

**K163000 AMPLATZER TorqVue 45x45 Delivery Sheath**Dec 23, 2016  
56 days to decisionK163000 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k163000/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Oct 28, 2016
Decision date	Dec 23, 2016
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aga Medical CO</b> (Wholly Owned by St. Jude Medical CO)
Location	Plymouth, MN, US
Contact	Mary Johnson
510(k) history	1 submissions · 1 cleared · 2016-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163000/> 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 2, 2026