

K242354 AIINEBApr 29, 2025
264 days to decisionK242354 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k242354/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Aug 8, 2024
Decision date	Apr 29, 2025
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Enchant Tek Co. , Ltd.
Location	Yilan County, TW
Contact	Ling Leonard
510(k) history	2 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	ProMedic, 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/k242354/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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