October 24, 2022

Neurosteer Inc.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K221563
Trade/Device Name: Neurosteer EEG Recorder
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMC, GXY
Dated: May 31, 2022
Received: May 31, 2022

Dear Janice Hogan:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221563

Device Name

Neurosteer EEG Recorder

Indications for Use *(Describe)*

The Neurosteer EEG Recorder is intended to record and store EEG signals, and to present the EEG signals in visual formats in real time. The visual signals assist trained medical staff to make neurological diagnoses. The EEG Recorder does not provide any diagnostic conclusion about the subject's condition and does not provide any automated alerts of an adverse clinical event. The EEG\ Recorder is intended to be used in a professional healthcare facility environment.

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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510(k) SUMMARY
Neurosteer Inc.'s Neurosteer EEG Recorder

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Neurosteer Inc.
375 South End Avenue Suite 26C
New York, NY 10280 USA
Phone: +1 844-444-5601
Contact Person: Nathan Intrator

Date Prepared: September 15, 2022

Device Information

Trade Name: Neurosteer EEG Recorder

Common or Usual Name: Electroencephalograph

Classification: 21 CFR 882.1400

Device Class: Class II

Product Code: OMC

Predicate Devices

Predicate devices:

Ceribell, Inc. Ceribell Pocket EEG Device (K170363)

Ceribell, Inc. Ceribell Instant EEG Headband (K171459)

Reference device:

Corscience gmBH EEG/ERP NeuroAmp (K193159)

Device Description

The Neurosteer brain monitoring platform is a portable single-channel EEG that measures and records electrical activity of the brain. An adhesive electrode strip is affixed to the subject's forehead to capture the brain activity signal. The strip is attached to a sensing device that transmits the signal via low-energy Bluetooth (BLE) to a local brain activity monitor.

The brain activity monitor provides technical status indicators about the recording (such as battery level, connection status, and electrode disconnection alert). It can also be used to provide auditory prompt sequences (using an external speaker) during monitoring.

The signal is sent via a secure Internet connection to the cloud (either wireless Wi-Fi or physical Ethernet) where the data is stored according to HIPAA guidelines. Data processing performed in the cloud transforms the raw electrical brain activity signal into a display representation of the signal.

When the Internet connection is available, both the raw and processed data can be viewed in real-time on the brain activity monitor and through the web portal. When the connection is not available, only the raw data can be viewed in real-time on the brain activity monitor.

Intended Use / Indications for Use

The Neurosteer EEG Recorder is intended to record and store EEG signals, and to present the EEG signals in visual formats in real time. The visual signals assist trained medical staff to make neurological diagnoses. The EEG Recorder does not provide any diagnostic conclusion about the subject's condition and does not provide any automated alerts of an adverse clinical event. The EEG Recorder is intended to be used in a professional healthcare facility environment.

Substantial Equivalence

The Neurosteer EEG Recorder and the predicate devices have the same intended use and very similar technological features, including an integrated array of cutaneous electrodes, a sensor, portable monitor, and software intended for recording and viewing EEG signals. The differences between the Neurosteer EEG Recorder and its predicate devices raise no new issues of safety or effectiveness. Performance testing confirms that the device functions as intended, supporting substantial equivalence. The characteristics of the subject and predicate device are summarized in the following table:

Attribute	Subject Device: Neurosteer EEG Recorder	Predicate Devices: Ceribell Pocket EEG Device (K170363) & Ceribell Instant EEG Headband (K171459)	Comparison
Device class and regulation	Class II per 882.1400; 882.1320,	Class II per 882.1400 (K170363); 882.1320 (K171459)	Same
Product codes	OMC and GXY	OMC (K170363) and GXY (K171459)	Same
Indications for use	The Neurosteer EEG Recorder is intended to record and store EEG signals, and to present the EEG signals in visual formats in real time. The visual signals assist trained medical staff to make neurological diagnoses. The EEG Recorder does not provide any diagnostic conclusion about the subject's condition and does not provide any automated alerts of an adverse clinical event. The EEG Recorder is intended to be used in a professional healthcare facility environment.	The Ceribell Pocket EEG Device is intended to record and store EEG signals, and to present the EEG signals in visual and audible formats in real time. The visual and audible signals assist trained medical staff to make neurological diagnoses. The Pocket EEG Device does not provide any diagnostic conclusion about the subject's condition and does not provide any automated alerts of an adverse clinical event. The Pocket EEG Device is intended to be used in a professional healthcare facility environment. The Ceribell Instant EEG Headband is an electroencephalogram (EEG) electrode array intended for single patient use in the recording of EEGs in patients of 6 years and older. The Instant EEG Headband is intended for prescription use in the home, healthcare facility, or clinical research environment.	Substantially equivalent

Attribute	Subject Device: Neurosteer EEG Recorder	Predicate Devices: Ceribell Pocket EEG Device (K170363) & Ceribell Instant EEG Headband (K171459)	Comparison
System components	• EEG electrodes with conductive hydrogel • EEG sensor • Portable EEG monitor to display EEG data in real time in visual format and transfer EEG recording files to cloud storage platform via internet connection • Cloud storage platform • Browser-based EEG viewing software	• EEG electrodes with conductive gel • EEG sensor (included in same housing as portable EEG monitor) • Portable EEG monitor to display EEG data in real time in visual and auditory formats and transfer EEG recording files to a computer via wired connection • Application-based EEG viewing software	Same
EEG specifications [OMC]			
Montage	10/20	10/20	Same
Channels	1	8	Substantially equivalent
EEG presentation format(s)	Visual only (raw EEG waveform, spectrogram, metrics and bar graph views)	Visual (raw EEG waveform) and auditory	Substantially equivalent
Data transfer method(s)	Bluetooth 2.4 GHz and internet connection (ethernet or Wi-Fi)	Wired micro-USB or wireless Wi-Fi connection	Substantially equivalent
Data file format	Edf	Edf	Same
Type of use	Reusable	Reusable	Same
Power source	Lithium polymer battery – rechargeable with 100-240 V AC power adapter (device does not work when connected to AC to recharge)	Lithium ion batteries – rechargeable with 100-240 V AC power adapter (device does not work when connected to AC to recharge)	Same
Charging	Micro-USB charging cable; if connected to a computer, all EEG acquisition functions are automatically disabled	Micro-USB charging cable; if connected to a computer, all EEG acquisition functions are automatically disabled	Same
Cutaneous electrode specifications [GXY]			
Electrode type	Passive silver/silver-chloride (Ag/AgCl)	Passive silver/silver-chloride (Ag/AgCl)	Same
Number / locations of electrodes	3 (Locations: Fp1, Fpz, Fp2)	10 (Locations: Fp1, Fp2, F7, F8, T3, T4, T5, T6, O1, O2)	Substantially equivalent
Conductive electrolyte gel	Semi-solid hydrogel is included in a layer integrated into each electrode assembly.	Liquid gel is included in a packet gel reservoir integrated into each electrode assembly. User can apply additional gel if needed.	Substantially equivalent
Patient contact	Patient forehead (intact skin)	Patient scalp and forehead (intact skin)	Same
Securing method	Integrated adhesive layer	Spandex blend fabric headband	Substantially equivalent
Available sizes and dimensions	One size (10.5 cm)	Small (48.4 – 53.6 cm) Medium (53.3 – 56.5 cm) Large (55.5 – 62 cm)	Substantially equivalent
Type of use	Single use, non-sterile, disposable	Single use, non-sterile, disposable	Same
Connector	Integrated single-cable connector to connect to an EEG recording device	Integrated single-cable connector to connect to an EEG recording device	Same
Compatibility	Compatible with the Neurosteer EEG Recorder only	Compatible with the Ceribell Pocket EEG Device only	Both the subject and predicate device are intended to connect to external EEG recording devices

Performance Data

The following test data were submitted in support of substantial equivalence. All tests showed passing results.

<table>
<tr><th>Test</th><th>Test Method Summary</th><th>Results</th></tr>
<tr><td>Biocompatibility</td><td>The Electrode Strip was assessed in accordance with ISO 10993-1 and was tested in its final finished form for the following endpoints:
- Cytotoxicity (ISO MEM elution method per ISO 10993-5:2009);
- Irritation (rabbit irritation test per ISO 10993-10:2010);
- Sensitization (guinea pig maximization per ISO 10993-10:2010)</td><td>All samples passed the acceptance criteria. The subject device is as safe as the predicates with respect to biocompatibility.</td></tr>
<tr><td>Electrical Safety</td><td>Electrical safety testing was performed on the final finished Electrode Strip, Sensor, and Brain Activity Monitor, including the charger for the Sensor and the power adaptor for the Brain Activity Monitor. Testing was performed in accordance with IEC 60601-1.</td><td>All samples passed the acceptance criteria. The subject device is as safe as the predicates with respect to electrical safety.</td></tr>
<tr><td>Electromagnetic Compatibility (EMC)</td><td>Electromagnetic compatibility, emissions and immunity testing was performed on the final finished Electrode Strip and Sensor. Testing was performed in accordance with IEC 60601-1-2. The test also included conformance to ETSI EN 301 489-1.</td><td>All samples passed the acceptance criteria for each test. The subject device is as safe as the predicates with respect to EMC.</td></tr>
<tr><td>Battery Safety</td><td>The Sensor’s rechargeable lithium-ion polymer battery was tested in accordance with IEC 62133. The battery is not modified in any way for the Neurosteer EEG Recorder, so the testing was performed using samples from the original battery manufacturer.</td><td>All samples passed the acceptance criteria. The subject device is as safe as the predicates with respect to battery safety.</td></tr>
<tr><td>EEG Essential Performance</td><td>The essential performance of the Neurosteer EEG Recorder’s EEG components (i.e., Sensor and Brain Activity Monitor) was assessed via IEC 80601-2-26.</td><td>All samples passed the acceptance criteria. The subject device is as effective as the predicates with respect to EEG performance.</td></tr>
<tr><td>Electrode Performance</td><td>The performance of the Electrode Strip was assessed via ANSI/AAMI EC12 in accordance with the clauses and acceptance criteria shown below. The test samples were final finished Electrode Strips. An off-the-shelf, standard industry electrode was used as a reference comparator.
<table>
<tr><th>EC12 Clause / Test Description</th><th>Acceptance Criteria</th></tr>
<tr><td>5.2.2.1 (AC Impedance): AC impedance of electrode pairs of Electrode Strip connected hydrogel-to-hydrogel</td><td>≤3,000 ohm</td></tr>
<tr><td>5.2.2.2 (DC Offset Voltage): DC offset voltage of electrode pairs of Electrode Strip connected hydrogel-to-hydrogel following a 1 min stabilization period</td><td>≤100 mV</td></tr>
<tr><td>5.2.2.3 (Combined Offset Instability and Internal Noise): Peak-to-peak passband voltage measured between electrode pairs of Electrode Strip connected hydrogel-to-hydrogel measured for a 5 min period following a 1 min stabilization</td><td>≤150 uV</td></tr>
<tr><td>5.2.2.4 (Defibrillation Overload Recovery): DC offset voltage and AC impedance of electrode pairs of Electrode Strip connected gel-to-gel following 4 simulated defibrillation discharge events</td><td>• Discharge time to 2V ≤2,000ms
• Recovery to <200mV
• Electrode voltage decreases at rate <1mV/s</td></tr>
<tr><td>5.2.2.5 (Bias Current Tolerance): DC offset voltage of electrode pairs of Electrode Strip connected gel-to-gel over the course of 8 hours with an applied bias current of 200 nA</td><td>≤100 mV</td></tr>
</table></td><td>All samples passed the acceptance criteria. The subject device is as effective as the predicates with respect to electrode performance.</td></tr>
</table>

Conclusions

The Neurosteer EEG Recorder has the same intended use and similar indications for use, technological characteristics, and principles of operation as the predicate devices. The minor technological differences between the Neurosteer EEG Recorder and its predicate devices raise no new or different questions of safety or effectiveness. Performance data demonstrate that the Neurosteer EEG Recorder is as safe and effective as the predicate devices. Thus, the Neurosteer EEG Recorder is substantially equivalent.