

K952893 THE SWIRLER AEROSOL SYSTEMNov 3, 1995
133 days to decisionK952893 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k952893/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Nebulizer (direct Patient Interface) (CAF) |
| Date received | Jun 23, 1995 |
| Decision date | Nov 3, 1995 |
| Days to decision | 133 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k952893/> 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 21, 2026