

**K150515 IQSense Flow Sensor Mouthpiece**Jan 12, 2016  
316 days to decisionK150515 · Product code: **BZG** · Anesthesiology  
Source: <https://www.510kdatabase.net/k150515/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Mar 2, 2015
Decision date	Jan 12, 2016
Days to decision	316 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sdi Diagnostics, Inc.</b>
Location	North Easton, MA, US
Contact	COSIMO CARIOLO
510(k) history	10 submissions · 10 cleared · 1993-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k150515/> 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