

K063449 DELUXE NEBULIZERMar 1, 2007
106 days to decisionK063449 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k063449/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Nov 15, 2006
Decision date	Mar 1, 2007
Days to decision	106 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Access Point Medical, LLC
Location	Potomac, MD, US
Contact	JAMES W SANDBERG
510(k) history	4 submissions · 4 cleared · 2005-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063449/> 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 24, 2026