

K042758 POLYTECH PULMONARY FUNCTION FILTERAug 29, 2005
329 days to decisionK042758 · Product code: **BZG** · AnesthesiologySource: <https://www.510kdatabase.net/k042758/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Spirometer, Diagnostic (BZG) |
| Date received | Oct 4, 2004 |
| Decision date | Aug 29, 2005 |
| Days to decision | 329 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Polytechnic Resources, Inc. |
| Location | Baltimore, MD, US |
| Contact | TIMOTHY BYRD |
| 510(k) history | 1 submissions · 1 cleared · 2005-2005 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042758/> 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 25, 2026