FDA 510(k) Premarket Notification

K011470 SDI SB OFFICE, MODEL 29-

CLEARED

Oct 12, 2001
151 days to decision

K011470 · Product code: **BZG** · Anesthesiology
Source: https://www.510kdatabase.net/k011470/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	May 14, 2001
Decision date	Oct 12, 2001
Days to decision	151 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k011470/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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