

K232915 EpiMonitorFeb 15, 2024
149 days to decisionK232915 · Product code: **POS** · Neurology
Source: <https://www.510kdatabase.net/k232915/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Physiological Signal Based Seizure Monitoring System (POS)
Date received	Sep 19, 2023
Decision date	Feb 15, 2024
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Empatica S.R.L.
Location	Milano, IT
Contact	Alberto Poli
510(k) history	8 submissions · 8 cleared · 2018-2025

CLINICAL EVIDENCE - NCT03207685**Generalized Seizure Detection And Alerting In The EMU With The Empatica Embrace Watch And Smartphone-Based Alert System**

Status	Unknown - <i>No results published to ClinicalTrials.gov</i>
Enrollment	100 patients (estimated)
Study sites	2 sites
Condition studied	Epilepsy
Primary purpose	Supportive_care
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jan 1, 2022
Sponsor	Empatica, Inc. (Industry)

Primary outcome

Comparison of Video-EEG to Embrace System

Secondary outcome

Alarm System Comparison

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03207685