

**K111246 SPIRALE DRUG DELIVERY SYSTEM**Aug 10, 2012  
464 days to decisionK111246 · Product code: **CAF** · AnesthesiologySource: <https://www.510kdatabase.net/k111246/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	May 4, 2011
Decision date	Aug 10, 2012
Days to decision	464 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Armstrong Medical , Ltd.</b>
Location	Coleraine, IE
Contact	IAN STEWART
Website	<a href="http://www.armstrongmedical.net/">http://www.armstrongmedical.net/</a>
510(k) history	1 submissions · 1 cleared · 2012-2012

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111246/> 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