

**K981944 BREATHERITE**Aug 24, 1998  
82 days to decisionK981944 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k981944/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jun 3, 1998
Decision date	Aug 24, 1998
Days to decision	82 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Ventlab Corp.</b>
Location	Hackensack, NJ, US
Contact	E.J. Smith
510(k) history	22 submissions · 22 cleared · 1989-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k981944/> 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 24, 2026