

K013812 SPIROLAB II, MODEL 29Feb 11, 2002
88 days to decisionK013812 · Product code: **BZG** · AnesthesiologySource: <https://www.510kdatabase.net/k013812/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Nov 15, 2001
Decision date	Feb 11, 2002
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sdi Diagnostics, Inc.
Location	North Easton, MA, US
Contact	MICHAEL J BOYLE
510(k) history	10 submissions · 10 cleared · 1993-2016

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