

K231058 Hudson RCI® AddiPak® Unit Dose VialJan 4, 2024
266 days to decisionK231058 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k231058/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Apr 13, 2023
Decision date	Jan 4, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medline Industries, LP
Location	Nortfield, IL, US
Contact	Phyllis Kondor
Website	https://www.medline.com
510(k) history	29 submissions · 29 cleared · 2022-2026

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