

K031643 SPIROTEL, MODEL 29-1020Dec 9, 2003
196 days to decisionK031643 · Product code: **BZG** · Anesthesiology
Source: <https://www.510kdatabase.net/k031643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	May 27, 2003
Decision date	Dec 9, 2003
Days to decision	196 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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