FDA 510(k) Premarket Notification

K033939 FLOSENSE II, MODEL 29-8040

CLEARED

Jan 30, 2004
46 days to decision

K033939 · Product code: **BZG** · Anesthesiology
Source: https://www.510kdatabase.net/k033939/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Dec 15, 2003
Decision date	Jan 30, 2004
Days to decision	46 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/k033939/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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