 Identification of Predicate Devices

Device Name	Primary Predicate X-Series System	Additional Predicate Rythmlink Disc electrodes
Manufacturer	Advanced Brain Monitoring	Rhythmlink International, LLC
510(k) Number	K131383	K061148
Regulatory Class	II	II
Regulation Number	882.1400	882.1320
Product Code	GWQ, OMC	GXY
Common Name	X-10 / X-24	Rhythmlink Disc electrodes
Clearance Date	November 27, 2013	May 10, 2006

5.4 Device Description

The Neuronaute is a wearable and wireless equipment, which allows acquisition, recording, storage, transmission and displaying of electroencephalogram (EEG).

The Neuronaute is composed of a textile cap where twenty-one titanium dry electrodes are attached. An electronic box is attached to the cap (EEG recording) associated to batteries. The system operates on battery power only.

The system is connected to a device (i.e. smart phone or a digital tablet) loaded with a separate stand-alone software program ("app"). The app works with a cloud backend service, which allows the user management and authentication, the data storage for application recordings and access to this data via a web-based interface, the devices management and authentication, the recording scheduling, the download of the latest firmware version.

The acquired signals are saved in a universal data format (European Data Format, EDF) that is intended to be visualized by a Physician through the web-based interface.

5.5 Indications for Use

The Neuronaute is indicated for acquiring, recording, storing, transmitting, and displaying physiological data in adult patients. It can be used with patients in health care facility or clinical research environment. The Neuronaute requires operation by a trained healthcare professional. The Neuronaute acquires, records, stores, transmits, and displays electroencephalogram (EEG). The Neuronaute only acquires and displays physiological signals, no claims are being made for analysis of the acquired signals with respect to the accuracy, precision and reliability.

5.6 Comparison to Predicate Devices

The primary purpose of the Neuronaute is the recording of physiological signals, specifically EEG. In comparison with the Primary predicates, the Neuronaute does not contain ECG/EOG/EMG electrodes or accelerometer technology (for actigraphy). These additional features are not required for EEG recording; therefore, these differences do not affect the safety and effectiveness of the Neuronaute.

The Neuronaute has similar indications for use for EEG measurements and uses the same fundamental technology as the X-Series System for most features including the electrophysiological (EEG) and wireless acquisitions and actigraphy. Like the X-Series system, the Neuronaute acquires, records and transmits EEG signals. The technologies used in the Neuronaute are used in a similar manner as the X-Series System and do not raise new questions of safety and effectiveness.

5.7 Performance Data

Support for the substantial equivalence of the Neuronaute was provided as a result of risk management and testing which included electrical and biological safety, performance and software tests. Testing has provided reasonable assurance of safety and effectiveness for the intended use and supports a determination of substantial equivalence.

The cleaning and disinfection procedures must be applied depending on the components. Procedures are provided in the User Manual.

Biocompatibility was assessed following ISO 10993 “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”. The skin contact of the Neuronaute device is limited to 24 hours. Hence, per ISO 10993, Part 1, and the FDA-modified Matrix (“Use of International Standard ISO-10993 “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”) the following tests are conducted to determine biocompatibility of Neuronaute: Cytotoxicity, Irritation, Sensitization. Neuronaute is not intended to be used on unhealthy skin and skin with open wounds. The yarns used in the Neuronaute and in contact with the skin were preferentially chosen according to OEKO-TEX® product Class I and Class II suitable for use in babies and textiles close to the skin such as underwear. The dry EEG electrodes are made of titanium alloy Ti6Al4V (Ti-64) extra- low interstitial (ELI). Titanium and its alloys have a proven track record as biomedical implants due to their excellent biocompatibility.

The firmware in the Neuronaute, the mobile app and the Cloud have been tested through verification and validation according to the IEC 62304:2006 standard and as per the FDA Guidance “General Principles for Software Validation”. The results of the verification and validation activities demonstrate that the software meet the requirements for safety, function and intended use.

Electromagnetic compatibility and electrical safety testing of the Neuronaute was conducted following recognized standards for electro-medical equipment. Compliance to the specific standards IEC 60601-2-26:2002 “Particular requirements for the safety or electroencephalographs” regarding the operational and mechanical performance has been demonstrated.

The reusable EEG dry electrodes used with the Neuronaute have been tested to demonstrate their electrical and signal acquisition performance. While the scope of the standards does not cover EEG electrodes testing using applicable methods defined in chapter 4 of AAMI/ANSI EC12:2000 (R)2010 Disposable ECG electrodes has been conducted, as well as for another cleared EEG electrode, Rythmlink Disc Electrodes (K061148). Testing performed show that the dry titanium EEG electrodes has similar electrical performance as the Rythmlink Disc Electrodes (K061148).

EEG signals testing has been performed on the Neuronaute in comparison with the gold standard, assimilated to another cleared EEG electrode, Rythmlink Disc Electrodes (K061148) to demonstrate the acceptability of the signals quality. Testing performed show that the dry titanium EEG electrodes has similar signal performance as the Rythmlink Disc Electrodes (K061148).

EEG signals testing has been performed on the Neuronaute to demonstrate the acceptability of the signals quality. The Impedance tests were performed on a cohort of 24 subjects. The Alpha Rhythm tests were performed on a cohort of 26 healthy adult subjects. The Chirp and Ramp tests demonstrate an acceptable lag between the box and presented no data lost with the current version of software. The physiological tests showed a normal presence of alpha modulation in the eyes opening/closing task. Most impedances were below 1MOhms. Altogether, the latest hardware and software versions of the Neuronaute show acceptable results for a release.

Finally, as part of the Design Control, other testing has been performed to ensure that the specifications defined have been met.

5.8 Technological Characteristics

Specification	Neuronaute (Bioserenity)	Primary Predicate X-series System (Advanced Brain Monitoring)	Additional Predicate Rythmlink Disc Electrodes (Rhythmlink International, LLC)
510(k) number	Current Submission (K170138)	K131383	K061148
Clinical characteristics			
Indications for use	The Neunoraute is a medical, wireless and mobile equipment, which allows acquisition, record, storage, transmission and displaying of electroencephalogram (EEG) from adult patients. It can be used with patients in health care facility (data acquisition and reporting) or clinical research environment. The Neuronaute requires operation by a trained healthcare professional. The Neuronaute only acquires and displays physiological signals, no claims are being made for analysis of the acquired signals with respect to the accuracy, precision and reliability.	The X-Series System is intended for prescription use in the home, healthcare facility, or clinical research environment to acquire, transmit, display and store physiological signals from patients ages 6 and older. The X-Series system requires operation by a trained technician. The X-Series System acquires, transmits, displays and stores electroencephalogram (EEG), electrooculogramn (EOG), electrocardiogram (ECG), and/or electromyogram (EMG), and accelerometer signals. The X-Series System only acquires and displays physiological signals, no claims are being made for analysis of the acquired signals with respect to the accuracy, precision and reliability.	The Rythmlink Disc Electrodes are intended for non-invasive use with recording and monitoring equipment, (active and reference), of Electromyography (EMG), Electroencephalography (EEG) and Evoked Potentials.
Intended use	Acquire, display, store and archive electroencephalograph signals from the brain using a full montage array (i.e, 16 or more electrodes) and user specified locations.		Acquisition of signals for the purpose of monitoring and recording of EEG, EMG and Evoked potentials (EP)
Class	II		
Product Code	GWQ, GXY	GWQ, OMC	GXY
CFR Section	882.1400		882.1320
Device Panel	Neurology		
Patient population	Adults	Ages 6 and older	Not found
User	Trained Healthcare professional	Trained Technician	Healthcare professional / technicians

Specification	Neuronaute (Bioserenity)	Primary Predicate X-series System (Advanced Brain Monitoring)	Additional Predicate Rythmlink Disc Electrodes (Rhythmlink International, LLC)
Anatomical sites	Forehead, Scalp	Scalp and Chest	Head and body
Environment of Use	Healthcare facility (data acquisition and reporting) Clinical Research Environment	Home (data acquisition) Healthcare facility (data acquisition, analysis and reporting) Clinical Research Environment	Healthcare facility Clinical Research Environment
User Interface	Usual control, visual indicators		N/A
Technological characteristics			
EEG			
EEG electrodes	21 reusable dry titanium electrodes plus 2 referential channels using Ag/AgCl disc electrodes	Up to 20 differential or referential channels	Ag/Ag Cl disc electrodes
Contact electrode type	Dry electrode	Wet electrode composed by a metal film part, an adhesive foam and EEG paste.	Wet electrode (to be used with EEG paste)
Shape	Comb-like electrodes (hair design) Conical electrodes (frontal design)	Metal film part. Cylindrical adhesive foam.	Disc electrode
Method of use	Reusable	Reusable metal film part. Disposable adhesive foam and synapse cream.	Disposable
Raw material	Titanium	Ag/AgCl	Ag/AgCl
Signal processing techniques (e.g. filtering, etc.)	Sampling rate: 500 s/s No Highpass applied on raw data. Hardware filtering: 125Hz lowpass Various filters are applicable in the viewer software	Sampling rate: 256 s/s 0.1 Hz High Pass100 Hz Low Pass, hardware	N/A
Accuracy, variance and error of measurements	Sampling rate: 500 s/s Dynamic range: =+/- 600mV Noise : < 6µVpp	Sampling rate: 256 s/s Dynamic range: =+/- 1000µV Noise: 3.7µV (typical)	N/A
ECG	Not available	Dual lead ECG	N/A
EOG/EMG Electrodes	Not available	Up to 4 optional single channels either dual lead electrooculogram (EOG) or electromyogram (EMG)	N/A

Specification	Neuronaute (Bioserenity)	Primary Predicate X-series System (Advanced Brain Monitoring)	Additional Predicate Rythmlink Disc Electrodes (Rhythmlink International, LLC)
Linked Mastoid Sensors	Disposable Ag/Cl sensors with adhesive		N/A
Signals Acquired	• Forehead/head 21 EEG channels	• Up to 20 EEG scalp channels • 3-D actigraphy • 4 optional single channel either dual lead EOG or EMG • Single optional ECG channel	• EEG, EMG signals • EP
CMRR	115dB	110dB	N/A
Input Impedance	1Gohm	100Gohm	N/A
Power Supply	2 x 2300mAH 3.7V Li-Ion batteries	2 to 4 X 240mAH 3.7 Li-Ion batteries	N/A
Battery Charging	Operators – external battery pack	Via JED Connector connected to USB port or USB wall charger	N/A
Typical Charging Time	0.5-3.0 hours depending of discharge depth	0.5-5.0 hours	NA
Acquisition modes	Record	Monitor only	N/A
Operating Time	4.0 hours	Monitoring Days after Charge Hours of Use • 0-4 Days: 16 to 17 hours • 5-10 Days: 14 to 15 hours	N/A
Data storage	Streaming data	Not used. The X-Series system does not include a record mode where data is stored on the recorder	N/A
File size per 8 hours recording	1000MB (edf files) 1000MB (video)	512 MB	N/A
Dimensions	Different sizes of caps are available	5.0'' long, 2.25'' widen 1.0' deep	10mm diameter Cable length: 150cm
Weight	Electronic boxes: 2 ounces Battery pack: 2.68 ounces	3.9 ounces with two batteries	< 1 ounce

Specification	Neuronaute (Bioserenity)	Primary Predicate X-series System (Advanced Brain Monitoring)	Additional Predicate Rythmlink Disc Electrodes (Rhythmlink International, LLC)
Cleaning	For EEG electrodes: the chlorhexidine based disinfection process supported by hospital services For clothes: any soft neutral pH detergent	Cleaned and disinfected by rubbing with isopropyl alcohol	Cleaned with water and soft detergent. Disinfection with common used disinfectant at hospital diluted at 2%
Data transfer from SD card	Not applicable	USB Dongle	N/A
Wireless data transfer	Bluetooth and Wifi	Bluetooth 2.0	N/A
Maximum Bluetooth wireless transfer distance and rate	Transfer distance 10 meters line of sight, maximum transfer not specified	Transfer distance 10 meters line of sight, maximum transfer rate 3 Mbaud	N/A
Compatibility	For the mobile app: iOS 9 and higher iPhone® 6, 6 plus, 6S, 6S plus iPad air, iPad air 2, iPad Pro For the Cloud (Bioserenity.force.com): any web navigators	Windows 8, 7, and XP, PC with 2.0 GHz or higher processor & 1 GB of RAM	N/A
Estimate file size per minute	2000 KB/min	45 KB/Min	N/A
File format type	European data format (EDF)		N/A
Software	Software presents waveforms		N/A
Biological characteristics			
Category of device	Surface Device		
Type of contact	Intact skin		
Contact duration	Limited		N/A
Non-Clinical Testing			
Biocompatibility	Testing in compliance with FDA Guidance “Use of International Standard ISO10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing was performed and demonstrated substantially equivalent performance to identified predicate devices. The following non-clinical tests have been performed: Cytotoxicity, Sensitization and Irritation.		

Specification	Neuronaute (Bioserenity)	Primary Predicate X-series System (Advanced Brain Monitoring)	Additional Predicate Rythmlink Disc Electrodes (Rhythmlink International, LLC)
Electromagnetic compatibility and electrical safety	Testing in compliance with FDA Guidance "Information to support a claim of electromagnetic compatibility (EMC) of electrically-powered medical devices was performed and demonstrated substantially equivalent to primary predicate device.		