March 21, 2023

Ceribell, Inc.
Raymond Woo, PhD
Chief Technical Officer
360 N Pastoria Ave
Sunnyville, California 94085

Re: K223086
Trade/Device Name: Ceribell Instant EEG Headcap
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: January 24, 2023
Received: January 25, 2023

Dear Dr. Woo:

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine 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)*
K223086

Device Name
Ceribell Instant EEG Headband

Indications for Use *(Describe)*
The Ceribell Instant EEG Headcap is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired.

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 is being submitted in accordance with the requirements of 21 CFR 807.92.

Applicant Information:

Ceribell, Inc.
360 North Pastoria Avenue
Sunnyvale, California 94085

Contact Person:

Raymond Woo, PhD
CTO
Telephone: (650) 556-4349
E-mail: ray@ceribell.com

Device Information:

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

Predicate Device:

K200162, Wuhan Greentek Disposable EEG Electrodes (MODEL: DL, E-CAP, FLEX-CAP)

Date Prepared:

January 24, 2023

Device Description:

The Ceribell Instant EEG Headcap is a single-use, non-sterile, disposable EEG electrode device that includes a minimum of 9 EEG electrodes that are placed on the subject's scalp. The Headcap is intended to collect and provide EEG signals to an EEG recording or monitoring device.

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

- An elastic fabric headcap
- An elastic chin strap
- A minimum of 9 silver/silver chloride (Ag/AgCl) electrodes
- A cable attached to the headcap to allow connection to an EEG acquisition/recording device

Indications for Use:

The Ceribell Instant EEG Headcap is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired.

Comparison of Intended Use and Technological Characteristics with the Predicate Device:

Compared to the predicate device, the subject device has the same intended use, similar product design and the same product effectiveness as the predicate device as summarized in the following table.

Attribute	**Subject Device** Ceribell Instant EEG Headcap (Ceribell, Inc.)	**Predicate Device** Disposable EEG Electrodes, K200162 (Wuhan Greentek Pty Ltd.)	**Comparison**
Classification Regulation	Class II per 21 CFR 882.1320, E Cutaneous electrode	Class II per 21 CFR 882.1320, E Cutaneous electrode	Same
Product Code	GXY, Electrode, cutaneous	GXY, Electrode, cutaneous	Same
Indications for Use	The Ceribell Instant EEG Headcap is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired.	Disposable EEG Electrodes (MODEL: DL, E-CAP, FLEX-CAP) is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired.	Same
Intended Patient population	Adults and children	Adults and children	Same
Environment of Use	Electrophysiological	Electrophysiological	Same
Where Used	On the head	On the head	Same
Device Description	Disposable EEG electrode array with three sizes consisting of: • Between 9 and 19 silver/silver-chloride (Ag/AgCl) electrodes • Cable to connect to an EEG recording device • A spandex fabric headcap to secure the electrodes to the patient	Disposable EEG electrode array with three models (DL, E-CAP, FLEX-CAP) consisting of: • Between 2 to 128 silver/silver-chloride (Ag/AgCl) electrodes • Cable to connect to an EEG recording device • A spandex fabric headcap to secure the electrodes to the patient	Same

Attribute	**Subject Device** Ceribell Instant EEG Headcap (Ceribell, Inc.)	**Predicate Device** Disposable EEG Electrodes, K200162 (Wuhan Greentek Pty Ltd.)	**Comparison**
Number of Electrodes	9 -19	2 - 128 electrodes	Yes, the number of electrodes of the subject device falls within the possible customizable number of electrodes of the predicate device (between 2 to 128 electrodes).
Electrode Locations	The placement of the electrodes is according to the International 10-20 system of electrode placement or the American Electroencephalographic Society positioning system (10-10). The number of the electrodes in use is according to the needs of clinical practice.	The placement of the electrodes is according to the International 10-20 system of electrode placement or the American Electroencephalographic Society positioning system (10-10). The number of the electrodes in use is according to the needs of clinical practice.	Same
Available Sizes	Various sizes (overall head size range 26cm – 66cm)	Various sizes (babies to large: overall head size range 26cm – 66cm)	Same
Cap Material	Spandex blend: Black Nylon Knitted Fabric, 82% Nylon and 18% Spandex	Spandex	The biocompatibility testing and electrical performance testing completed are the same and follow the FDA guidance document "*Cutaneous Electrodes for Recording Purposes- Performance Criteria for Safety and Performance Based Pathway*," August 2020.
Electrode Mounts	Soft thermoplastic elastomer (TPE)	Silicone	The electrical performance and biocompatibility testing completed are the same and follow the FDA guidance document "*Cutaneous Electrodes for Recording Purposes- Performance Criteria for Safety and Performance Based Pathway*," August 2020.

Attribute	**Subject Device** Ceribell Instant EEG Headcap (Ceribell, Inc.)	**Predicate Device** Disposable EEG Electrodes, K200162 (Wuhan Greentek Pty Ltd.)	**Comparison**
Electrode Material	Silver/silver-chloride-coated photopolymer base	Silver/silver chloride ink printed on PET (polyethylene terephthalate) or silver/silver chloride-plated ABS base	The electrical performance and biocompatibility testing completed are the same and follow the FDA guidance document "*Cutaneous Electrodes for Recording Purposes- Performance Criteria for Safety and Performance Based Pathway*," August 2020.
Type of Connector	Touch-proof safety socket DIN 42-802 (ø1.5mm)	Touch-proof safety socket DIN42-802 (ø1.5mm)	The electrical performance testing completed met the same requirements per FDA guidance document "*Cutaneous Electrodes for Recording Purposes- Performance Criteria for Safety and Performance Based Pathway*," August 2020.
Biocompatibility Requirements	ISO 10993-1 ISO 10993-5 (Cytotoxicity) ISO 10993-10 (Sensitization, Irritation or Intracutaneous Reactivity)	ISO 10993-1 ISO 10993-5 (Cytotoxicity) ISO 10993-10 (Sensitization, Irritation or Intracutaneous Reactivity)	The biocompatibility testing met the same requirements per FDA guidance document "*Use of International Standard ISO 10993-1*," issued Sep 2020, for surface device with intact skin contact.
Cable	0.1m-3.0m integrated single cable	0.1m-3.0m standard ribbon cable and lead wires	Both designed in conformance with AAMI/ ANSI ES60601-1:2005(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (consolidated text) Medical electrical equipment- Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, mod). The electrical connection compliance met the same requirements per FDA guidance document "*Cutaneous Electrodes for Recording Purposes- Performance Criteria for Safety and Performance Based Pathway*," August 2020.

Attribute	**Subject Device** Ceribell Instant EEG Headcap (Ceribell, Inc.)	**Predicate Device** Disposable EEG Electrodes, K200162 (Wuhan Greentek Pty Ltd.)	**Comparison**
Electrical Performance Requirements	ANSI/AAMI EC12 • Average AC Impedance: ≤ 2 kΩ (individual pairs ≤ 3kΩ). • DC Offset Voltage: ≤ 100 mV • Combined Offset Instability and Internal Noise: ≤ 150 µV • Bias Current Tolerance: ≤ 100 mV	ANSI EC12 • AC Impedance: < 2 kΩ (at 10 Hz) • DC Offset Voltage: < 100 mV • Combined Offset Instability and Internal Noise: < 150 µV • Bias Current Tolerance: < 100 mV	The electrical performance testing met the same requirements per FDA guidance document "*Cutaneous Electrodes for Recording Purposes- Performance Criteria for Safety and Performance Based Pathway,*" August 2020.
Electrical Connection Compliance	• Conductive Connection Compliance (Patient Leads or Patient Cables) per ES 60601-1 consensus standard • IEC 60601-1 clause 8.5.2.3 • 21 CFR 898.12	AAMI/ANSI ES60601-1 clause 8.5.2.3	The electrical connection compliance met the same requirements per FDA guidance document "*Cutaneous Electrodes for Recording Purposes- Performance Criteria for Safety and Performance Based Pathway,*" August 2020.

The results of completed testing demonstrate that any differences in technology do not raise different questions of safety and effectiveness for the subject device compared to the predicate device.

Performance Data:

In accordance with FDA guidance document, "Cutaneous Electrodes for Recording Purposes- Performance Criteria for Safety and Performance Based Pathway", issued on August, 14, 202, the following performance data were provided to demonstrate safety and efficacy in support of substantial equivalence determination:

- Electrical Performance
  - AC Impedance per FDA-recognized consensus standard, ANSI/AAMI EC12 *Disposable ECG Electrodes*
  - Offset Voltage per FDA-recognized consensus standard, ANSI/AAMI EC12 *Disposable ECG Electrodes*
  - Combined offset instability and internal noise per FDA-recognized consensus standard, ANSI/AAMI EC12 *Disposable ECG Electrodes*
  - Bias Current Voltage (DC Voltage Offset) per FDA-recognized consensus standard, ANSI/AAMI EC12 *Disposable ECG Electrodes*
- Shelf life testing per FDA-recognized consensus standards, ANSI/AAMI EC12 *Disposable ECG Electrodes* and IEC 60601-2-2 *Medical electrical equipment- Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

- Biocompatibility testing per ISO 10993-1, ISO 10993-5, and ISO 10993-10

Summary:

The Ceribell Instant EEG Headcap 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 Headcap is substantially equivalent to the cleared predicate device.