

**K173825 MC 300R\* Nebulizer**May 2, 2018  
135 days to decisionK173825 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k173825/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Dec 18, 2017
Decision date	May 2, 2018
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Trudell Medical International</b>
Location	London, CA
Contact	Marianne Tanton
510(k) history	9 submissions · 9 cleared · 2015-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173825/> 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 27, 2026