

**K061712 SPIROBANK II**Dec 1, 2006  
165 days to decisionK061712 · Product code: **BZG** · Anesthesiology  
Source: <https://www.510kdatabase.net/k061712/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Jun 19, 2006
Decision date	Dec 1, 2006
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mir Medical Intl. Research Srl</b>
Location	Roma, IT
Contact	SIMON FOWLER
510(k) history	10 submissions · 10 cleared · 1998-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k061712/> 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