April 3, 2026

Ceribell, Inc.
Raymond Woo
Chief Technology Officer
360 N. Pastoria Ave.
Sunnyvale, California 94085

Re: K260363
Trade/Device Name: Ceribell Brain Monitor Headband
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: February 3, 2026
Received: February 4, 2026

Dear Raymond 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Tushar Bansal, PhD
Acting 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260363

Please provide the device trade name(s).

Ceribell Brain Monitor Headband

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary – K260363

1. SUBMITTER

Ceribell, Inc.
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Date Prepared: April 01, 2026

2. DEVICE

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

3. PREDICATE DEVICE

Primary: Ceribell Instant EEG Headset, K254033
Secondary: Ceribell Instant EEG Headband, K232052

4. DEVICE DESCRIPTION

The Ceribell Brain Monitor Headband is a single-use, non-sterile, disposable EEG electrode device that includes 10 EEG electrodes that are placed on the subject's scalp. The headband is a prescription-use device intended to collect and provide EEG signals to an EEG recording or monitoring device.

The Ceribell Brain Monitor Headband includes the following components:

- Elastic fabric headband
- Electrode assemblies, each consisting of the following:
  - Passive silver/silver chloride (Ag/AgCl) electrode
  - Reservoir filled with conductive electrolyte gel

- Mechanism for dispensing gel onto patient scalp
- Scalp-contacting prongs to prepare scalp for electrode contact
- Scalp-contacting foam rings for added comfort

- Cable attached to the headband to allow connection to an EEG acquisition/recording device

5. INDICATIONS FOR USE

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

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

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

Attribute	**Primary Predicate Device** Ceribell Instant EEG Headset (K254033)	**Secondary Predicate Device** Ceribell Instant EEG Headband (K232052)	**Subject Device** Ceribell Brain Monitor Headband	**Comparison**
Classification Regulation	Class II per 21 CFR 882.1320, Cutaneous Electrode	Class II per 21 CFR 882.1320, Cutaneous Electrode	Same as **both predicates**.	Same
Product Code	GXY, Electrode, cutaneous	GXY, Electrode, cutaneous; GWQ, full-montage standard electroencephalograph	GXY, Electrode, cutaneous	Same
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.	Same as **both predicates**.	Same
Indications for Use	The Ceribell Instant EEG Headset is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired.	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.	The Ceribell Brain Monitor Headband is intended for use in routine clinical settings where rapid placement of a number of EEG electrodes is desired.	The subject device and both predicate devices include the same intended use as passive cutaneous electrodes for EEG. The subject device indications for use is identical

Attribute	Primary Predicate Device Ceribell Instant EEG Headset (K254033)	Secondary Predicate Device Ceribell Instant EEG Headband (K232052)	Subject Device Ceribell Brain Monitor Headband	Comparison
				to the primary predicate.
Intended Patient Population	Patients within the head size range of 45.1cm – 62.0cm. Not intended for use in neonates/newborns.	Any patient within the head size range of 45.1cm – 62.0cm	Patients within the head size range of 45.1cm – 62.0cm. Not intended for use in neonates/newborns.	Same
Type of Patient Contact	Contacts patient's scalp	Contacts patient's scalp	Same as **both predicates**.	Same
Type of Use	Single use, non-sterile, disposable	Single use, non-sterile, disposable	Same as **both predicates**.	Same
Device Description	Single use, non-sterile, disposable EEG electrode array consisting of: - Silver/silver-chloride (Ag/AgCl) electrodes - Plastic packet gel reservoirs pre-filled with conductive electrolyte gel - Integrated cable connector to connect to an EEG recording device - A spandex blend fabric headset to secure the electrodes to the patient	Single use, non-sterile, disposable EEG electrode array consisting of: - Silver/silver-chloride (Ag/AgCl) electrodes - Plastic packet gel reservoirs pre-filled with conductive electrolyte gel - Integrated 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: - Silver/silver-chloride (Ag/AgCl) electrodes - Plastic packet gel reservoirs pre-filled with conductive electrolyte gel - Integrated cable connector to connect to an EEG recording device - A spandex blend fabric headband to secure the electrodes to the patient	Same
Principle of Operation	Appropriately sized headset is fit on the patient's head. Hair is cleared from the electrode contact surface and the skin prepared for electrode connection. Electroconductive gel is applied to the scalp contact area, creating a conductive bridge from the scalp to the headset electrodes. The cable of the headset is connected to an EEG acquisition/recording device for recording of EEG signals.	Appropriately sized headband is fit on the patient's head. Hair is cleared from the electrode contact surface and the skin prepared for electrode connection. Electroconductive gel is applied to the scalp contact area, creating a conductive bridge from the scalp to the headband electrodes. The cable of the headband is connected to an EEG acquisition/recording device for recording of EEG signals.	Same as **both predicates**.	Same
Number of Electrodes	Up to 20 electrodes.	Ten (10) electrodes.	Ten (10) electrodes.	The number of electrodes in the subject device is the same as the secondary predicate.
Electrode Locations	The placement of the electrodes is according to	Electrode locations using the 10-20 naming	Electrode locations using the 10-20 naming	Same

Attribute	Primary Predicate Device Ceribell Instant EEG Headset (K254033)	Secondary Predicate Device Ceribell Instant EEG Headband (K232052)	Subject Device Ceribell Brain Monitor Headband	Comparison
	the International 10-20 system of electrode placement. The number of electrodes in use is according to the needs of clinical practice.	convention are: Fp1, F7, T3, T5, and O1 on the left side; Fp2, F8, T4, T6, and O2 on the right side.	convention are: Fp1, F7, T3, T5, and O1 on the left side; Fp2, F8, T4, T6, and O2 on the right side.	
Available Sizes	Various sizes (overall head size range 45.1cm – 62.0cm)	Various sizes (overall head size range 45.1cm – 62.0cm)	Same as **both predicates**.	Same
Patient-Contacting Materials	• Nylon/Spandex blend • Thermoplastic elastomer (TPE) • Aluminum oxide powder • UV adhesive • Electroconductive gel	• Nylon/Spandex blend • Thermoplastic elastomer (TPE) • Aluminum oxide powder • UV adhesive • Electroconductive gel	• Nylon/Spandex blend • Polyurethane (PUR) foam • Thermoplastic elastomer (TPE) • Aluminum oxide powder • UV adhesive • Electroconductive gel	The subject device patient-contacting materials are the same, with the addition of a PUR foam.
Biocompat-ibility	ISO 10993-1 ISO 10993-5 (Cytotoxicity) ISO 10993-10 (Sensitization) ISO 10993-23 (Irritation or Intracutaneous Reactivity) Attachment G of FDA's 2023 Biocompatibility Guidance	ISO 10993-1 ISO 10993-5 (Cytotoxicity) ISO 10993-10 (Sensitization) ISO 10993-23 (Irritation or Intracutaneous Reactivity)	ISO 10993-1 ISO 10993-5 (Cytotoxicity) ISO 10993-10 (Sensitization) ISO 10993-23 (Irritation or Intracutaneous Reactivity) Attachment G of FDA's 2023 Biocompatibility Guidance	Biocompatibility evaluations are the same and follow the FDA guidance document "*Cutaneous Electrodes for Recording Purposes- Performance Criteria for Safety and Performance Based Pathway*", August 2020.
Cable	0.1m – 3.0m integrated cable	0.1m – 3.0m integrated cable	Same as **both predicates**.	Same
Electrical Performance	ANSI/AAMI EC12 • Average AC Impedance: ≤ 2 kΩ (individual pairs ≤ 3kΩ)	ANSI/AAMI EC12 • Average AC Impedance: ≤ 2 kΩ (individual pairs ≤ 3kΩ)	Same as **both predicates**.	Electrical performance evaluations are the same and follow the FDA guidance document "*Cutaneous Electrodes for*

Attribute	Primary Predicate Device Ceribell Instant EEG Headset (K254033)	Secondary Predicate Device Ceribell Instant EEG Headband (K232052)	Subject Device Ceribell Brain Monitor Headband	Comparison
	• DC Offset Voltage: ≤ 100 mV • Combined Offset Instability and Internal Noise: ≤ 150 µV • Bias Current Tolerance: ≤ 100 mV	• DC Offset Voltage: ≤ 100 mV • Combined Offset Instability and Internal Noise: ≤ 150 µV • Bias Current Tolerance: ≤ 100 mV		*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	• 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	Same as **both predicates**.	Electrical connection compliance requirements are the same and follow the FDA guidance document "*Cutaneous Electrodes for Recording Purposes- Performance Criteria for Safety and Performance Based Pathway*", August 2020.

The results of the completed evaluations and testing demonstrate that any differences do not raise different questions of safety and effectiveness, and the performance data demonstrate acceptable safety and performance compared to the predicate devices.

7. PERFORMANCE DATA

In accordance with the FDA guidance document, "*Cutaneous Electrodes for Recording Purposes- Performance Criteria for Safety and Performance Based Pathway*", issued on August 14, 2020, the following performance data were provided to demonstrate safety and efficacy in support of substantial equivalence determination.

Electrode Characterization:

- Electrical Performance per FDA-recognized consensus standard, ANSI/AAMI EC12 *Disposable ECG Electrodes*

  - AC Impedance
  - Offset Voltage
  - Combined offset instability and internal noise
  - Bias Current Voltage (DC Voltage Offset)
- Shelf-Life 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*
- Conductive Connection Compliance – The design of the subject device is in conformance with subclause 8.5.2.3 of FDA-recognized consensus standard, ANSI/AAMI ES 60601-1 *Medical Electrical Equipment Part 1 – General requirements for basic safety and essential performance.*

Biocompatibility Evaluation:

- Biocompatibility per ISO 10993-1, ISO 10993-5, ISO 10993-10, and ISO 10993-23. The biocompatibility of the subject device is also based on the use of skin-contacting, low biocompatibility risk materials with a long history of safe use in accordance with Attachment G of the FDA/s 2023 Biocompatibility Guidance.

8. SUMMARY

The Ceribell Brain Monitor Headband has the same intended use as the predicate devices. The differences in technological characteristics do not raise different questions of safety and effectiveness, and the performance data demonstrate that the Ceribell Brain Monitor Headband is substantially equivalent to the cleared predicate devices.