

K250583 AdheResp Smart Breath-actuated Mesh NebulizerJun 20, 2025
113 days to decisionK250583 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k250583/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Feb 27, 2025
Decision date	Jun 20, 2025
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hcmed Innovations Co., Ltd.
Location	Taipei City, TW
Contact	Michelle Pieh
510(k) history	2 submissions · 2 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	ProMedic Consulting, LLC
Contact	Paul Dryden

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250583/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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