

K042595 SPIRO'AIRMay 4, 2005
223 days to decisionK042595 · Product code: **BZG** · Anesthesiology
Source: <https://www.510kdatabase.net/k042595/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Spirometer, Diagnostic (BZG) |
| Date received | Sep 23, 2004 |
| Decision date | May 4, 2005 |
| Days to decision | 223 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Morgan Scientific, Inc. |
| Location | Haverhill, MA, US |
| Contact | PATRICK MORGAN |
| 510(k) history | 6 submissions · 6 cleared · 2002-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042595/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026