FDA 510(k) Premarket Notification

K223163 Sleepiz One+

CLEARED

Aug 18, 2023
315 days to decision

K223163 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k223163/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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