FDA 510(k) Premarket Notification

K234134 AirFit F30i Mask System

CLEARED

Sep 24, 2024
270 days to decision

K234134 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k234134/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Dec 29, 2023
Decision date	Sep 24, 2024
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	AirFit F30i NM Mask System; Arcadia Mask System

APPLICANT

Company	**Resmed Pty Ltd (Registration Number: 3004604967)**
Location	Bella Vista, AU
Contact	Shu-Ying Huang
510(k) history	3 submissions · 3 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	**Remed 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