

K254033 Ceribell Instant EEG HeadsetFeb 9, 2026
55 days to decisionK254033 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k254033/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Electrode, Cutaneous (GXY)
Date received	Dec 16, 2025
Decision date	Feb 9, 2026
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
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...