FDA 510(k) Premarket Notification

K191301 Ceribell Pocket EEG Device

CLEARED

Sep 11, 2019
120 days to decision

K191301 · Product code: **OMB** · Neurology
Source: https://www.510kdatabase.net/k191301/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Full-montage Electroencephalograph (OMB)
Date received	May 14, 2019
Decision date	Sep 11, 2019
Days to decision	120 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...