FDA 510(k) Premarket Notification

K251889 myAir

CLEARED

Apr 8, 2026
292 days to decision

K251889 · Product code: **MNS** · Anesthesiology
Source: https://www.510kdatabase.net/k251889/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Continuous, Non-life-supporting (MNS)
Date received	Jun 20, 2025
Decision date	Apr 8, 2026
Days to decision	292 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**ResMed Corp**
Location	Poway, CA, US
Contact	Rose Malonzo
Website	http://www.resmed.com/
510(k) history	15 submissions · 15 cleared · 1997-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k251889/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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