

**K062014 FAMILIES OF MASTER NEB, PRIMO NEB, SC03, NEB  
AID, 4.2.NEB, Q03, FJ03, AND WALKIE-NEB**Mar 22, 2007  
248 days to decisionK062014 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k062014/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jul 17, 2006
Decision date	Mar 22, 2007
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Flaem Nuova S.P.A.</b>
Location	North Reading, MA, US
Contact	MAUREEN O'CONNELL
510(k) history	2 submissions · 2 cleared · 2007-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062014/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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