

**K090243 REMSTAR M-SERIES AUTO WITH AFLEX CPAP SYSTEM**

May 8, 2009  
95 days to decision

K090243 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k090243/>

**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Special                                       |
| Device classification | Ventilator, Non-continuous (respirator) (BZD) |
| Date received         | Feb 2, 2009                                   |
| Decision date         | May 8, 2009                                   |
| Days to decision      | 95 days                                       |
| Third-party review    | No  |
| Summary / Statement   | Summary                                       |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Respironics Inc., Sleep &amp; Home Respiratory Group</b> |
| Location       | Murrysville, PA, US   |
| Contact        | ZITA A YURKO  |
| 510(k) history | 21 submissions · 21 cleared · 2007-2010                     |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k090243/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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