June 24, 2026

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

Re: K260998
Trade/Device Name: Ceribell Neurology Review Software
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMB, OLT
Dated: March 26, 2026
Received: March 26, 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260998

Device Name
Ceribell Neurology Review Software

Indications for Use *(Describe)*
The Ceribell Neurology Review Software is intended for the review, monitoring and analysis of EEG recordings made by electroencephalogram (EEG) devices using scalp electrodes and to aid neurologists in the assessment of EEG. This device is intended to be used by qualified clinical practitioners who will exercise professional judgment in using the information.

The Artifact Reduction component is intended to reduce artifact in EEG recordings. The Artifact Reduction component does not remove the entire artifact signal and may modify portions of waveforms representing cerebral activity. Waveforms must still be read by a qualified clinical practitioner trained in recognizing artifact, and any interpretation or diagnosis must be made with reference to the original waveforms.

The Epileptiform Abnormality Detection component is intended to mark previously acquired sections of the patient's EEG recordings that may correspond to epileptiform abnormalities in order to assist qualified clinical practitioners in the assessment of EEG traces. The Epileptiform Abnormality Detection component is intended to be used in patients at least one year old.

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.

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510(k) Summary – K260998

1. SUBMITTER

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Director, Regulatory Affairs
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Date Prepared: March 23, 2026

2. DEVICE

Trade Name: Ceribell Neurology Review Software
Common Name: Automatic Event Detection Software for Full-Montage Electroencephalograph
Classification: Electroencephalograph (21 CFR 882.1400)
Device Class: II
Product Code: OMB, OLT

3. PREDICATE DEVICES

Primary: encevis, K240993
Secondary: autoSCORE, K243743

4. DEVICE DESCRIPTION

The Ceribell Neurology Review Software is intended for analyzing EEG data acquired from legally marketed EEG devices to aid qualified clinical practitioners in the review of EEG data. In particular, the subject device is intended to reduce artifact and identify sections of EEG that may correspond to epileptiform abnormalities.

5. INDICATIONS FOR USE

The Ceribell Neurology Review Software is intended for the review, monitoring and analysis of EEG recordings made by electroencephalogram (EEG) devices using scalp electrodes and to aid neurologists in the assessment of EEG. This device is intended to be used by qualified clinical practitioners who will exercise professional judgment in using the information.

The Artifact Reduction component is intended to reduce artifact in EEG recordings. The Artifact Reduction component does not remove the entire artifact signal and may modify portions of waveforms representing cerebral activity. Waveforms must still be read by a qualified clinical practitioner trained in recognizing artifact, and any interpretation or diagnosis must be made with reference to the original waveforms.

The Epileptiform Abnormality Detection component is intended to mark previously acquired sections of the patient's EEG recordings that may correspond to epileptiform abnormalities in order to assist qualified clinical practitioners in the assessment of EEG traces. The Epileptiform Abnormality Detection component is intended to be used in patients at least one year old.

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** encevis (K240993)	**Secondary Predicate Device** autoSCORE (K243743)	**Subject Device** Ceribell Neurology Review Software	**Comparison**
Product Codes	OMB, OLT, OMA	OMB	OMB, OLT	Same
Indications for Use	(Only relevant portions of the Indications for Use are replicated here) 1. encevis is intended for the review, monitoring and analysis of EEG recordings made by electroencephalogram (EEG) devices using scalp electrodes and to aid neurologists in the	(Only relevant portions of the Indications for Use are replicated here) 1. autoSCORE is intended for the review, monitoring and analysis of EEG recordings made by electroencephalogram (EEG) devices using scalp electrodes and to aid	The Ceribell Neurology Review Software is intended for the review, monitoring and analysis of EEG recordings made by electroencephalogram (EEG) devices using scalp electrodes and to aid neurologists in the	The subject device and both predicates are indicated for the review, monitoring, and analysis of EEG recordings. The Indications for Use of the Artifact Reduction

Attribute	Primary Predicate Device encevis (K240993)	Secondary Predicate Device autoSCORE (K243743)	Subject Device Ceribell Neurology Review Software	Comparison
	assessment of EEG. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information. 7. encevis PureEEG (Artifact Reduction) is intended to reduce EMG and electrode artifacts in a standard 10-20 EEG recording. PureEEG does not remove the entire artifact signal and is not effective for other types of artifacts. PureEEG may modify portions of waveforms representing cerebral activity. Waveforms must still be read by a qualified medical practitioner trained in recognizing artifact, and any interpretation or diagnosis must be made with reference to the original waveforms.	neurologists in the assessment of EEG. This device is intended to be used by qualified medical practitioners who will exercise professional judgment in using the information. 3. autoSCORE is intended to assess the probability that previously acquired sections of EEG recordings contain abnormalities, and classifies these into pre-defined types of abnormalities, including epileptiform and non-epileptiform abnormalities. autoSCORE does not have a user interface. autoSCORE sends this information to the EEG reviewing software to indicate where markers indicating abnormality are to be placed in the EEG. autoSCORE also provides the probability that EEG recordings include abnormalities and the type of abnormalities. The user is required to review the EEG and exercise their clinical judgement to independently make a conclusion supporting or not supporting brain disease.	assessment of EEG. This device is intended to be used by qualified clinical practitioners who will exercise professional judgment in using the information. The Artifact Reduction component is intended to reduce artifact in EEG recordings. The Artifact Reduction component does not remove the entire artifact signal and may modify portions of waveforms representing cerebral activity. Waveforms must still be read by a qualified clinical practitioner trained in recognizing artifact, and any interpretation or diagnosis must be made with reference to the original waveforms. The Epileptiform Abnormality Detection component is intended to mark previously acquired sections of the patient's EEG recordings that may correspond to epileptiform abnormalities in order to assist qualified clinical practitioners in the assessment of EEG traces. The Epileptiform Abnormality Detection component is intended to be used in patients at least one year old.	component of the subject device is shared with encevis and the Indications for Use of the Epileptiform Abnormality Detection component of the subject device is shared with autoSCORE.
Intended Patient Population	Adults	> 3 months	Ages 1+	As demonstrated by clinical performance data, age range for

Attribute	Primary Predicate Device encevis (K240993)	Secondary Predicate Device autoSCORE (K243743)	Subject Device Ceribell Neurology Review Software	Comparison
				the subject device does not raise any new or different questions of safety or effectiveness.
Intended Location of Use	Professional healthcare facilities	Professional healthcare facilities	Professional healthcare facilities	Same

7. NON-CLINICAL TESTING

Software verification and validation testing was conducted, and documentation provided as recommended by FDA Guidance for Industry and FDA Staff, "*Content of Premarket Submissions for Device Software Functions*."

Software verification and validation activities support the safety and effectiveness of the Ceribell Neurology Review Software.

8. PERFORMANCE DATA

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

Artifact Reduction

The Artifact Reduction module is validated using a dataset of 120 EEG recordings collected from three geographically diverse clinical sites. This dataset represents real-world clinical use cases without any inclusion/exclusion criteria applied.

A Clinical Reference Standard was established by three expert EEG reviewers who identified segments containing common artifacts (EKG, eye blinks, EMG, and electrical noise). Consensus was defined as agreement between at least two of the three reviewers.

The Ceribell Artifact Reduction algorithm was compared against a legally marketed artifact reduction algorithm (Persyst) using two primary metrics: Signal-to-Noise Ratio (SNR) Improvement and Waveform Distortion. A non-inferiority analysis was performed to ensure the Ceribell algorithm effectively reduces artifact while maintaining the integrity of the underlying EEG signal.

Performance Measure	Paired Difference [Ceribell - Persyst] [95% CI]	Result
SNR Improvement (dB)	1.12 [0.51, 1.74]	**Pass** (Non-Inferior)
Waveform Distortion (%)	-2.40 [-3.92, -0.88]	**Pass** (Non-Inferior)

This analysis was also performed at each of the three contributing sites to ensure generalizable performance. This analysis is provided below.

Site	SNR Improvement (Ceribell - Persyst)	Distortion (Ceribell - Persyst)
Temple University Hospital (n=14)	Ceribell: 7.38 Persyst: 5.37 Difference: 2.01 dB [0.75, 3.26]	Ceribell: 11.6% Persyst: 14.1% Difference: -2.49% [-5.61%, 0.64%]
Stanford Hospital (n=14)	Ceribell: 8.06 Persyst: 6.81 Difference: 1.25 dB [0.30, 2.20]	Ceribell: 8.66% Persyst: 11.3% Difference: -2.67% [-4.26%, -1.07%]
Massachusetts General Hospital (n=12)	Ceribell: 8.35 Persyst: 8.30 Difference: 0.05 dB [-1.00, 1.10]	Ceribell: 13.6% Persyst: 15.5% Difference: -1.92% [-5.55%, 1.71%]
All sites	Ceribell: 7.95 Persyst: 6.82 Difference: 1.12 dB [0.505, 1.74]	Ceribell: 11.0% Persyst: 13.4% Difference: -2.40% [-3.92%, -0.88%]

Epileptiform Abnormality Detection

The Epileptiform Abnormality Detection module is validated by evaluating the performance of the epileptiform abnormality detection algorithm on a dataset of EEG recordings representative of the intended patient population. The validation dataset consisted of EEG recordings obtained from patients 1 year of age and older (n=1,362) who received continuous EEG monitoring within the hospital environment. There were no patient inclusion or exclusion criteria applied. To form the reference standard for epileptiform abnormalities, the EEG recordings were retrospectively reviewed by a panel of three expert neurologists. A two-thirds majority agreement was required to form a determination of epileptiform abnormalities.

The reviewing neurologists did not have access to any of the outputs from the Epileptiform Abnormality Detection module; the experts were fully blinded. Importantly, none of the data in the validation dataset were used for training of the epileptiform abnormality detection algorithm; the validation dataset is completely independent.

Acceptance Criteria

Performance of the Epileptiform Abnormality Detection algorithm was assessed by evaluating the positive percent agreement (PPA) and the false positive rate per hour (FP/hr) of the algorithm compared to the expert reviewer reference standard:

- PPA: For each threshold of Epileptiform Abnormality Burden activity (Frequent, Abundant, Continuous) **Lower bound of the 95% confidence interval ≥ 70% PPA**
- FP/hr: For each threshold of Epileptiform Abnormality Burden activity (Frequent, Abundant, Continuous) **Upper bound of the 95% confidence interval ≤ 0.446 FP/hr**

Device Performance

Performance against the acceptance criteria was assessed. In the overall dataset, the acceptance criteria were met and the Epileptiform Abnormality Detection algorithm passes. The detailed results for PPA and FP/hr are shown in the following table:

Activity Category	Positive Percent Agreement (PPA)	95% Confidence Interval	False Positive Rate (FP/hr)	95% Confidence Interval	Pass / Fail
Epileptiform Abnormality Episodes with Epileptiform Abnormality Burden ⩾ 10% (meeting ACNS definition of 'Frequent' activity)	98.29%	[93.35, 99.44]	0.286	[0.270, 0.302]	Pass
Epileptiform Abnormality Episodes with Epileptiform Abnormality Burden ⩾ 50% (meeting ACNS definition of 'Abundant' activity)	98.95%	[94.48, 100.00]	0.142	[0.130, 0.154]	Pass
Epileptiform Abnormality Episodes with Epileptiform Abnormality Burden ⩾ 90% (meeting ACNS definition of 'Continuous' activity)	94.37%	[86.62, 98.59]	0.052	[0.045, 0.060]	Pass
Acceptance Criteria: PPA: Lower bound of the 95% confidence interval ⩾ 70% PPA FP/hr: Upper bound of the 95% confidence interval ⩽ 0.446 FP/hr					

Performance was also evaluated across subject age. The results for PPA and FP/hr are shown in the following table:

Activity Category	Age (yrs)	Positive Percent Agreement (PPA)	95% Confidence Interval	False Positive Rate (FP/hr)	95% Confidence Interval
Epileptiform Abnormality Episodes with Burden ≥10% (meeting ACNS definition of 'Frequent' activity)	1-11	98.15%	[90.20, 100.00]	0.350	[0.315, 0.386]
	12-17	96.3%	[81.48, 100.00]	0.265	[0.234, 0.297]
	18+	98.94%	[94.38, 100.00]	0.268	[0.248, 0.289]
	Overall	98.29%	[93.35, 99.44]	0.286	[0.270, 0.302]
	1-11	100.0%	[100, 100]	0.178	[0.151, 0.206]

Epileptiform Abnormality Episodes with Burden ≥50% (meeting ACNS definition of 'Abundant' activity)	12-17	100.0%	[100, 100]	0.099	[0.081, 0.123]
	18+	98.51%	[92.31, 100]	0.146	[0.130, 0.163]
	Overall	98.95%	[94.48, 100]	0.142	[0.130, 0.154]
Epileptiform Abnormality Episodes with Burden ≥90% (meeting ACNS definition of 'Continuous' activity)	1-11	100.0%	[100, 100]	0.071	[0.054, 0.092]
	12-17	100.0%	[100, 100]	0.038	[0.025, 0.056]
	18+	92.16%	[81.63, 98.04]	0.050	[0.040, 0.062]
	Overall	94.37%	[86.62, 98.59]	0.052	[0.045, 0.060]

The below table presents the epileptiform abnormality episode count across each burden level and age subgroup:

Activity Category	1-11	12-17	18+	Total
≥10% burden	54	27	94	175
≥50% burden	20	8	67	95
≥90% burden	11	9	51	71

9. SUMMARY

The Ceribell Neurology Review Software 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 Neurology Review Software have been validated through performance testing. Therefore, the Ceribell Neurology Review Software is substantially equivalent to the cleared predicate devices.