

**K103575 SPIRO PD**Nov 9, 2011  
338 days to decisionK103575 · Product code: **BZG** · Anesthesiology  
Source: <https://www.510kdatabase.net/k103575/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Dec 6, 2010
Decision date	Nov 9, 2011
Days to decision	338 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pmd Healthcare</b>
Location	Crofton, MD, US
Contact	E.J. Smith
510(k) history	1 submissions · 1 cleared · 2011-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103575/> 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