

**K091803 SMARTTRACK SYSTEM**Oct 9, 2009  
115 days to decisionK091803 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k091803/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jun 16, 2009
Decision date	Oct 9, 2009
Days to decision	115 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nexus6, Ltd.</b>
Location	Auckland, NZ
Contact	GARTH SUTHERLAND
510(k) history	2 submissions · 2 cleared · 2009-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091803/> 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