

K092846 AIRVO SERIES HUMIDIFIERSJan 27, 2010
134 days to decisionK092846 · Product code: **BTT** · Anesthesiology
Source: <https://www.510kdatabase.net/k092846/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Sep 15, 2009
Decision date	Jan 27, 2010
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fisher &Paykel Healthcare , Ltd.
Location	Auckland, New Zealand, NZ
Contact	JAMES THOMPSON
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...
