

**K223163 Sleepiz One+**Aug 18, 2023  
315 days to decisionK223163 · Product code: **DRT** · CardiovascularSource: <https://www.510kdatabase.net/k223163/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Oct 7, 2022
Decision date	Aug 18, 2023
Days to decision	315 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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