FDA 510(k) Premarket Notification

CLEARED

K243515 EpiWatch Monitoring System

Mar 7, 2025
114 days to decision

K243515 · 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