November 21, 2025

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

Re: K252070
Trade/Device Name: Ceribell Infant Seizure Detection Software
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMB
Dated: October 23, 2025
Received: October 23, 2025

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252070

Device Name
Ceribell Infant Seizure Detection Software

Indications for Use *(Describe)*
The Ceribell Infant Seizure Detection Software is intended to mark previously acquired sections of EEG recordings in newborns (defined as preterm or term neonates of 25-44 weeks postmenstrual age) and infants less than 1 year of age that may correspond to electrographic seizures in order to assist qualified clinical practitioners in the assessment of EEG traces. The Seizure Detection Software also provides notifications to the user when detected seizure prevalence is "Frequent", "Abundant", or "Continuous", per the definitions of the American Clinical Neurophysiology Society Guideline 14. Delays of up to several minutes can occur between the beginning of a seizure and when the Seizure Detection notifications will be shown to a user.

The Ceribell Infant Seizure Detection Software does not provide any diagnostic conclusion about the subject's condition and Seizure Detection notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a trained expert.

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 - K252070

1. SUBMITTER

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Sunnyvale, California 94085

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Regulatory Affairs Manager
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Date Prepared: November 11, 2025

2. DEVICE

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

3. PREDICATE DEVICE

Ceribell Seizure Detection Software, K241589

4. DEVICE DESCRIPTION

The Ceribell Infant Seizure Detection Software is a software-only device that is intended to mark previously acquired sections of EEG recordings that may correspond to electrographic seizures in order to assist qualified clinical practitioners in the assessment of EEG traces.

5. INDICATIONS FOR USE

The Ceribell Infant Seizure Detection Software is intended to mark previously acquired sections of EEG recordings in newborns (defined as preterm or term neonates of 25-44 weeks postmenstrual age) and infants less than 1 year of age that may correspond to electrographic seizures in order to assist qualified clinical practitioners in the assessment of EEG traces. The Seizure Detection Software also provides notifications to the user when detected seizure prevalence is "Frequent", "Abundant", or "Continuous", per the definitions of the American Clinical Neurophysiology Society Guideline 14. Delays of up to several minutes can occur between the beginning of a seizure and when the Seizure Detection notifications will be shown to a user.

The Ceribell Infant Seizure Detection Software does not provide any diagnostic conclusion about the subject's condition and Seizure Detection notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a trained expert.

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

Compared to the predicate device, the subject device has the same intended use and is indicated for an expanded patient population under 1 year of age. The subject device software algorithm has been updated and clinically validated for the intended patient population. Apart from the difference in indicated patient population, the subject device and predicate device share the same technological characteristics, clinical workflow, and underlying operating principles. The following table summarizes the substantial equivalence comparison between the subject device and the predicate device.

Attribute	**Predicate Device** Ceribell Seizure Detection Software (K241589)	**Subject Device** Ceribell Infant Seizure Detection Software	**Comparison**
Intended Use	The Ceribell Seizure Detection Software is intended to mark previously acquired sections EEG recordings that may correspond to electrographic seizures in order to assist qualified clinical practitioners in the assessment of EEG traces.	The Ceribell Infant Seizure Detection Software is intended to mark previously acquired sections EEG recordings that may correspond to electrographic seizures in order to assist qualified clinical practitioners in the assessment of EEG traces.	Same
Indications for Use	The Ceribell Seizure Detection Software is intended to mark previously acquired sections of EEG recordings in patients greater or equal to 1 year of age	The Ceribell Infant Seizure Detection Software is intended to mark previously acquired sections of EEG recordings in newborns (defined as preterm or term	Yes, the revised indications for use fall within the same intended use as that of the predicate device. As

Attribute	Predicate Device Ceribell Seizure Detection Software (K241589)	Subject Device Ceribell Infant Seizure Detection Software	Comparison
	that may correspond to electrographic seizures in order to assist qualified clinical practitioners in the assessment of EEG traces. The Seizure Detection Software also provides notifications to the user when detected seizure prevalence is "Frequent", "Abundant", or "Continuous, per the definitions of the American Clinical Neurophysiology Society Guideline 14. Delays of up to several minutes can occur between the beginning of a seizure and when the Seizure Section notifications will be shown to a user. The Ceribell Seizure Detection Software does not provide any diagnostic conclusion about the subject's condition and Seizure Detection notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a training expert.	neonates of 25-44 weeks postmenstrual age) and infants less than 1 year of age that may correspond to electrographic seizures in order to assist qualified clinical practitioners in the assessment of EEG traces. The Seizure Detection Software also provides notifications to the user when detected seizure prevalence is "Frequent", "Abundant", or "Continuous, per the definitions of the American Clinical Neurophysiology Society Guideline 14. Delays of up to several minutes can occur between the beginning of a seizure and when the Seizure Detection notifications will be shown to a user. The Ceribell Infant Seizure Detection Software does not provide any diagnostic conclusion about the subject's condition and Seizure Detection notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a trained expert.	demonstrated by clinical performance data, the change in intended age range for the patient population of the Infant Seizure Detection Software does not raise new or different questions of safety or effectiveness.
Intended Patient Population	Ages 1 and older	Newborns and infants less than 1 year of age	Yes. As demonstrated by clinical performance data, the change in age range for the subject device does not raise any new or different questions of safety or effectiveness. The revised indications for use fall within the same intended use as that of the predicate device.
Intended Location of Use	Professional healthcare facilities	Same as predicate device	Yes, no change.

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.” In addition, tests according to “IEC 62366-1:2015, Medical Devices Part 1- Application of usability engineering to medical devices” have been performed.

Software verification and validation activities support the safety and effectiveness of the Ceribell Infant Seizure Detection Software.

8. PERFORMANCE DATA

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

The Ceribell Infant Seizure Detection Software is validated by evaluating the performance of the seizure detection algorithm on a dataset of EEG recordings representative of the intended patient population. The validation dataset consisted of EEG recordings obtained from patients less than 1 year of age who received continuous EEG monitoring within the hospital environment. There were no patient inclusion or exclusion criteria applied; therefore, the data are fully representative of the intended patient population. To form the reference standard for seizures, the EEG recordings were retrospectively reviewed by a panel of 3 expert pediatric neurologists who were fellowship trained in epilepsy or clinical neurophysiology. A two-thirds majority agreement was required to form a determination of seizures.

The reviewing neurologists did not have access to any of the outputs from the Infant Seizure Detection Software; the experts were fully blinded. Importantly, none of the data in the validation dataset were used for training of the Seizure Detection algorithm; the validation dataset is completely independent.

The patient’s postmenstrual age (PMA) at the time of EEG recording, stated in weeks, is the terminology used for the validation dataset. Postmenstrual age is gestational age plus chronological age. Gestational age is the time elapsed between the first day of the last menstrual period and the day of delivery and chronological age is the time elapsed since birth.

PERFORMANCE VALIDATION DATASET

	Number of Patients
25-36 weeks	155
37-44 weeks	321
> 44 weeks	237
Total	713

DISTRIBUTION OF SEIZURE EPISODES MEETING THE ACNS DEFINITIONS OF FREQUENT, ABUNDANT, AND CONTINUOUS PER THE ESTABLISHED MAJORITY AGREEMENT BETWEEN 3 EXPERT REVIEWERS

Seizure Burden Category	25-36 weeks	37-44 weeks	> 44 weeks	Total
Seizure Episodes with Seizure Burden ≥10% (meeting ACNS definition of 'Frequent' activity)	76	171	54	301
Seizure Episodes with Seizure Burden ≥50% (meeting ACNS definition of 'Abundant' activity)	25	66	23	114
Seizure Episodes with Seizure Burden ≥90% (meeting ACNS definition of 'Continuous' activity)	8	13	13	34

Acceptance Criteria

Performance of the Seizure Detection algorithm is 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 Seizure Burden activity (Frequent, Abundant, Continuous) **Lower bound of the 95% confidence interval ≥ 70% PPA**
- FP/hr: For each threshold of Seizure 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 intended patient population. In the overall dataset, the acceptance criteria were met and the Seizure Detection algorithm PASSES. The detailed results for PPA and FP/hr are shown in the following table:

Activity Category	Age (PMA)	Positive Percent Agreement (PPA)	95% Confidence Interval	False Positive Rate (FP/hr)	95% Confidence Interval
Seizure Episodes with Seizure Burden ≥10% (meeting ACNS definition of 'Frequent' activity)	**25-36 weeks**	88.16%	[74.24, 98.44]	0.357	[0.281, 0.458]
	37-44 weeks	90.64%	[83.86, 94.76]	0.153	[0.127, 0.183]
	> 44 weeks	98.15%	[91.18, 100.0]	0.219	[0.181, 0.264]
	Overall	91.36%	[85.71, 94.91]	0.204	[0.180, 0.230]
Seizure Episodes with Seizure Burden ≥50% (meeting ACNS definition of 'Abundant' activity)	**25-36 weeks**	92.00%	[69.23, 100.00]	0.115	[0.074 0.177]
	37-44 weeks	90.91%	[78.19, 97.93]	0.056	[0.042, 0.077
	> 44 weeks	91.30%	[68.42, 100.00]	0.111	[0.084, 0.146]
	Overall	91.23%	[82.67, 96.57]	0.083	[0.069, 0.100]
Seizure Episodes with Seizure Burden ≥90% (meeting ACNS definition of 'Continuous' activity)	**25-36 weeks**	75.00%	[60.00, 100.00]	0.090	[0.054, 0.151]
	37-44 weeks	100.0%	[75.29, 100]*	0.033	[0.022, 0.048
	> 44 weeks	92.31	[62.50, 100.00]	0.081	[0.056, 0.115]
	Overall	91.18%	[75.00, 100.00]	0.057	[0.045, 0.072]

* For metrics where the point estimate reached 100%, the 95% confidence interval was calculated using the Clopper-Pearson exact method. Please note that correlation effects are not accounted for in this exact calculation. All other confidence intervals are calculated using the bootstrap method with patient-level sampling to account for correlation effects.

Subgroup Performance

Subgroup analyses were performed to assess the impact of sex, clinical study site, EEG recording duration, and as shown above, age. All subgroup analyses demonstrated acceptable variation among subgroups, supporting performance across the intended use population.

9. PREDETERMINED CHANGE CONTROL PLAN (PCCP)

The Ceribell Infant Seizure Detection Software has been cleared by the FDA with an Authorized PCCP. The Authorized PCCP outlines specific modifications intended to improve algorithm clinical or computational performance through the expansion of training data and optimization of the algorithm. The PCCP outlines Ceribell's data management and algorithm development practices, including how and when performance is evaluated.

The PCCP also defines the validation requirements for algorithm updates. Prior to release, the updated algorithm is validated through testing against previously established acceptance criteria using an independent validation data set. Updates will be implemented using a validated Software Update process. When an update is performed, Ceribell will update the operator manual and notify customers of the update.

10. SUMMARY

The Ceribell Infant Seizure Detection Software has the same intended use as the predicate device. In addition, it has the same technological characteristics, clinical workflow, and underlying operating principles. The expansion of the intended patient age range for the seizure detection software has been validated through performance testing using the same methodology and acceptance criteria as applied to the predicate device. Therefore, the Ceribell Infant Seizure Detection Software is substantially equivalent to the cleared predicate device.