

K223100 Hudson RCI AquaTherm III Plus External Adjustable Electronic Heater (050-14)Jun 27, 2023
270 days to decisionK223100 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k223100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Sep 30, 2022
Decision date	Jun 27, 2023
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medline Industries, Inc.
Location	Mchenry, IL, US
Contact	Nichole Schaffer
510(k) history	238 submissions · 234 cleared · 1977-2024

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Joy Gutermuth

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223100/>; 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 14, 2026