

**K162131 ExSpirom 1Xi**May 9, 2017  
281 days to decisionK162131 · Product code: **BZK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k162131/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Monitoring (w/wo Alarm) (BZK)
Date received	Aug 1, 2016
Decision date	May 9, 2017
Days to decision	281 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Respiratory Motion, Inc.</b>
Location	Waltham, MA, US
Contact	Edwin Rule
510(k) history	4 submissions · 4 cleared · 2012-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162131/> 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