

**K963349 DEVILBISS 8650D**Jun 13, 1997  
291 days to decisionK963349 · Product code: **BTI** · Anesthesiology  
Source: <https://www.510kdatabase.net/k963349/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Compressor, Air, Portable (BTI)
Date received	Aug 26, 1996
Decision date	Jun 13, 1997
Days to decision	291 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	MATT SMITH
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/k963349/> 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