

**K083620 SOMNOLYZER 24X7**Mar 6, 2009  
88 days to decisionK083620 · Product code: **MNR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k083620/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Dec 8, 2008
Decision date	Mar 6, 2009
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>The Siesta Group North America</b>
Location	Dedham, MA, US
Contact	ZVI LADIN
510(k) history	1 submissions · 1 cleared · 2009-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083620/> 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 24, 2026