June 30, 2026

Ceribell, Inc.
Raymond Woo, PhD
Cto
360 N. Pastoria Ave.
Sunnyvale, California 94085

Re: K261101
Trade/Device Name: Ceribell Monitor
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMC, GWQ
Dated: April 2, 2026
Received: April 2, 2026

Dear Dr. 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,

Patrick Antkowiak -S

for
Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic 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.	K261101

Please provide the device trade name(s).

Ceribell Monitor

Please provide your Indications for Use below.

The Ceribell Monitor is intended to acquire, transmit, display and store electroencephalogram (EEG) and optionally electrocardiogram (ECG) and video. The Ceribell Monitor is intended for prescription use in professional healthcare facilities.

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)
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

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510(k) Summary – K261101

1. SUBMITTER

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

Contact Person: Raymond Woo, PhD
Chief Technical Officer
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Alternative Contact: Tom McDougal
Director, Regulatory Affairs
E-mail: tom.mcdougal@ceribell.com

Date Prepared: June 8, 2026

2. DEVICE

Trade Name:	Ceribell Monitor
Common Name:	Reduced-Montage Standard Electroencephalograph
Classification:	Electroencephalograph (21 CFR 882.1400)
Device Class:	II
Product Code:	OMC, GWQ

3. PREDICATE DEVICES

Primary: Ceribell Pocket EEG Device, K170363
Secondary: Neuronaute Plus, K231366

4. DEVICE DESCRIPTION

The Ceribell Monitor is a portable, full-montage EEG system intended to acquire, transmit, display and store electroencephalogram (EEG) and optional electrocardiogram (ECG) and video signals. The Ceribell Monitor includes the following components:

- Ceribell Monitor Device: a portable, full-montage EEG monitoring system
- Power adapter: 100-240V AC power adapter used to charge and power the Ceribell Monitor
- USB cable: optional cable used to connect to a computer to transfer EEG recording files

- EEG Connector extension cable: optional cable used to extend the total cable length to the EEG electrodes
- ECG Connector cable: optional cable used to allow connection of ECG electrodes

5. INDICATIONS FOR USE

The Ceribell Monitor is intended to acquire, transmit, display and store electroencephalogram (EEG) and optionally electrocardiogram (ECG) and video. The Ceribell Monitor is intended for prescription use in professional healthcare facilities.

6. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Compared to the predicate devices, the subject device has the same intended use. The following table summarizes the substantial equivalence comparison between the subject device and the predicate devices.

Attribute	**Primary Predicate Device** Pocket EEG Device (K170363)	**Secondary Predicate Device** Neuronaute Plus (K231366)	**Subject Device** Ceribell Monitor	**Substantially Equivalent?**
Product Codes	OMC, GWQ	GWQ, GXY	OMC, GWQ	Yes, the subject device product codes are utilized by the predicates.
Indications for Use	The Ceribell Pocket EEG Device is intended to record and store EEG signals, and to present the EEG signals in visual and audible formats in real time. The visual and audible signals assist trained medical staff to make neurological diagnoses.	The Neuronaute Plus is a system intended to acquire, store, archive, and periodically transmit physiological signals from the brain using a full montage array to enable review at a physician's office, hospital, or other remote locations. It allows remote access by users via the BioSerenity Cloud. The Neuronaute Plus and its associated software are intended	The Ceribell Monitor is intended to acquire, transmit, display and store electroencephalogram (EEG) and optionally electrocardiogram (ECG) and video. The Ceribell Monitor is intended for prescription use in professional healthcare facilities.	Yes, the Indications for Use statements all cover the recording, storage, display, and transmission of physiological signals including EEG.

Attribute	Primary Predicate Device Pocket EEG Device (K170363)	Secondary Predicate Device Neuronaute Plus (K231366)	Subject Device Ceribell Monitor	Substantially Equivalent?
	The Pocket EEG Device does not provide any diagnostic conclusion about the subject's condition and does not provide any automated alerts of an adverse clinical event. The Pocket EEG Device is intended to be used in a professional healthcare facility environment.	to assist in the diagnosis of neurological disorders. The Neuronaute Plus and its components do not provide any diagnostic conclusions or automated alerts of an adverse clinical event about a patient's clinical condition. The Neuronaute Plus is intended to be used by trained healthcare professionals, technicians or patients above 15 years old. In case of a patient below 15 years old, Neuronaute Plus is intended to be used by a care giver. Adequate training is recommended for proper use of the device. Neuronaute IceCap 2 electrodes are able to be used on patients weighing at least 10 kg and having a head circumference above 43 cm. Neuronaute is not intended to replace direct communication with healthcare providers. The system		

Attribute	**Primary Predicate Device** Pocket EEG Device (K170363)	**Secondary Predicate Device** Neuronaute Plus (K231366)	**Subject Device** Ceribell Monitor	**Substantially Equivalent?**
		data should not be used alone, but should be used along with all other clinical data and exams to come to a diagnosis. The BioSerenity Cloud allows the display of signals in order to help aid in the diagnosis of physiological disorders through the data collected by recording. The BioSerenity Cloud should allow the analysis and filtering of data in order to aid doctors in diagnosing neurological disorders.		
Intended Location of Use	Professional healthcare facilities	Professional healthcare facilities and remote locations	Professional healthcare facilities	Yes, all devices are intended for use in professional healthcare facilities.
User Interface & Display	Integrated touchscreen display	External device interface via paired iOS/Android tablet or remote web browser	Integrated touchscreen display	Yes, the subject device and primary predicate both utilize a touchscreen display.
Video Integration	No	Optional auxiliary video recording via the N-DEO IP camera component	Yes, optional integrated video recording	Yes, the subject device and the secondary predicate both capture video.
Physiological Signals	EEG signals	EEG, ECG, EMG, EOG, and breathing signals	EEG, as well as optional ECG and video signals	Yes, the subject device records a subset of the signals recorded by

Attribute	**Primary Predicate Device** Pocket EEG Device (K170363)	**Secondary Predicate Device** Neuronaute Plus (K231366)	**Subject Device** Ceribell Monitor	**Substantially Equivalent?**
				the predicates.
EEG Channels & Montage	Reduced montage array utilizing 10 electrodes	Full montage array supporting 29 unipolar and 2 bipolar channels from 21 electrodes	Full and reduced montages supporting up to 19 electrodes and 1 dedicated ECG channel	Yes, the differences in montage do not raise new questions of safety and effectiveness and the subject device's electrode count is within the range of the predicate devices and additionally supports the same reduced-montage utilized by the primary predicate.
ECG Configuration	None	2 bipolar channels configured within the multi-signal input matrix	1 dedicated auxiliary ECG channel	Yes, both the subject device and the secondary predicate support integrated ECG recording.
Sampling Rate	500 Hz	250 or 500 Hz	500 Hz	Yes, all devices support a 500 Hz sampling rate.
Frequency Response	0.5 Hz to 100 Hz	0.1 Hz to 60 Hz (at -3 dB)	0.1 Hz to 100 Hz	Yes, the subject device provides the necessary operational bandwidth required for standard diagnostic encephalographic review.
ADC Resolution	24 bits	24 bits	24 bits	Yes, the subject device and both predicates feature a 24 bit ADC

Attribute	Primary Predicate Device Pocket EEG Device (K170363)	Secondary Predicate Device Neuronaute Plus (K231366)	Subject Device Ceribell Monitor	Substantially Equivalent?
				resolution.
Input Impedance	500 Mohm	> 1 Gohm	> 1 Gohm	Yes, the input impedance profiles match the highest threshold.
Input Noise	< 6μVp-p over a 0.1-50 Hz range	< 6μVp-p over a 0.1-50 Hz range	< 6μVp-p over a 0.1-50 Hz range	Yes, noise floors are restricted to the same limits demonstrated by the predicates.
Common Mode Rejection Rate (CMRR)	110 dB at 60 Hz	≥ -80 dB at 50 Hz and 60 Hz	≥ -80 dB at 50 Hz and 60 Hz	Yes, all devices incorporate differential amplification.
Wireless Communication	Wi-Fi 2.4/5 GHz	Wi-Fi 2.4/5 GHz & Bluetooth 5.0 Low Energy	Wi-Fi 2.4, 5, and 6 GHz interfaces (supporting standard WPA/WPA2 security)	Yes, all devices use Wi-Fi communication.
Wired Interface	USB local interface	Not specified for direct local data transfer	USB local interface	Yes, both the subject device and primary predicate feature a USB interface.
Power Source	Internal battery	Internal removable battery	Internal battery or external AC power supply	Yes, the ability to function while connected to a power supply is supported by non-clinical testing and does not raise new questions of safety and effectiveness.
Battery Specifications	Internal Li-ion battery (3.6 V nominal, 8250 mAh Li-ion	Removable Li-ion battery (Varta EasyPack XL, 3.7 V nominal, 2400	Internal Li-ion battery pack (14.4 V nominal, 5000 mAh)	Yes, all devices utilize lithium-ion batteries.

Attribute	**Primary Predicate Device** Pocket EEG Device (K170363)	**Secondary Predicate Device** Neuronaute Plus (K231366)	**Subject Device** Ceribell Monitor	**Substantially Equivalent?**
	battery pack)	mAh, 8.9 Wh)		
Physical Dimensions	180 mm x 80 mm x 28 mm	90 mm × 44.2 mm × 27 mm (Core module battery housing specification)	244 mm × 234 mm × 70 mm	Yes, the differences in physical dimensions do not affect substantial equivalence.
System Weight	400 g	49 g (weight of the battery component)	2 kg	Yes, the differences in weight do not affect substantial equivalence.
Mounting / Wearability	Tabletop / handheld	Wearable textile holding band worn over patient clothing	Integrated IV pole clamp / portable	Yes, mounting mechanisms align with intended workflows; the subject and primary predicate devices can be optionally secured to hospital infrastructure, whereas the secondary predicate attaches to the body.
Defibrillator Compatibility	Not defibrillation proof	Not defibrillation proof	Not defibrillation proof	Yes, all devices require immediate removal from the patient prior to executing external defibrillation shocks.
Magnetic Resonance (MR) Safety	MR Unsafe	MR Unsafe	MR Unsafe	Yes, all devices are categorized as MR Unsafe.

7. PERFORMANCE DATA

The following performance data were submitted to support a determination of substantial equivalence:

- Requirements for the basic safety and essential performance of electroencephalographs per IEC 80601-2-26
- Electromagnetic Compatibility and Electrical Safety Testing performed to applicable requirements of IEC 60601-1 and IEC 60601-1-2
- Wireless Coexistence Testing per C63.27
- Battery Safety Testing per IEC 62133
- Bench testing to verify system performance
- Shipping/distribution and vibration testing per ASTM D7386
- Software verification and validation testing per FDA Guidance for Industry and FDA Staff, “Content of Premarket Submissions for Device Software Functions.” and IEC 62304

8. SUMMARY

The Ceribell Monitor has the same intended use as both predicate devices. In addition, it has similar technological characteristics, clinical workflow, and underlying operating principles. Differences within the Ceribell Monitor have been validated through safety and performance testing. Therefore, the Ceribell Monitor is substantially equivalent to the cleared predicate devices.