

**K181861 Embrace**Dec 20, 2018  
161 days to decisionK181861 · Product code: **POS** · Neurology  
Source: <https://www.510kdatabase.net/k181861/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Physiological Signal Based Seizure Monitoring System (POS)
Date received	Jul 12, 2018
Decision date	Dec 20, 2018
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Empatica S.R.L.</b>
Location	Milano, IT
Contact	Simone Tognetti
510(k) history	8 submissions · 8 cleared · 2018-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181861/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026