

**K131895 AIRVO 2 HUMIDIFIER, MYAIRVO 2 HUMIDIFIER**Oct 24, 2013  
121 days to decisionK131895 · Product code: **BTT** · Anesthesiology  
Source: <https://www.510kdatabase.net/k131895/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Humidifier, Respiratory Gas, (direct Patient Interface) (BTT)
Date received	Jun 25, 2013
Decision date	Oct 24, 2013
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fisher &amp;Paykel Healthcare , Ltd.</b>
Location	Auckland, New Zealand, NZ
Contact	BRETT WHISTON
Website	<a href="https://www.fphcare.com/">https://www.fphcare.com/</a>
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...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131895/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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