

**K946095 DEVILBISS MODEL 5500**Aug 24, 1995  
253 days to decisionK946095 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k946095/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)         |
| Submission type       | Traditional                                |
| Device classification | Nebulizer (direct Patient Interface) (CAF) |
| Date received         | Dec 14, 1994                               |
| Decision date         | Aug 24, 1995                               |
| Days to decision      | 253 days                                   |
| Third-party review    | No   |
| Summary / Statement   | Summary                                    |

**APPLICANT**

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|----------------|---|
| Company        | <b>Devilbiss Health Care, Inc.</b>      |
| Location       | Somerset, PA, US                        |
| Contact        | BARRY IDDON                             |
| 510(k) history | 29 submissions · 28 cleared · 1989-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k946095/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026