

K171212 AirFit N20Sep 28, 2017
156 days to decisionK171212 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k171212/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Apr 25, 2017
Decision date	Sep 28, 2017
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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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