FDA 510(k) Premarket Notification

**CLEARED**

# K230457 Empatica Health Monitoring Platform

Oct 30, 2023
251 days to decision

K230457 · Product code: **MWI** · Cardiovascular
Source: https://www.510kdatabase.net/k230457/

## SUBMISSION DETAILS

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|---|---|
| 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 | **Empatica S.R.L.** |
| 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 - *No results published to ClinicalTrials.gov* |
| Sponsor | [Redacted] |

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04897529