

K915211 MICROCHAMBERMay 20, 1992
184 days to decisionK915211 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k915211/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Nov 18, 1991
Decision date	May 20, 1992
Days to decision	184 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Respiratory Delivery Systems, Inc.
Location	Lowell, MA, US
Contact	WALTER J MAKIEJ
510(k) history	2 submissions · 2 cleared · 1990-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k915211/> 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 26, 2026