

K992831 AERONEB II, MODEL APN 200Aug 25, 2000
368 days to decisionK992831 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k992831/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Aug 23, 1999
Decision date	Aug 25, 2000
Days to decision	368 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aerogen, Inc.
Location	Sunnyvale, CA, US
Contact	TRACI V. A EDWARDS
510(k) history	4 submissions · 4 cleared · 2000-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k992831/> 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 25, 2026