

**K072019 AKITA2 APIXNEB**Nov 5, 2007  
105 days to decisionK072019 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k072019/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jul 23, 2007
Decision date	Nov 5, 2007
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Activaero America, Inc.</b>
Location	Bonita Springs, FL, US
Contact	PAUL DRYDEN
510(k) history	3 submissions · 3 cleared · 2007-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k072019/> 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