

K211560 Airvo Nebulizer AdapterDec 10, 2021
204 days to decisionK211560 · Product code: **CAF** · AnesthesiologySource: <https://www.510kdatabase.net/k211560/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	May 20, 2021
Decision date	Dec 10, 2021
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fisher & Paykel Healthcare Limited
Location	Auckland, NZ
Contact	Reena Daken
510(k) history	8 submissions · 8 cleared · 2012-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211560/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026