

K230476 Oran Park MaskOct 19, 2023
239 days to decisionK230476 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k230476/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Feb 22, 2023
Decision date	Oct 19, 2023
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Resmed Pty Ltd (Registration Number: 3004604967)
Location	Bella Vista, AU
Contact	Daniellia Chan
510(k) history	3 submissions · 3 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	Resmed Corp (Registration Number: 3007573469)
Contact	Sheila Bruschi

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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