

K250515 EpiMonitorJun 19, 2025
118 days to decisionK250515 · Product code: **POS** · Neurology
Source: <https://www.510kdatabase.net/k250515/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Physiological Signal Based Seizure Monitoring System (POS)
Date received	Feb 21, 2025
Decision date	Jun 19, 2025
Days to decision	118 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

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