DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 21, 2017

Ceribell, Inc.
Josef Parvizi, MD, PhD
Chairman
2483 Old Middlefield Way, Suite 120
Mountain View, California 94043

Re: K171459
Trade/Device Name: Ceribell Instant EEG Headband
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: July 25, 2017
Received: July 27, 2017

Dear Dr. Parvizi:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

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)*
K171459

Device Name
Ceribell Instant EEG Headband

Indications for Use *(Describe)*
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.

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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510(K) SUMMARY

This summary of 510(k)- safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant Information:

Ceribell, Inc.
2483 Old Middlefield Way
Suite 120
Mountain View, California

Contact Person:

Josef Parvizi, MD, PhD, Chairman
Telephone: (650) 521-7003
E-mail: josef@ceribell.com

Device Information:

Trade Name:	Ceribell Instant EEG Headband
Common Name:	Cutaneous electrode
Classification Name:	Cutaneous electrode (21CFR 882.1320)
Device Class:	II
Product Code:	GXY

Predicate Devices:

Hydrodot Statnet EEG Headpiece (K092828).

Date Prepared:

August 17, 2017

Device Description:

The Ceribell Instant EEG Headband is a 10 electrode EEG headband. The headband is non-sterile and disposable for single patient use and designed to be used exclusively with the Ceribell Pocket EEG Device (K170363) for EEG acquisition and recording.

The Ceribell Instant EEG Headband is comprised of the following components:

- An elastic fabric headband
- A cable attached to the headband to allow connection to an EEG acquisition/recording device
- 10 electrode assemblies, each consisting of the following:
    - Passive Silver/silver-chloride electrode
    - Reservoir filled with conductive electrolyte gel
    - Mechanism for dispensing gel onto patient scalp
    - Scalp-contacting prongs to prepare scalp for electrode contact

Indications for Use:
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.

Comparison of Intended Use and Technological Characteristics with the Predicate Devices:
The subject and the predicate device share the same intended use: an integrated array of cutaneous electrodes intended for the recording of EEG signals. The characteristics of the subject device and the predicate device are summarized in the following table.

Attribute	**Predicate Device** Hydrodot StatNet EEG Headpiece (K092828)	**Subject Device** Ceribell Instant EEG Headband	**Substantially Equivalence**
Intended Use	A single-use disposable headpiece with an integrated array of 17 passive cutaneous electrodes that are applied to the patient's head to record EEG signals when connected to an EEG recording device.	A single-use disposable headpiece with an integrated array of 10 passive cutaneous electrodes that are applied to the patient's head to record EEG signals when connected to an EEG recording device.	• The subject device and predicate device all both intended for use as single use, disposable, passive cutaneous electrodes applied to the patient's head to record EEG signals. • The difference in number of electrodes does not raise any new or different questions of safety or effectiveness
Classification Regulation	Class II per 21CFR882.1320, cutaneous electrode	Class II per 21CFR882.1320, cutaneous electrode	Same as predicate.
Product Code	GXY, Electrode, cutaneous	GXY, Electrode, cutaneous	Same as predicate.
Type of Patient Contact	Contacts patient scalp	Contacts patient scalp	Same as predicate.
Type of use	Single use, non-sterile, disposable.	Single use, non-sterile, disposable.	Same as predicate.
System Components, Technological Features, and Materials	• 17 silver/silver-chloride (Ag/AgCl) electrodes • Foam gel reservoir sponges pre-filled with conductive electrolyte gel • Electrodes integrated on a plastic film substrate • Integrated single-cable connector to connect to an EEG recording device	• 10 silver/silver-chloride (Ag/AgCl) electrodes • Packet gel reservoirs pre-filled with conductive electrolyte gel • Electrodes integrated on a fabric substrate • Integrated single-cable connector to connect to an EEG recording device	• The technological features of the subject device and predicate device are substantially equivalent. • Both devices include integrated pre-filled containers of conductive electrolyte gel. • Both devices contain electrodes integrated onto a substrate for application onto the patient's head. • Both devices include an integrated single-cable connector to connect to an EEG recording device. • The differences in system components, technological features, and materials do not raise any new or different questions of safety or effectiveness.

Attribute	**Predicate Device** Hydrodot StatNet EEG Headpiece (K092828)	**Subject Device** Ceribell Instant EEG Headband	**Substantially Equivalence**
Electrodes	17 passive Ag/AgCl electrodes	10 passive Ag/AgCl electrodes	• Both the subject device and the predicate device contain integrated Ag/AgCl electrodes intended to be applied to the patient's scalp and provide coverage of both left and right hemispheres of the patient's head • The difference in number of electrodes does not raise any new or different questions of safety or effectiveness
Connector	Integrated single-cable connector to connect to an EEG recording device	Integrated single-cable connector to connect to an EEG recording device	Same as predicate.
Compatibility	Can connect to various EEG devices using included custom adapter cable.	Compatible with the Ceribell Pocket EEG Device only.	• Both the subject device and the predicate device are intended to be connected to external EEG recording devices. • The difference in EEG recording device compatibility does not raise any new or different questions of safety or effectiveness.
Available Sizes and Dimensions	Large (56 – 62 cm) Medium (50 – 56 cm)	Small (48.4 – 53.6 cm) Medium (53.3 – 56.5 cm) Large (55.5 – 62 cm)	• The subject device and predicate device are sized to encompass the range of expected head sizes for their intended patient population; and the maximum head size for both devices is the same. • The differences in headband size range do not raise any new or different questions of safety or effectiveness.
Conductive Electrolyte Gel	Electrodes are pre-filled with an electrolyte gel filled sponge adhered to each electrode.	Conductive electrolyte gel is included in a packet gel reservoir integrated into each electrode assembly. User is also able to add additional electrolyte gel when needed using a syringe.	• The pre-filled conductive electrolyte gel components in the subject device and predicate device are substantially equivalent. • The differences in electrolyte gel application do not raise any new or different questions of safety or effectiveness.
Bio-compatibility	Biocompatibility of patient contacting components verified with Irritation, Sensitization, and Cytotoxicity testing per ISO 10993-5:2009 and ISO 10993-10:2010	Biocompatibility of patient contacting components verified with Irritation, Sensitization, and Cytotoxicity testing per ISO 10993-5:2009 and ISO 10993-10:2010	Same as predicate.

Performance Data:

The following table summarizes test data that were provided to demonstrate safety and efficacy in support of a substantial equivalence determination. All of the performance testing described below was performed on the subject device.

Test	Test Description	Test Results
Electrode Impedance	AC impedance of electrode pairs of subject device connected gel-to-gel using the test methodology and acceptance criteria of ANSI/AAMI EC12 5.2.2.1.	All samples passed. The test results do not raise any new or different questions of safety or effectiveness
Electrode DC Offset Voltage	DC offset voltage of electrode pairs of subject device connected gel-to-gel following a 1 min stabilization period using the test methodology and acceptance criteria of ANSI/AAMI EC12 5.2.2.2.	All samples passed. The test results do not raise any new or different questions of safety or effectiveness
Combined Offset Instability and Internal Noise	Peak-to-peak passband voltage measured between electrode pairs of subject device connected gel-to-gel measured for a 5 min period following a 1 min stabilization using the test methodology and acceptance criteria of ANSI/AAMI EC12 5.2.2.3	All samples passed. The test results do not raise any new or different questions of safety or effectiveness
Defibrillation Overload Recovery	DC offset voltage and AC impedance of electrode pairs of subject device connected gel-to-gel following 4 simulated defibrillation discharge events using the test methodology and acceptance criteria of ANSI/AAMI EC12 5.2.2.4	All samples passed. The test results do not raise any new or different questions of safety or effectiveness
Bias Current Tolerance	DC offset voltage of electrode pairs of subject device connected gel-to-gel over the course of 8 hours with an applied bias current of 200 nA using the test methodology and acceptance criteria of ANSI/AAMI EC12 5.2.2.5.	All samples passed. The test results do not raise any new or different questions of safety or effectiveness
Conductive Gel Delivery/Skin Prep Testing	Subject devices are functionally tested to verify that integrated conductive gel can be dispensed, additional gel can be added by the user, and aluminum oxide powder is present on the scalp contacting surfaces.	All samples passed. The test results do not raise any new or different questions of safety or effectiveness
Headband Size Range Testing	Headband size ranges of subject devices measured with calibrated ruler.	All samples passed. The test results do not raise any new or different questions of safety or effectiveness
Simulated Use Testing	Small, medium, and large size subject devices tested under simulated use conditions using mannequin heads with long hair.	All samples passed. The test results do not raise any new or different questions of safety or effectiveness

Test	Test Description	Test Results
Packaging Performance Testing	Subject devices packaging subjected to environmental conditioning and shipping test per ASTM D7386. After environmental conditioning and shipping, devices were visually inspected, functionally tested under simulated use conditions, and electrically tested.	All samples passed. The test results do not raise any new or different questions of safety or effectiveness
Biocompatibility Testing	Patient contacting materials used in subject device subjected to biocompatibility testing for devices that contact surface/intact skin for limited duration (< 24 hours). Cytotoxicity testing conducted per ISO 10993-5; Irritation and Sensitization testing conducted per ISO 10993-10.	All samples passed. The test results do not raise any new or different questions of safety or effectiveness

Summary:

The Ceribell Instant EEG Headband has the same intended use as the predicate device. In addition, it has similar technological characteristics; performance data demonstrates that any differences in technological characteristics do not raise different questions of safety or effectiveness. Therefore, the Ceribell Instant EEG Headband is substantially equivalent to the cleared predicate device**.**