

K162553 AirSpiral Heated Breathing TubeDec 20, 2018
828 days to decisionK162553 · Product code: **BTT** · Anesthesiology
Source: <https://www.510kdatabase.net/k162553/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Sep 13, 2016
Decision date	Dec 20, 2018
Days to decision	828 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fisher & Paykel Healthcare
Location	Auckland, NZ
Contact	STEPHANIE ELVIN
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...
