

K210126 Sodium Chloride Inhalation Solutions, 3%, 3.5%, 7% and 10%Dec 3, 2021
318 days to decisionK210126 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k210126/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jan 19, 2021
Decision date	Dec 3, 2021
Days to decision	318 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	The Ritedose Corporation
Location	Columbia, SC, US
Contact	Linda Valentine
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210126/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026