

**K914385 OPTICAL VALVULOTOME**Mar 2, 1992  
153 days to decisionK914385 · Product code: **MGZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k914385/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Valvulotome (MGZ)
Date received	Oct 1, 1991
Decision date	Mar 2, 1992
Days to decision	153 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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