

K253479 Optiflow Switch+ Filtered Nasal Interface with CO2 Sampling (AA042J)

Dec 19, 2025
66 days to decision

K253479 · Product code: **BTT** · Anesthesiology
Source: <https://www.510kdatabase.net/k253479/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Oct 14, 2025
Decision date	Dec 19, 2025
Days to decision	66 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	Jung Yun Lee
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...