FDA 510(k) Premarket Notification

CLEARED

K244035 Portable mesh nebulizer (JM821)

Sep 19, 2025
263 days to decision

K244035 · Product code: **CAF** · Anesthesiology
Source: https://www.510kdatabase.net/k244035/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Dec 30, 2024
Decision date	Sep 19, 2025
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Jermei Medical Device Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Fang Li
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Joyantech Consulting Co., Ltd.**
Contact	James Tsai

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