

**K042546 FUNHALER, MODEL FH 101**Jan 3, 2005  
105 days to decisionK042546 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k042546/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Sep 20, 2004
Decision date	Jan 3, 2005
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Infamed , Ltd.</b>
Location	South West Ranches, FL, US
Contact	JOHN D GREENBAUM
510(k) history	2 submissions · 2 cleared · 2005-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042546/> 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