

K260270 FindAir ONE for pMDI (FAO-MDI-V12-GRE-001)Jun 2, 2026
125 days to decisionK260270 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k260270/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jan 28, 2026
Decision date	Jun 2, 2026
Days to decision	125 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	FindAir Sp. z o.o.
Location	Kraków, PL
Contact	Anna Pawlik
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Pure Global
Contact	Oliver Eikenberg

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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