

**K925283 VALVULOTOME**Feb 10, 1994  
478 days to decisionK925283 · Product code: **MGZ** · CardiovascularSource: <https://www.510kdatabase.net/k925283/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Valvulotome (MGZ)
Date received	Oct 20, 1992
Decision date	Feb 10, 1994
Days to decision	478 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Intramed Laboratories, Inc.</b>
Location	San Diego, CA, US
Contact	STEPHEN A SOSNOWSKI
510(k) history	14 submissions · 14 cleared · 1987-1996

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k925283/> 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 22, 2026