FDA 510(k) Premarket Notification

K234053 F&P Optiflow Flow Diverter

CLEARED

Aug 9, 2024
231 days to decision

K234053 · Product code: **CBP** · Anesthesiology
Source: https://www.510kdatabase.net/k234053/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Valve, Non-rebreathing (CBP)
Date received	Dec 22, 2023
Decision date	Aug 9, 2024
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fisher &Paykel Healthcare , Ltd.**
Location	Auckland, New Zealand, NZ
Contact	Reena Daken
Website	https://www.fphcare.com/
510(k) history	70 submissions · 70 cleared · 1988-2025

Fisher &Paykel Healthcare, Ltd. is a medical device manufacturer based in Auckland, New Zealand. The company has driven innovation in healthcare technologies for over 50 years. Fisher &Paykel Healthcare has received FDA 510(k) clearances from total submissions since 1988. The company specializes in Anesthesiology devices, which represent 91% of its regulatory submissions. The latest clearance was granted in 2025, confirming active ongoing development. Recent cleared devices include high-flow nasal therapy systems, noninvasive ventilation masks, and respiratory support int...