

**K974379 ULTRANEB**Feb 18, 1998  
90 days to decisionK974379 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k974379/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Nov 20, 1997
Decision date	Feb 18, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Bremed Italia, S.R.L.</b>
Location	Arnold, MO, US
Contact	MARK HEBENSTREIT
510(k) history	3 submissions · 3 cleared · 1997-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k974379/> 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