

K952910 THE SWIRLER NEBULIZERMar 19, 1997
632 days to decisionK952910 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k952910/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jun 26, 1995
Decision date	Mar 19, 1997
Days to decision	632 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Amici, Inc.
Location	Royersford, PA, US
Contact	MICHAEL BONO
510(k) history	8 submissions · 8 cleared · 1987-2007

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