

**K241091 SIMEOX 200 Airway Clearance Device**Dec 23, 2024  
245 days to decisionK241091 · Product code: **SDT** · Anesthesiology  
Source: <https://www.510kdatabase.net/k241091/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intra-pulmonary Percussive Vibration (ipv) Devices (SDT)
Date received	Apr 22, 2024
Decision date	Dec 23, 2024
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Inogen, Inc.</b>
Location	Goleta, CA, US
Contact	Carole Harris
510(k) history	4 submissions · 4 cleared · 2004-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Nilo Medical Consulting Group</b>
Contact	Michael Nilo

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241091/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026