

**K072163 HAPPYNEB II, HAPPYNEB III, SPEEDY, NEBBY PLUS
AND MYNEB, MODEL 5**Mar 6, 2008
213 days to decisionK072163 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k072163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Aug 6, 2007
Decision date	Mar 6, 2008
Days to decision	213 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	3A Health Care S.R.L.
Location	North Reading, MA, US
Contact	MAUREEN O'CONNELL
510(k) history	1 submissions · 1 cleared · 2008-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k072163/> 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