FDA 510(k) Premarket Notification

CLEARED

K251611 Optiflow+ Nasal Cannula - Small (OPT942)

Jun 25, 2025
29 days to decision

K251611 · Product code: **BTT** · Anesthesiology
Source: https://www.510kdatabase.net/k251611/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	May 27, 2025
Decision date	Jun 25, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Optiflow+ Nasal Cannula - Medium (OPT944); Optiflow+ Nasal Cannula - Large (OPT946); Optiflow+ Nasal Cannula Small (MYOPT9SMALL); Optiflow+ Nasal Cannula Medium (MYOPT9MEDIUM); Optiflow+ Nasal Cannula Large (MYOPT9LARGE)

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...