December 8, 2025

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

Re: K251936
Trade/Device Name: Ceribell Delirium Monitor System
Regulation Number: 21 CFR 882.1440
Regulation Name: Neuropsychiatric Interpretive Electroencephalograph Assessment Aid
Regulatory Class: Class II
Product Code: NCG
Dated: November 7, 2025
Received: November 7, 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

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.	K251936

Please provide the device trade name(s).

Ceribell Delirium Monitor System

Please provide your Indications for Use below.

The Ceribell Delirium Monitor System is intended to analyze features associated with diffuse slowing electroencephalogram (EEG) patterns that may be indicative of delirium. The Ceribell Delirium Monitor software is intended to aid in the screening and monitoring of delirium with clinical assessments in adult patients in critical care settings within hospitals.

The Ceribell Delirium Monitor System analyzes discrete segments of EEG to notify clinicians when EEG patterns associated with delirium are detected while monitoring the patient. Changes in patient condition that are detected by the device should be verified before commencing any interventions.

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

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

510(k) Summary – K251936

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Sponsor Information:

Company	Ceribell, Inc. 360 N Pastoria Ave Sunnyvale, CA 94085
Contact	Raymond Woo, Ph.D. Chief Technology Officer Ceribell, Inc. 360 N Pastoria Ave Sunnyvale, CA 94085 Phone: (800) 436-0826 E-mail: ray@ceribell.com
Alternate Contact	Tom McDougal Associate Director of Regulatory Ceribell, Inc. 360 N Pastoria Ave Sunnyvale, CA 94085 E-mail: tom.mcdougal@ceribell.com
Date Prepared	November 7, 2025

2. Device Information:

Trade Name:	Ceribell Delirium Monitor System
Common Name:	Neuropsychiatric Interpretive Electroencephalograph Assessment Aid
Regulation Number:	21 CFR 882.1440
Classification Name:	Neuropsychiatric Interpretive Electroencephalograph Assessment Aid
Device Class:	II
Product Code:	NCG

3. Predicate Device:

Primary Predicate:
K222680: DeltaScan Monitor

Secondary Predicates:
K191301: Ceribell Pocket EEG Device
K232052: Ceribell Instant EEG Headband

4. Indications for Use:

The Ceribell Delirium Monitor System is intended to analyze features associated with diffuse slowing electroencephalogram (EEG) patterns that may be indicative of delirium. The Ceribell Delirium Monitor System is intended to aid in the screening and monitoring of delirium with clinical assessments in adult patients in critical care settings within hospitals.

The Ceribell Delirium Monitor System analyzes discrete segments of EEG to notify clinicians when EEG patterns associated with delirium are detected while monitoring the patient. Changes in patient condition that are detected by the device should be verified before commencing any interventions.

5. Device Description:

Ceribell's Delirium Monitor System is a novel device that uses EEG to aid in the detection of delirium. The device is comprised of the Delirium Monitor software as well as Ceribell's previously cleared EEG acquisition system (K191301) and EEG headband (K232052) for recording and processing the EEG.

Once the EEG is recorded and processed the Delirium Monitor software performs the following steps:

1) Extraction of EEG features relevant to delirium assessment in 30-minute segments
2) Analysis of the extracted features of each segment with a machine-learning based delirium assessment model
3) Providing delirium-positive or delirium-negative assessment output to the intended users after the first 30 minutes of recording, including audible and visible notifications on the Ceribell Pocket EEG Device in the event of delirium-positive findings
4) Thereafter, providing delirium-positive or delirium-negative assessment output to the intended users once every 15 minutes, generating a notification when the assessment transitions from negative to positive.

Once generated, the output of the Delirium Monitor will be interpreted by the clinician alongside other relevant information to determine whether a diagnosis of delirium is appropriate.

6. Substantial Equivalence:

The Delirium Monitor is considered a Neuropsychiatric Interpretive Electroencephalograph Assessment Aid (for delirium) per 21 CFR 882.1440 and shares the same intended use as the DeltaScan Monitor predicate device. Specifically, both the DeltaScan device and the Delirium Monitor are prescription use devices that use EEG to provide an assessment of a neuropsychiatric condition. Both devices also serve as aids to the assessment of a condition and are not intended to provide a stand-alone diagnosis. The Delirium Monitor differs in its indications for use as it is designed for the assessment of delirium rather than acute encephalopathy like the predicate device. However, the difference in indications for use do not

represent a new intended use; instead, it reflects differences in the neuropsychiatric disorders that is being diagnosed.

The Delirium Monitor and DeltaScan predicate device also have similar technological characteristics. Both devices extract EEG features to provide an assessment of the presence of a neuropsychiatric condition. Differences include the features of the EEG that form the basis of the diagnosis which reflect the different psychiatric conditions that each device is intended to diagnose. The outputs are also different in that the Delirium Monitor provides a binary assessment related to whether the patient is currently experiencing delirium or not while the DeltaScan device provides a binary assessment related to whether the patient has acute encephalopathy or not. These differences in technology did not raise new questions of safety and effectiveness and were addressed using data from a clinical performance test.

Comparison of Ceribell Delirium Monitor versus predicate:

Table 1: Comparison of Ceribell Delirium Monitor versus predicate			
Characteristics	**DeltaScan Monitor (K222680)**	**Ceribell Delirium Monitor (Subject Device)**	**Discussion**
Regulatory Classification	Neuropsychiatric Interpretive Electroencephalograph Assessment Aid (21 CFR 882.1440)	Neuropsychiatric Interpretive Electroencephalograph Assessment Aid (21 CFR 882.1440)	Same 21 CFR 882.1440 describes Neuropsychiatric Interpretive Electroencephalograph Assessment Aid as "*a prescription device that uses a patient's electroencephalograph (EEG) to provide an interpretation of the patient's neuropsychiatric condition. The neuropsychiatric interpretive EEG assessment aid is used only as an assessment aid for a medical condition for which there exists other valid methods of diagnosis*". Similar to the proposed predicate, the Ceribell Delirium Monitor can be classified under this regulation based on the following: • It is a prescription only device • It uses EEG to provide an interpretation of delirium which is a neuropsychiatric condition • It is intended to be used as an assessment aid for a medical condition for which there are valid methods of diagnosis (e.g., clinical assessment according to DSM-5 criteria) • It is used to support further clinical evaluation of the patient based on standard of care procedures.
Indications for Use	The DeltaScan Monitor provides the binary DeltaScan Output based on a technical index of polymorphic delta (PMD) waveshape detections made in the EEG from the bipolar Fp2 and Pz channel on adult patients (over 60 years of age) to aid in the diagnosis of acute encephalopathy.	The Ceribell Delirium Monitor System is intended to analyze features associated with diffuse slowing electroencephalogram (EEG) patterns that may be indicative of delirium. The Ceribell Delirium Monitor System is intended to aid in the screening and monitoring of delirium with clinical	Different The indications are different in terms of the neuropsychiatric conditions that are being assessed; however, this does not constitute a new intended use since both the Ceribell Delirium Monitor, and the proposed predicate are EEG-based assessments aids for neuropsychiatric conditions.

	DeltaScan should only be used by a healthcare provider as a component of a complete clinical evaluation or as support for the clinician's decision to pursue further testing. The device is NOT to be used as a stand-alone method in the evaluation or diagnosis of acute encephalopathy. The intended patient is a hospitalized, awake adult, who is at risk of acute encephalopathy and delirium as decided by the responsible licensed healthcare physician or a medical professional working under the responsibility of a licensed healthcare physician. The use environment is in hospitals: • non-sterile environments; • ICUs, wards, and other patient	assessments in adult patients in critical care settings within hospitals. The Ceribell Delirium Monitor System analyzes discrete segments of EEG to notify clinicians when EEG patterns associated with delirium are detected while monitoring the patient. Changes in patient condition that are detected by the device should be verified before commencing any interventions.	

	evaluation locations; The DeltaScan Monitor is intended to be used in combination with the DeltaScan Patch (K222671) through a proprietary connector design. Please refer to the Instructions for Use and the Instructions for Use on the Primary packaging of the DeltaScan Patch for more information.		
Intended Patient Population	Adults over 60 years of age who are at risk of encephalopathy and/or delirium.	Adult patients in critical care settings that are at risk of delirium.	Same Both the subject device and primary predicate are indicated for the same patient population with the exception of age range. However, this difference does not represent a new intended use. The effectiveness of the subject device in the intended patient population is supported through clinical performance testing. The secondary predicates do not have an age restriction on intended patient populations.
Intended User Population	Medical professionals qualified to assess inpatient disorders and who are experienced in diagnosing acute encephalopathy and/or delirium	Medical professionals in the critical care setting qualified and experienced in delirium	Same Both the Ceribell Delirium Monitor System and the predicate device are intended to be used by medical professionals who are well-trained or experienced in the standard of care associated with similar neurophysiological conditions.
Prescription Use Only	Yes	Yes	Same

Technological Characteristics			
Medical Device Type	Hardware (EEG recording system) and software	Hardware (EEG recording system) and software	Same The predicate device uses its hardware systems to record and process EEG, and the Delirium Monitor System uses EEG collected from its FDA cleared EEG acquisition system (K191301) and EEG headband (K232052). This difference does not raise new question of safety and effectiveness, as the principle of operation is similar (see below).
Principle of Operation	DeltaScan Monitor records EEG to calculate a technical index of polymorphic data (PMD) to aid in the diagnosis of acute encephalopathy.	The Ceribell Delirium Monitor extracts EEG features and uses machine-learning based algorithms to detect the presence of delirium.	Similar The principle of operation of both the Delirium Monitor and the predicate device is similar in that both devices include software algorithms that extract particular features of the EEG to aid in the identification of a neuropsychiatric condition. The EEG features that are used for the diagnosis reflect the patient population and the specific condition that the software is attempting to identify. The effectiveness of using the Delirium Monitor as an aid to the assessment of delirium was supported by clinical performance data.
Patient Input	EEG signals recorded from the patient's scalp.	EEG signals recorded from the patient's scalp.	Same
Device Output	Two categories based on a threshold of the amount of PMD waveshapes detected in the EEG: - NEGATIVE for acute encephalopathy - POSITIVE for acute encephalopathy	Audible or visible notifications presented on the Ceribell Pocket EEG device interface which states either "Delirium Suspected" or "Delirium Not Suspected".	Same Aside from the difference in detected condition, the two outputs are the same. The safety and effectiveness of the Delirium Monitor System to perform a delirium assessment was supported by clinical performance data. The secondary predicate Pocket EEG Device provides audible or visible notifications for seizure. This is equivalent to the audible or visible notifications provided by the subject device and the change in target condition does not introduce new questions of safety or effectiveness.
Connectivity	None	Wi-fi communication with cloud-based server infrastructure.	Same The Delirium Monitor uses an internet connection to send collected EEG signals to the cloud and receive algorithm results in return. This is performed using the wi-fi and server architecture of the cleared Pocket EEG Device. As such, this feature is shared with the secondary predicates.

7. Performance Data:

7.1 Non-clinical Testing

Software verification and validation testing was completed, and documentation was provided per FDA's guidance entitled *Content of Premarket Submissions for Device Software Functions.*

7.2 Clinical Testing

Clinical data was collected and analyzed to determine the performance of the Ceribell Delirium Monitor. EEG data was collected from 225 adults (22 years or older) in a critical care environment. The EEG hardware that was used to acquire the recordings were previously cleared systems (Ceribell Instant EEG Headband: K232052 and Ceribell Pocket EEG Device: K191301). Clinical assessment of the patient (according to the DSM-5 criteria for delirium diagnosis) was also conducted up to three times a day by a qualified clinician. The recorded EEG data and corresponding clinical delirium diagnosis were analyzed retrospectively to determine the performance of the Delirium Monitor. The results of the Delirium Monitor were compared against the ground truth established by the clinical diagnosis of delirium by a qualified clinician. The performance of the EEG analysis algorithm was determined by the sensitivity and specificity of the algorithm against the expert clinical diagnosis.

The performance goals for the device software were set to the following:

- Sensitivity: lower-bound of the 95% confidence interval greater than or equal to 70%
- Specificity: lower-bound of the 95% confidence interval greater than or equal to 70%

Patient Demographics:

There were 135 males (60.0%) and 90 females (40.0%) in the sample. The average age was 62.4 years (standard deviation = 14.8). The minimum age was 24 and the maximum was 92. There were 115 (51.1%) subjects below age 65 and 110 (48.9%) subjects who were 65 or older.

The performance of the Delirium Monitor algorithm on the validation dataset is shown in Table 2 along with the 95% confidence intervals. 95% confidence interval estimates (bias-corrected accelerated bootstrapping) were calculated both on all individual assessments and on a per-subject level (bootstrap substitution for all assessments from a subject, to correct for potential within-subject correlations).

Table 2: Delirium Monitor algorithm validation results					
	Sensitivity [95% C.I.]	**Specificity [95% C.I.]**	**AUROC [95% C.I.]**	**PPV [95% C.I.]**	**NPV [95% C.I.]**
Confidence Interval calculated for individual assessments	81% [76-87]	81% [78-84]	0.87 [83-89]	0.57 [51-63]	0.93 [91-95]
Confidence Interval calculated at the subject-level	81% [73-89]	81% [74-85]	0.87 [81-91]	0.57 [46-67]	0.93 [89-96]

Subgroup Performance:

Subgroup analyses demonstrated acceptable variation among subgroups, supporting performance across the intended use population.

Repeatability Results:

To demonstrate the repeatability of the algorithm performance, we calculated Cohen's kappa value between pairs of EEG segments taken from the same subjects. The Delirium Monitor algorithm uses 30-minute segments of EEG. For the repeatability measurement, the two non-overlapping EEG segments were selected as those closest in time to each expert clinician delirium assessment. Of the 857 assessments included in the validation dataset, 243 assessments were excluded from this analysis because the EEG duration in the vicinity of the assessment was not sufficiently long to include two non-overlapping EEG segments. With these 243 exclusions, the repeatability evaluation included 614 individual assessments

The results shown in Table 3 indicated high repeatability:

Table 3: Cohen's kappa indicating high algorithm reliability		
	Cohen's Kappa	**Kappa 95% Confidence Interval**
Repeatability evaluation of 614 paired test/re-test EEG segments	0.76	0.71-0.80

A Cohen's kappa value of 0.76 corresponds to a categorization of "substantial agreement" using the Landis and Koch kappa interpretation scale. The percent agreement above random chance was 34.94%

Conclusions:

The risks of the device are based on the data collected in a clinical validation study. The major risks associated with the device is a false positive or a false negative result. Based on the performance validation study results, the risks to the patient of false negatives or false positives are very low – particularly given that the Delirium Monitor is intended as an aid to screening of delirium. It is not intended to take the place of diagnosis by a qualified clinician. Besides, assessments such as the CAM-ICU will still be performed per the hospital's usual workflow.

The probable benefits of the device are also informed by the data collected in the performance validation study. The results of the study indicated that the Delirium Monitor has 81% sensitivity (95% CI: 76% - 87%) and 81% specificity (95% CI: 78% - 84%) and demonstrates high repeatability with Cohen's Kappa of 0.76. These results suggest the device is likely to benefit the patient, particularly when compared to current standard of care. Since this device is intended to be used as an aid in the assessment of delirium in conjunction with the standard of care, the risk of harm to the patient in the event of a false negative or false positive is fairly low. Moreover, the reliable and robust clinical performance of the device suggests that the benefits to the patients and clinicians clearly outweigh the risks of the Delirium Monitor.

8. Predetermined Change Control Plan (PCCP):

The Ceribell Delirium Monitor System 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 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 this operator manual and notify customers of the update.

9. Summary:

The Ceribell Delirium Monitor System has the same intended use as the predicate device. In addition, it has similar technological characteristics; performance data demonstrates that any differences in technological characteristics do not raise different questions of safety or effectiveness. Therefore, the Ceribell Delirium Monitor System is substantially equivalent to the predicate device.