

K250934 Respiree Cardio- Respiratory Monitor SystemAug 5, 2025
130 days to decisionK250934 · Product code: **BZQ** · Anesthesiology
Source: <https://www.510kdatabase.net/k250934/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Breathing Frequency (BZQ)
Date received	Mar 28, 2025
Decision date	Aug 5, 2025
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Propharma Group
Contact	Cherita James

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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