

K251572 eRapid with eTrack SystemDec 19, 2025
211 days to decisionK251572 · Product code: **CAF** · AnesthesiologySource: <https://www.510kdatabase.net/k251572/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	May 22, 2025
Decision date	Dec 19, 2025
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pari Respiratory Equipment, Inc.
Location	Midlothian, VA, US
Contact	Michael Judge
510(k) history	10 submissions · 10 cleared · 2009-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251572/> 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 13, 2026