

**K162905 SleepWeaver 3D Nasal Mask**Mar 15, 2017  
149 days to decisionK162905 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k162905/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Oct 17, 2016
Decision date	Mar 15, 2017
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Circadiance, LLC</b>
Location	Murrysville, PA, US
Contact	JAMES GIANOUTSOS
510(k) history	5 submissions · 5 cleared · 2009-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162905/> 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