FDA 510(k) Premarket Notification

K170924 AirFit F20

CLEARED

Jan 3, 2018
280 days to decision

K170924 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k170924/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Mar 29, 2017
Decision date	Jan 3, 2018
Days to decision	280 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Resmed, Ltd.**
Location	Poway, CA, US
Contact	Johanna Wright
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