

**K122130 WINX SLEEP THERAPY SYSTEM**Oct 31, 2012  
105 days to decisionK122130 · Product code: **OZR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k122130/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intraoral Pressure Gradient Device (OZR)
Date received	Jul 18, 2012
Decision date	Oct 31, 2012
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Apnicure, Inc.</b>
Location	Redwood City, CA, US
Contact	CHRIS DANIEL
510(k) history	4 submissions · 4 cleared · 2012-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122130/> 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