

**K053440 AMPLATZER SIZING BALLOON II**Dec 30, 2005  
21 days to decisionK053440 · Product code: **MJN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k053440/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Dec 9, 2005
Decision date	Dec 30, 2005
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aga Medical Corp.</b>
Location	Plymouth, MN, US
Contact	AMANDA JOHNSON
510(k) history	14 submissions · 14 cleared · 2000-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053440/> 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 June 14, 2026