

K161978 AirFit N20Nov 17, 2016
122 days to decisionK161978 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k161978/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Jul 18, 2016
Decision date	Nov 17, 2016
Days to decision	122 days
Third-party review	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

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