

**K951227 DX1**Aug 11, 1995  
144 days to decisionK951227 · Product code: **BZG** · Anesthesiology  
Source: <https://www.510kdatabase.net/k951227/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Spirometer, Diagnostic (BZG)       |
| Date received         | Mar 20, 1995                       |
| Decision date         | Aug 11, 1995                       |
| Days to decision      | 144 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Creative Biomedics, Inc.</b>       |
| Location       | San Clemente, CA, US                  |
| Contact        | DANIEL BROWN                          |
| 510(k) history | 4 submissions · 4 cleared · 1995-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k951227/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026