

K253388 Sleepiz One+ (Model 2.5)Jan 28, 2026
120 days to decisionK253388 · Product code: **DRT** · Cardiovascular
Source: <https://www.510kdatabase.net/k253388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Sep 30, 2025
Decision date	Jan 28, 2026
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sleepiz AG
Location	Zurich, CH
Contact	Marta Stepien
510(k) history	3 submissions · 3 cleared · 2023-2026

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