

K242547 AirFit F20 Mask SystemMay 19, 2025
265 days to decisionK242547 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k242547/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Aug 27, 2024
Decision date	May 19, 2025
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	AirFit F20 NM Mask System

APPLICANT

Company	Resmed Pty , Ltd.
Location	Bella Vista, AU
Contact	Lawrence Colin Kwan
510(k) history	3 submissions · 3 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	Resmed Corp
Contact	Jason Gorman

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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