

K063103 AG-EDGE, MODEL 91200Jan 8, 2007
90 days to decisionK063103 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k063103/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Oct 10, 2006
Decision date	Jan 8, 2007
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medel S.P.A.
Location	Cary, NC, US
Contact	TERRENCE O' BRIEN
510(k) history	4 submissions · 4 cleared · 2006-2009

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