

K170363 Ceribell Pocket EEG DeviceMay 8, 2017
91 days to decisionK170363 · Product code: **OMC** · Neurology
Source: <https://www.510kdatabase.net/k170363/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reduced- Montage Standard Electroencephalograph (OMC)
Date received	Feb 6, 2017
Decision date	May 8, 2017
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ceribell, Inc.
Location	Sunnyvale, CA, US
Contact	Josef Parvizi
Website	https://ceribell.com
510(k) history	13 submissions · 13 cleared · 2017-2026

Ceribell, Inc. is a medical technology company focused on transforming diagnosis and management of patients with serious neurological conditions. Headquartered in Sunnyvale, California, the company has developed a point-of-care electroencephalography (EEG) platform combining portable hardware with artificial intelligence-powered algorithms for rapid diagnosis and continuous monitoring in acute care settings. Ceribell has received FDA 510(k) clearances from total submissions since its first clearance in 2017. The company specializes exclusively in Neurology devices, with i...
