

**K223747 Whitsundays Mask System**Jul 6, 2023  
204 days to decisionK223747 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k223747/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Dec 14, 2022
Decision date	Jul 6, 2023
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Resmed Pty Ltd (Registration Number: 3004604967)</b>
Location	Bella Vista, AU
Contact	Shu-Ying Huang
510(k) history	3 submissions · 3 cleared · 2023-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Resmed Corp (Registration Number: 3007573469)</b>
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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