

**K944020 AIRSEP NEWLIFE AIR OUTLET OPTION**Mar 16, 1995  
212 days to decisionK944020 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k944020/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Aug 16, 1994
Decision date	Mar 16, 1995
Days to decision	212 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Airsep Corp.</b>
Location	Buffalo, NY, US
Contact	EDWARD E VRANA
510(k) history	18 submissions · 17 cleared · 1987-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944020/> 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