

**K092362 SLEEPWEAVER NASAL CPAP MASK**Nov 2, 2009  
90 days to decisionK092362 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k092362/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Traditional                                   |
| Device classification | Ventilator, Non-continuous (respirator) (BZD) |
| Date received         | Aug 4, 2009                                   |
| Decision date         | Nov 2, 2009                                   |
| Days to decision      | 90 days                                       |
| Third-party review    | No  |
| Summary / Statement   | Summary                                       |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Circadiance, LLC</b>               |
| Location       | Murrysville, PA, US                   |
| Contact        | DAVID GROLL                           |
| 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/k092362/> 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