

**K234134 AirFit F30i Mask System**Sep 24, 2024  
270 days to decisionK234134 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k234134/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Dec 29, 2023
Decision date	Sep 24, 2024
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	AirFit F30i NM Mask System; Arcadia Mask System

**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>Remed 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)**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k234134/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026