

**K203343 Wesper Lab**Dec 21, 2021  
403 days to decisionK203343 · Product code: **MNR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k203343/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Nov 13, 2020
Decision date	Dec 21, 2021
Days to decision	403 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wesper, Inc.</b>
Location	New York, NY, US
Contact	Amir Reuveny
Website	<a href="https://wesper.co">https://wesper.co</a>
510(k) history	4 submissions · 4 cleared · 2021-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203343/> 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 26, 2026