

**K191270 Proneb Max**Jan 23, 2020  
255 days to decisionK191270 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k191270/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	May 13, 2019
Decision date	Jan 23, 2020
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pari Respiratory Equipment, Inc.</b>
Location	Midlothian, VA, US
Contact	Michael Judge
510(k) history	10 submissions · 10 cleared · 2009-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191270/> 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