

K212031 F&P 850 AirSpiral Adult NIV and NHF Circuit KitApr 22, 2022
297 days to decisionK212031 · Product code: **BTT** · Anesthesiology
Source: <https://www.510kdatabase.net/k212031/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Jun 29, 2021
Decision date	Apr 22, 2022
Days to decision	297 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...