

**K253148 RX-1 Sleep**Jun 22, 2026  
270 days to decisionK253148 · Product code: **MNR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k253148/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Sep 25, 2025
Decision date	Jun 22, 2026
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vivaquant, Inc. Db a Rhythm Express</b>
Location	Arden Hills, MN, US
Contact	Brian Brockway
510(k) history	1 submissions · 1 cleared · 2026-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253148/> 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 July 11, 2026