

**K052941 I-NEB INSIGHT AAD SYSTEM**Dec 9, 2005  
50 days to decisionK052941 · Product code: **CAF** · AnesthesiologySource: <https://www.510kdatabase.net/k052941/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Oct 20, 2005
Decision date	Dec 9, 2005
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Profile Therapeutics Plc</b>
Location	Mccordsville, IN, US
Contact	BARBARA CAMPBELL
510(k) history	3 submissions · 3 cleared · 2004-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k052941/> 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