FDA 510(k) Premarket Notification

K242354 AIINEB

CLEARED

Apr 29, 2025
264 days to decision

K242354 · 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