FDA 510(k) Premarket Notification

K053203 MYNEB NEBULIZER, MODEL RDD100

CLEARED

Dec 20, 2005
34 days to decision

K053203 · Product code: **CAF** · Anesthesiology
Source: https://www.510kdatabase.net/k053203/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Nov 16, 2005
Decision date	Dec 20, 2005
Days to decision	34 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Respironics New Jersey, Inc.**
Location	Cedar Grove, NJ, US
Contact	Lauren Ziegler
510(k) history	5 submissions · 5 cleared · 2004-2011

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k053203/ 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