

K001528 PC FLOW +Jan 18, 2001
246 days to decisionK001528 · Product code: **BZG** · Anesthesiology
Source: <https://www.510kdatabase.net/k001528/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Spirometer, Diagnostic (BZG) |
| Date received | May 17, 2000 |
| Decision date | Jan 18, 2001 |
| Days to decision | 246 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Spirometrics Medical Equipment Co. |
| Location | N. Attleboro, MA, US |
| Contact | JAMES R VEALE |
| 510(k) history | 3 submissions · 3 cleared · 1996-2001 |

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