

K220703 F&P 950 Respiratory HumidifierJun 16, 2023
463 days to decisionK220703 · Product code: **BTT** · Anesthesiology
Source: <https://www.510kdatabase.net/k220703/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Mar 10, 2022
Decision date	Jun 16, 2023
Days to decision	463 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...
