

**K230457 Empatica Health Monitoring Platform**Oct 30, 2023  
251 days to decisionK230457 · Product code: **MWI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k230457/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Feb 21, 2023
Decision date	Oct 30, 2023
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	EmbracePlus; Empatica Care; Care Portal

**APPLICANT**

---

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

**CLINICAL EVIDENCE - NCT04897529**

---

**[Trial of device that is not approved or cleared by the U.S. FDA]**

Status	Withheld - <i>No results published to ClinicalTrials.gov</i>
Sponsor	[Redacted]

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04897529](https://clinicaltrials.gov/study/NCT04897529)

---

510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230457/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)), ClinicalTrials.gov (U.S. National Library of Medicine). 510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 24, 2026