

K132887 AIRFIT N10Dec 20, 2013
95 days to decisionK132887 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k132887/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Sep 16, 2013
Decision date	Dec 20, 2013
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Resmed, Ltd.
Location	Poway, CA, US
Contact	JIM CASSI
Website	http://www.resmed.com/
510(k) history	103 submissions · 103 cleared · 1996-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132887/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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