DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 8, 2017

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

Re: K170363
Trade/Device Name: Ceribell Pocket EEG Device
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OMC
Dated: February 2, 2017
Received: February 6, 2017

Dear Dr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170363

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 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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

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.

Applicant Information:

Ceribell, Inc.
2483 Old Middlefield Way
Suite 120
Mountain View, California

Contact Person:

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

Device Information:

Trade Name:	Ceribell Pocket EEG Device
Common Name:	Reduced-montage standard Electroencephalograph
Classification Name:	Electroencephalograph (21CFR 882.1400)
Device Class:	II
Product Code:	OMC

Predicate Device:

Oxford Medilog 9000 EEG System, K830295

Date Prepared:

February 2nd, 2017

Device Description:

The Ceribell Pocket EEG Device (subject) is a portable 8-channel EEG monitoring system. The device connects to 10 patient electrodes (5 left, 5 right), which are used to form the 8 channels, and may be used with any scalp EEG electrodes. The Device includes the following items:

- 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.

Indications for Use:
The Ceribell Pocket EEG Device is intended to record and store EEG signals, and to present the EEG signals in visual and audible formats in real time. The visual and audible signals assist trained medical staff to make neurological diagnoses. The 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.

Comparison of Intended Use and Technological Characteristics with the Predicate Device:
The subject and the predicate devices 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. It does not provide any diagnostic conclusion about the subject's condition or any automated alerts of an adverse clinical event.

The subject and predicate device are based on the following same technological elements:

- Portable, battery powered EEG acquisition and recording of 8 channels
- EEG data presented in both visual and audible formats
- Review of EEG recordings on an external Replay Module or computer

Whereas the predicate device uses analog technology for presentation, processing, storage and replay of data, the subject device utilizes digital technology. The predicate uses 16 electrodes to form 8 channels of EEG data; the subject uses 10 electrodes to form 8 channels of EEG data.

Performance Data:
The following performance data were provided to demonstrate safety and efficacy in support of substantial equivalence determination:

- Requirements for the basic safety and essential performance of electroencephalographs per IEC 60601-2-26
- Electromagnetic Compatibility and Electrical Safety Testing performed to applicable requirements of IEC 60601-1 and IEC 60601-1-2
- Battery Safety Testing per IEC 62133
- Bench testing to verify system performance
- Shipping/distribution and vibration testing per ASTM D7386

Summary:
The Ceribell Pocket EEG 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 Pocket EEG Device is substantially equivalent to the cleared predicate device.