

K242737 Empatica Health Monitoring PlatformJun 6, 2025
268 days to decisionK242737 · Product code: **MWI** · CardiovascularSource: <https://www.510kdatabase.net/k242737/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Sep 11, 2024
Decision date	Jun 6, 2025
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
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

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