FDA 510(k) Premarket Notification

K223681 Respiree Cardio-Respiratory Monitor

CLEARED

Mar 8, 2023
90 days to decision

K223681 · Product code: **BZQ** · Anesthesiology
Source: https://www.510kdatabase.net/k223681/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	Dec 8, 2022
Decision date	Mar 8, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Respiree Pte, Ltd.**
Location	Singapore, SG
Contact	Gurpreet Singh
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	**Msquared Associates, Inc.**
Contact	Cherita James

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