

**K221024 tremoflo C2 Airwave Oscillometry System**Jun 20, 2023  
440 days to decisionK221024 · Product code: **PNV** · Anesthesiology  
Source: <https://www.510kdatabase.net/k221024/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Impedance Measuring Device Utilizing Oscillation Techniques (PNV)
Date received	Apr 6, 2022
Decision date	Jun 20, 2023
Days to decision	440 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Thorasys Thoracic Medical Systems, Inc.</b>
Location	Montreal, CA
Contact	Paul Donnelly
510(k) history	2 submissions · 2 cleared · 2017-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221024/> 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