August 7, 2023

Ceribell, Inc.
Raymond Woo
CTO
360 North Pastoria Avenue
Sunnyvale, California 94085

Re: K232052
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 10, 2023
Received: July 10, 2023

Dear Mr. 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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director
THT5B3: 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)*
K232052

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. 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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K232052 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 Ave
Sunnyvale, California 94085

Contact Person:

Raymond Woo, PhD
CTO
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 Device:

K210805, Ceribell Instant EEG Headband (Ceribell, Inc.)

Date Prepared:

July 10, 2023

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. 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 device is identical to the predicate device with exception of the modified Indications for Use Statement and associated labeling.

Performance Data:

None required.

Summary:

The modified Ceribell Instant EEG Headband has the same intended use as the predicate devices. In addition, it has the same technological characteristic. Therefore, the modified Ceribell Instant EEG Headband is substantially equivalent to the cleared predicate device.