

**K932009 THE SAMUELS RETROGRAD VALVULOTOME**Sep 21, 1993  
151 days to decisionK932009 · Product code: **MGZ** · CardiovascularSource: <https://www.510kdatabase.net/k932009/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Valvulotome (MGZ)                  |
| Date received         | Apr 23, 1993                       |
| Decision date         | Sep 21, 1993                       |
| Days to decision      | 151 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---|
| Company        | <b>Vascutech, Inc.</b>                  |
| Location       | Washington, DC, US                      |
| Contact        | GEORGE W LEMAITRE                       |
| 510(k) history | 14 submissions · 14 cleared · 1985-2000 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k932009/> 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 20, 2026