August 30, 2021

Ceribell, Inc.
Raymond Woo, PhD
CTO
2483 Old Middlefield Way, Suite 120
Mountain View, California 94043

Re: K210805
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: August 18, 2021
Received: August 19, 2021

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 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)*
K210805

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 2 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:

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

K171459: Ceribell Instant EEG Headband (Predicate Device #1)
K200162: Wuhan Greentek Disposable EEG Electrodes (MODEL: DL, E-CAP, FLEX-CAP) (Predicate Device #2)

Date Prepared:

August 27, 2021

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 (K191301) 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 2 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, Indications for Use, and Technological Characteristics with the Predicate Devices:

The Subject Device and both predicate devices share the same intended use: an integrated array of cutaneous electrodes intended for the recording of EEG signals.

The Subject Device is a modified version of Predicate #1 (Ceribell Instant EEG Headband). The EEG Headband materials have been updated to allow the EEG Headband to accommodate an increased range of head sizes. This expands the intended patient population age range to include patients aged 2 and older. The number of sizes offered for the EEG Headband has been reduced from three sizes (Small, Medium, Large) to two sizes (Small, Medium/Large). The Indications for Use and labeling are updated accordingly for the modifications.

The Subject Device shares the same technological characteristics and intended use as Predicate #2 (Wuhan Greentek Disposable EEG Electrodes). Predicate #2 is available in various sizes and is intended for use on all patient ages. The Subject Device and both predicate devices use passive Ag/AgCl electrodes that are placed on a spandex blend fabric substrate.

The intended use, indications for use, and technological characteristics of the Subject Device and both predicate devices are summarized in the following table.

Attribute	**Subject Device** Modified Ceribell Instant EEG Headband	**Predicate Device #1** Ceribell Instant EEG Headband (K171459)	**Predicate Device #2** Disposable EEG Electrodes (K200162)	**Substantially equivalent?**
Classification Regulation	Class II per 21 CFR 882.1320, E Cutaneous electrode	Class II per 21 CFR 882.1320, E Cutaneous electrode	Class II per 21 CFR 882.1320, E Cutaneous electrode	Yes, the classification regulation is the same as both predicates.
Product Code	GXY, Electrode, cutaneous	GXY, Electrode, cutaneous	GXY, Electrode, cutaneous	Yes, the product code is the same as both predicates.

Attribute	**Subject Device** Modified Ceribell Instant EEG Headband	**Predicate Device #1** Ceribell Instant EEG Headband (K171459)	**Predicate Device #2** Disposable EEG Electrodes (K200162)	**Substantially equivalent?**
Intended Use	A single-use disposable headpiece with an integrated array of 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 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 passive cutaneous electrodes that are applied to the patient's head to record EEG signals when connected to an EEG recording device.	Yes, the intended use is the same as both predicates.
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 2 years and older. The Instant EEG Headband is intended for prescription use in the home, healthcare facility, or clinical research 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.	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.	Yes, the Indications for Use is substantially equivalent to both predicates. • The Indications for Use for the Subject Device are identical to those of Predicate #1 with the exception of an expanded age range of 2 years and older, instead of 6 years and older. The Indications for Use of the Subject Device are equivalent to the Indications for Use of Predicate #2, which do not state any age limit for the patient population.
Intended Patient population	2 and older	6 and older	Adults and children, no age range limitations.	Yes, both predicates have an intended patient population that includes adults and children. The specific age range of 2 and older falls within the intended patient population of Predicate #2.
Type of Patient Contact	Contacts patient scalp	Contacts patient scalp	Contacts patient scalp.	Yes, the type of patient contact is the same as both predicates.
Type of Use	Single use, non-sterile, disposable.	Single use, non-sterile, disposable.	Non-sterile, disposable	Yes, the type of use is the same as both predicates.
Device Description	Single use, non-sterile, disposable EEG electrode array consisting of: • 10 silver/silver-chloride (Ag/AgCl) electrodes • Plastic packet gel reservoirs pre-filled with conductive electrolyte gel • Integrated single-cable connector to connect to an EEG recording device • A spandex blend fabric headband to secure the electrodes to the patient	Single use, non-sterile, disposable EEG electrode array consisting of: • 10 silver/silver-chloride (Ag/AgCl) electrodes • Plastic packet gel reservoirs pre-filled with conductive electrolyte gel • Integrated single-cable connector to connect to an EEG recording device • A spandex blend fabric headband to secure the electrodes to the patient	Single use, non-sterile, disposable EEG electrode array with three models (DL, E-CAP, FLEX-CAP) consisting of: • Between 2 to 128 silver/silver-chloride (Ag/AgCl) electrodes (E-CAP and DL: coated Ag/AgCL electrodes; FLEX-CAP: printed Ag/AgCl electrodes) • Integrated single-cable connector to connect to an EEG recording device • A spandex blend fabric headcap to secure the electrodes to the patient	Yes. • The device description is the same as of Predicate #1 • The Subject Device and both predicate devices contain an integrated array of silver/silver-chloride (Ag/AgCl) electrodes intended to acquire EEG signals. • The Subject Device and both predicate devices include an integrated single cable connector for connection to EEG recording device. • The Subject Device and both predicate devices affix the electrodes to a spandex blend fabric headpiece that is placed on the patient's head.
Available Sizes	Small (45.1 – 54.5cm) Medium/Large (53.3-62.0cm)	Small (48.4 – 53.6 cm) Medium (53.3 – 56.5 cm) Large (55.5 – 62 cm)	Various sizes (overall head size range 26cm – 66cm)	Yes, the available sizes fall within the available sizes of Predicate #2.

Attribute	**Subject Device** Modified Ceribell Instant EEG Headband	**Predicate Device #1** Ceribell Instant EEG Headband (K171459)	**Predicate Device #2** Disposable EEG Electrodes (K200162)	**Substantially equivalent?**
Number of Electrodes	10 (Locations: Fp1, F7, T3, T5, O1, Fp2, F8, T4, T6, O2)	10 (Locations: Fp1, F7, T3, T5, O1, Fp2, F8, T4, T6, O2)	Various configurations supporting between 2 to 128 electrodes.	Yes. • The number of electrodes is the same as Predicate #1. • The number of electrodes falls within the possible customizable number of electrodes of Predicate #2 (between 2 to 128 electrodes).
Conductive Electrolyte Gel	Conductive electrolyte gel is included in sealed gel packets integrated into each electrode assembly. User is also able to add additional electrolyte gel when needed using a syringe.	Conductive electrolyte gel is included in sealed gel packets integrated into each electrode assembly. User is also able to add additional electrolyte gel when needed using a syringe.	Conductive electrolyte gel is not included. User applies conductive gel with a syringe.	Yes, the Subject Device and both predicates use conductive electrolyte gel to form an electrical connection between the patient scalp and the Ag/AgCl electrode.

Performance Data:

The following performance data were provided to demonstrate safety and efficacy in support of substantial equivalence determination:

- Biocompatibility testing per ISO 10993-1, ISO 10993-5, and ISO 10993-10
- Bench testing and simulated use testing to verify system performance including testing and evaluation to ANSI EC12-2000 and IEC 60601-1 requirements.
- Shelf life testing

Summary:

The modified Ceribell Instant EEG Headband has the same intended use as the predicate devices. 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 modified Ceribell Instant EEG Headband is substantially equivalent to the cleared predicate devices.