

**K130481 SLEEPWEAVER ANEW FULL FACE SOFT CLOTH PAP MASK**

May 24, 2013  
88 days to decision

K130481 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k130481/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Feb 25, 2013
Decision date	May 24, 2013
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Circadiance, LLC</b>
Location	Murrysville, PA, US
Contact	RYAN T KASUN
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/k130481/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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