

**K965137 FOGARTY VALVULOTOME MODEL 700091**Jun 4, 1997  
163 days to decisionK965137 · Product code: **MGZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k965137/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Valvulotome (MGZ)
Date received	Dec 23, 1996
Decision date	Jun 4, 1997
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Baxter Edwards</b>
Location	Irvine, CA, US
Contact	PAULA TORRIANNI
510(k) history	11 submissions · 10 cleared · 1993-2000

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