

K243515 EpiWatch Monitoring SystemMar 7, 2025
114 days to decisionK243515 · Product code: **POS** · Neurology
Source: <https://www.510kdatabase.net/k243515/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Physiological Signal Based Seizure Monitoring System (POS)
Date received	Nov 13, 2024
Decision date	Mar 7, 2025
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Epiwatch, Inc.
Location	Baltimore, MD, US
Contact	Teresa Prego
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Healthcare Innovation Catalysts, Inc.
Contact	Brittany Valdez Nava

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243515/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026