

K232523 Sodium Chloride Inhalation Solution, USP 0.9%, 3% & 7%Apr 10, 2024
236 days to decisionK232523 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k232523/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Aug 18, 2023
Decision date	Apr 10, 2024
Days to decision	236 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mankind Pharma Limited
Location	New Delhi, IN
Contact	Rajender Singh
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Lifestar Pharma, LLC (A Mankind Group Company)
Contact	Parimal Upadhyay

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

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