FDA 510(k) Premarket Notification

K221338 F&P Airvo 3

CLEARED

Jan 27, 2023
263 days to decision

K221338 · Product code: **QAV** · Anesthesiology
Source: https://www.510kdatabase.net/k221338/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	High Flow/high Velocity Humidified Oxygen Delivery Device (QAV)
Date received	May 9, 2022
Decision date	Jan 27, 2023
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fisher & Paykel Healthcare**
Location	Auckland, NZ
Contact	Reena Daken
Website	http://www.fphcare.com/
510(k) history	5 submissions · 5 cleared · 2017-2024

Fisher & Paykel Healthcare is a global medical device manufacturer driving innovation in healthcare technologies for over 50 years. The company operates with a manufacturing facility in Auckland, New Zealand, and specializes in respiratory care, humidification systems, and therapeutic devices for hospital and home settings. The company has received FDA 510(k) clearances from total submissions since 2017. Anesthesiology devices represent the dominant category, accounting for approximately 80% of regulatory submissions. The latest clearance was received in 2024, demonstrati...