September 11, 2019

Ceribell, Inc.
Josef Parvizi
Chairman
2483 Old Middlefield Way, Suite 120
Mountain View, California 94043

Re: K191301
Trade/Device Name: Ceribell Pocket EEG Device
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMB, OMC, GWQ
Dated: May 13, 2019
Received: May 14, 2019

Dear Josef Parvizi:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191301

Device Name
Ceribell Pocket EEG Device

Indications for Use *(Describe)*
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 Pocket EEG Device is intended to be used in a professional healthcare facility environment.

Additionally, the EEG Recording Viewer Software component of the Pocket EEG Device incorporates a Seizure Detection component that is intended to mark previously acquired sections of EEG recordings in patients greater than or equal to 18 years of age that may correspond to electrographic seizures in order to assist qualified clinical practitioners in the assessment of EEG traces. The Seizure Detection component 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. Notifications include an on-screen display on the Pocket EEG Device and the optional sending of an e-mail message to a clinician. 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 Pocket EEG Device 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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K191301
510(k) Summary

This 510(k) summary was prepared on 9/11/2019 to provide an understanding of the basis for a determination of substantial equivalence in accordance with the requirements outlined in 21 CFR 807.92.

Submitter Information

Ceribell, Inc.
2483 Old Middlefield Way Suite 120
Mountain View, California 94043
1(800)436-0826

Contact Person

Dr. Josef Parvizi, MD, PhD Chairman
Telephone: (650) 521-7003
E-mail: josef@ceribell.com

Subject Device Information

Trade Name:	Ceribell Pocket EEG Device
Classification Name:	Electroencephalograph
Regular Description:	EEG or Electroencephalograph
Device Class:	Class II; 882.1400
Product Code:	OMB
OMB Device:	Automatic Event Detection Software for Full-Montage Electroencephalograph
Additional Pro Codes:	OMC, GWQ (full-montage standard electroencephalograph)

Predicate Device

Primary Predicate:	**K170363** Ceribell Pocket EEG Device 882.1400, OMC (reduced- montage standard electroencephalograph), GWQ
Secondary Predicate	**K151929** Persyst 13 (P13) 882.1400, OMB, OLT (non-normalizing quantitative electroencephalograph software)

Device Description

The Ceribell Pocket EEG Device is a previously cleared EEG monitoring system which includes a portable 8-channel system that is being upgraded in this 510(k) notification K191301 to include a seizure detection module. The device connects to 10 patient electrodes (5 left, 5 right), which are used to form the 8 channels. The device may be used with any scalp EEG electrodes, and the system includes the following components:

- Pocket EEG Device: a portable, battery powered, 8-channel EEG monitoring system.
- Power adapter: 100-240 V AC power adapter used to charge the Pocket EEG Device.
- Micro-USB cable: cable used to connect Pocket EEG Device to power adapter for charging and to connect to a computer to transfer EEG recording files. When the Pocket EEG Device is connected to a power adapter of a computer, all EEG acquisition functions are automatically

disabled.

- EEG Recording Viewer Software: EEG review software for viewing EEG recordings on a computer. The EEG Recording Viewer Software includes a Seizure Detection software module that assists qualified users in reviewing and annotating EEG by marking previously acquired sections of EEG that may correspond to electrographic seizures.

Intended Use

The Ceribell Pocket EEG Device is a portable EEG monitoring system that records, stores and presents EEG signals in visual and audible formats in real time. The visual and audible signals assist trained medical staff to make neurological diagnoses. The Pocket EEG Device EEG Recording Viewer software incorporates a Seizure Detection component that is intended to mark previously acquired sections of EEG recordings in patients greater than or equal to 18 years of age that may correspond to electrographic seizures in order to assist qualified clinical practitioners in the assessment of EEG traces. The device 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.

Table 1: Comparison of Indications for Use

Subject Device K191301 (Rx only)	Predicate K170363 (Rx only)	Predicate K151929 (Rx only)
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 Pocket EEG Device is intended to be used in a professional healthcare facility environment. Additionally, the EEG Recording Viewer Software component of the Pocket EEG Device incorporates a Seizure Detection component that is intended to mark previously acquired sections of EEG recordings in patients greater than or equal to 18 years of age that may correspond to electrographic seizures in order to assist qualified clinical practitioners in the assessment of EEG traces. The Seizure Detection component 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. Notifications include an on-screen display on the Pocket EEG Device and the optional sending of an e-mail message to a clinician. 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 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 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.	1. Persyst 13 EEG Review and Analysis 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 medical practitioners who will exercise professional judgment in using the information. 2. The Seizure Detection component of Persyst 13 is intended to mark previously acquired sections of adult (greater than or equal to 18 years) EEG recordings that may correspond to electrographic seizures, in order to assist qualified clinical practitioners in the assessment of EEG traces. EEG recordings should be obtained with a full scalp montage according to the standard 10/20 system. 3. The Spike Detection component of Persyst 13 is intended to mark previously acquired sections of the patient's EEG recordings that may correspond to spikes, in order to assist qualified clinical practitioners in the assessment of EEG traces. The Spike Detection component is intended to be used in patients at least one month old. Persyst 13 Spike Detection performance has not been assessed for intracranial recordings. 4. Persyst 13 includes the calculation and display of a set of quantitative measures intended to monitor and analyze the EEG waveform. These include FFT,

Table 1: Comparison of Indications for Use		
Subject Device K191301 (Rx only)	**Predicate K170363 (Rx only)**	**Predicate K151929 (Rx only)**
The Pocket EEG Device 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.		Rhythmicity, Peak Envelope, Artifact Intensity, Amplitude, Relative Symmetry and Suppression Ration. Automatic event marking is not applicable to the quantitative measures. These quantitative EEG measures should always be interpreted in conjuction with review of the original EEG waveforms. 5. The aEEG functionality included in Persyst 13 is intended to monitor the state of the brain. The automated event marking function of Persyst 13 is not applicable to aEEG. 6. Persyst 13 provides notifications for seizure detection, quantitative EEG and aEEG that can be used when processing a record during acquisition. These include an on screen display and the optional sending of an email message. Delays of up to several minutes can occur between the beginning of a seizure and when the Persyst 13 notifications will be shown to a user. Persyst 13 notifications cannot be used as a substitute for real time monitoring of the underlying EEG by a trained expert. 7. Persyst AR (Artifact Reduction) is intended to reduce EMG, eye movement, and electrode artifacts in a standard 10-20 EEG recording. AR does not remove the entire artifact signal, and is not effective for other types of artifacts. AR 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 waveform. This device does not provide any diagnostic conclusion about the patient's condition to the user.

Comparison of Intended Use and Technological Characteristics with Predicates K170363 & K151929
The subject device and predicate **K170363** Ceribell Pocket EEG Device share the same intended use as a portable EEG monitoring system that records, stores, and presents EEG signals in visual and audible formats. The recorded EEG signals assist trained medical staff to make neurological diagnoses. The subject device and **K170363** are identical with exception of the modification to introduce the EEG Recording Viewer Software to **K170363** in order to include an additional Seizure Detection software module.

The subject device and **K151929** Persyst 13 (P13) share the same intended use for analyzing EEG files to identify possible seizure episodes and then mark previously acquired sections of adult EEG. The subject

device and **K151929** differ only by the number of patient electrodes used for seizure detection, the manner of the presentation of seizure detection output, and the types of seizure detection notifications provided.

Non-clinical Performance Data

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

1. IEC 60601-1:2005+A1:2012, edition 3.1, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. This test report also includes national differences testing to the FDA recognized consensus standard, ANSI/AAMI ES60601- 1:2005+A1:2012, C1:2009, A2:2010.
2. IEC 60601-2-26:2012, edition 1.0, Medical electrical equipment – Part 2-26: Requirements for the basic safety and essential performance of electroencephalographs.
3. IEC 60601-1-6:2010+A1:2013, edition 3.1, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.
4. IEC 62366:2007, edition 1.0, Medical devices – Application of usability engineering to medical devices.
5. IEC 62133:2012, edition 2.0, Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary sells, and for batteries made from them, for use in portable applications.
6. IEC 60601-1-2:2007, edition 3.0: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility. The table below compares the Wi-Fi modules between **K170363** and **K191301.** The subject device Wi-Fi communications module has been upgraded to a more recent version within the same family; the new Wi-Fi module is the ST Microelectronics model SPWF04SA, the previous module in the predicate device was the ST Microelectronics model SPWF01SA. There are no other hardware differences between the subject device and the predicate Pocket EEG Device of K170363.

Table 2: Specifications of Previous and Updated Wi-Fi Modules		
	Predicate Device (K170363) Module ST Microelectronics SPWF01SA	**Subject Device (K191301) Module ST Microelectronics SPWF04SA**
WiFi frequency/standard	2.4 GHz IEEE 802.11 b/g/n	2.4 GHz IEEE 802.11 b/g/n
Transmit power	18.3 dBm @ 1 Mbps DSSS 13.7 dBm @ 54 Mbps OFDM	18.3 dBm @ 1 Mbps DSSS 13.7 dBm @ 54 Mbps OFDM
Receive sensitivity	-96.0 dBm @ 1 Mbps DSSS -74.5 dBm @ 54 Mbps OFDM	-96.0 dBm @ 1 Mbps DSSS -74.5 dBm @ 54 Mbps OFDM
Antenna type	Integrated	Integrated
Form factor/dimensions	Surface mount PCB module 26.92 x 15.24 x 2.35 mm	Surface mount PCB module 26.92 x 15.24 x 2.35 mm
Integrated processor and memory	STM32 ARM Cortex-M3 processor with 64 kB RAM	STM32 ARM Cortex-M4 processor with 256 KB RAM
FCC approval	Full modular approval FCC ID: VRA-SG9011203	Full modular approval FCC ID: S9NSPWFS04

Clinical Performance Data

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

Demographics

The demographics of Ceribell's seizure detection validation dataset are as follows:

Table 3: Seizure Detection Validation Dataset Demographics	
Total subjects	60
Gender	Male: 29 (48.3%) Female: 31 (51.7%)
Age	Average: 56.5 Minimum: 22 Maximum: 88

Patient Baseline Characteristics

The validation dataset had no inclusion/exclusion criteria related to patient baseline characteristics. In general, ICU patients who receive EEG monitoring present with one or more neurological diagnoses that are potentially indicate an increased risk of seizures. EMU patients typically have a prior history of seizures that warrants EEG monitoring.

Enrollment

The validation dataset was obtained from previous studies that retrospectively reviewed all adult EEGs from patients who underwent inpatient EEG monitoring over a period of time. Data from one hospital was used for ICU EEG data, and data from a second hospital was used for EMU EEG data. From the ICU and EMU source datasets, a total of 60 subjects aged 18 or older were randomly selected for inclusion in the Ceribell seizure detection validation study; 30 from the ICU dataset and 30 from the EMU dataset.

Masking

All of the EEG data used for Ceribell's seizure detection validation was retrospectively obtained from pre-existing EEG databases. The EEG trained neurologists who reviewed the data to provide the clinical reference were masked. The EEGs used for the validation protocol were selected with

no knowledge of how the Ceribell or Persyst 13 seizure detection would perform. No patients from the validation dataset were used for algorithm training or development.

General Summary

The following is a summary of the validation procedure performed:

- A validation dataset of full montage EEG recordings obtained from adult (18 years and older) patients were chosen for validation testing. This dataset was completely separate and independent from the data used to design and train the algorithm.
- A reference standard was established for the validation dataset by EEG trained neurologists who reviewed and annotated the EEG recordings for seizure episodes.
- Both Ceribell Pocket EEG Device and predicate Persyst 13 (K151929) Seizure Detection modules were run on the validation dataset and performance metrics were calculated for each as compared to the reference standard established per above.
- Statistical analysis was performed on the results to evaluate and compare the performance to the predetermined acceptance criteria.

Selection of Validation Sets

The validation was performed as a retrospective analysis of EEG data gathered from patients in the Intensive Care Unit (ICU) and Epilepsy Monitoring Unit (EMU). These two locations are representative of EEGs taken throughout the hospital environment and thus reflect the intended use of the subject device.

For the validation data set, 50% of the data was from the ICU and 50% was from the EMU. The reference standard for the validation data set was obtained by having trained experts review and annotate the EEG files for onset and conclusion of seizure episodes.

The expert EEG reviewers used to generate the reference standard were affiliated with multiple different institutions. All were fellowship trained in epilepsy or clinical neurophysiology. To validate seizure detection notifications, positive percent agreement (PPA) and false positives/ hour (FP/hr) were calculated for the Ceribell Seizure Detection module and Persyst 13 with respect to the reference standard.

The three levels of seizure detection notification for Ceribell ("Frequent," "Abundant," and "Continuous") are additive – the "Frequent" notification must always occur first before the "Abundant" or "Continuous" notification. Therefore, it is most relevant to compare the Ceribell "Frequent" notification output to the Persyst 13 seizure notification output. The Ceribell "Frequent" notification output represents the detection of 30 seconds or more of seizure activity within a 5-minute moving window. The Persyst 13 seizure notification output represents the detection of 11 seconds or more of continuous seizure activity. There is no clinically relevant distinction between these two types of notifications. The validation protocol requires that the PPA and FP/hr for the Ceribell "Frequent" notification output must be statistically non-inferior to the Persyst 13 seizure detection notification output. Additionally, to assess device effectiveness and clinical utility, performance of all Ceribell's notification levels, "Frequent," "Abundant," and "Continuous," with respect to the reference standard are calculated and presented with the results along with their 95% confidence intervals. The criteria for minimally acceptable device performance was to have a positive percent agreement with a 95% CI lower bound above 70% and a false positive rate with a 95% CI upper bound below 0.446 per hour.

Validation was based upon demonstrating that Ceribell was non-inferior to Persyst 13 with a 10% non-inferiority Margin.

Results of Clinical Performance Testing

Table 4: Contingency Table of Ceribell Device Output For "Abundant" Notification With Respect To Clinical Reference For The Validation Dataset

		Clinical Reference (Review and Annotation of validation datasets by EEG-trained neurologists)			
		No seizure or Seizure Duration < 150 seconds	**150 seconds ≤ Seizure Duration < 270 seconds**	**Seizure Duration ≥ 270 seconds**	**Total**
Ceribell Device Output	**Below 50% Threshold (no "Abundant" notification provided)**	NA	2	1	**3**
	Above 50% Threshold ("Abundant" notification provided)	FP/hr = 0.1996	18	22	**40**
	Total	NA	20	23	**43**
	Sensitivity	NA	90.0%	95.6%	**93.02%**

Table 5: Contingency Table of Ceribell Device Output For "Continuous" Notification With Respect To Clinical Reference For The Validation Dataset

		Clinical Reference (Review and Annotation of validation datasets by EEG-trained neurologists)		
		No seizure or Seizure Duration < 270 seconds	**Seizure Duration ≥ 270 seconds**	**Total**
Ceribell Device Output	**Below 90% Threshold (no "Continuous" notification provided)**	NA	2	**2**
	Above 90% Threshold ("Continuous" notification provided)	FP/hr = 0.1247	21	**21**
	Total	NA	23	**23**
	Sensitivity	NA	91.3%	**91.3%**

Reference Standards

For both the ICU and EMU datasets:

The neurologist reviews are completed prior to the start of any validation testing, and the same reference standard is used to test the performance of both the Ceribell seizure detection feature and the Persyst 13 seizure detection. Therefore, it is not possible for a neurologist to bias his or her review in a way that affects the outcome of the validation testing. EEG trained neurologists (physicians who have obtained fellowship training in epilepsy or neurophysiology) reviewed and annotated the EEG recordings for seizure episodes. Each seizure episode was manually annotated by an expert panel, with agreement between at least two neurologists required to determine the reference standard.

Pass Fail Criteria

The seizure detection notification validation tests performed and their acceptance criteria are summarized below in **Table 6**. The seizure burden output validation tests performed and their acceptance criteria are summarized below in **Table 7.**

Table 6: Summary of Validation Testing for Seizure Notifications	
Test Description	**Acceptance Criteria**
"Frequent" seizure activity notifications (≥10% seizure burden), PPA and FP/hr	Ceribell non-inferior to Persyst 13 with 10% non-inferiority margin
"Frequent" seizure activity notifications (≥10% seizure burden), PPA and FP/hr	PPA: 95% CI lower bound ≥ 70% FP/hr: 95% CI upper bound ≤ 0.446
"Abundant" seizure activity notifications (≥50% seizure burden), PPA and FP/hr	PPA: 95% CI lower bound ≥ 70% FP/hr: 95% CI upper bound ≤ 0.446
"Continuous" seizure activity notifications (≥90% seizure burden), PPA and FP/hr	PPA: 95% CI lower bound ≥ 70% FP/hr: 95% CI upper bound ≤ 0.446

Table 7: Summary of Validation Testing for Seizure Burden Output	
Test Description	**Acceptance Criteria**
Seizure Burden output, L1-distance vs. reference standard	Ceribell non-inferior to Persyst 13 with 10% non-inferiority margin

Results

Table 8 below summarizes the results for performance metrics, PPA and FP/hr for all three Ceribell's seizure notification levels of "Frequent," "Abundant," and "Continuous" along with their 95% confidence intervals. The percentage agreement for the three notification levels ranged from 91.30% to 94.67%. The false positive rate ranged from 0.1247 to 0.2145.

Table 8: Performance Metrics for Seizure Notifications for All Three of Ceribell's Level of Seizure Activity Notification, As Compared To Reference Standard						
Ceribell Seizure Activity Notification Level	**PPA**	**PPA 95% CI**	**Conformance to PPA Acceptance Criteria**	**FP/hr**	**FP/hr 95% CI**	**Conformance to FP/hr Acceptance Criteria**
"Frequent"	94.67%	[90.00%, 97.33%]	90.00% > 70%, therefore, PASS	0.2145	[0.119, 0.351]	0.351 < 0.446, therefore, PASS
"Abundant"	93.02%	[81.39%, 100%]	81.39% > 70%, therefore, PASS	0.1996	[0.093, 0.381]	0.381 < 0.446, therefore, PASS
"Continuous"	91.30%	[78.26%, 100%]	78.26% > 70%, therefore, PASS	0.1247	[0.054, 0.272]	0.272 < 0.446, therefore, PASS

Conclusion

The Ceribell Pocket EEG Device has the same intended use as the predicate devices. In addition, it has similar technological characteristics. Evaluation of the results and the test methods to account for different technological characteristics of the submitted performance data demonstrated that differences in technological characteristics between the subject device and predicates do not raise different questions of safety or effectiveness. Therefore, the Ceribell Pocket EEG Device is substantially equivalent to the predicates.