

K252981 EmbraceMiniDec 22, 2025
96 days to decisionK252981 · Product code: **LEL** · Neurology
Source: <https://www.510kdatabase.net/k252981/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Sleep Assessment (LEL)
Date received	Sep 17, 2025
Decision date	Dec 22, 2025
Days to decision	96 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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