

K252070 Ceribell Infant Seizure Detection SoftwareNov 21, 2025
143 days to decisionK252070 · Product code: **OMB** · Neurology
Source: <https://www.510kdatabase.net/k252070/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Full-montage Electroencephalograph (OMB)
Date received	Jul 1, 2025
Decision date	Nov 21, 2025
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Ceribell, Inc.
Location	Sunnyvale, CA, US
Contact	Raymond Woo
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...