

**K121611 AMPLATZER TORQVUE FX**Aug 23, 2012  
83 days to decisionK121611 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k121611/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jun 1, 2012
Decision date	Aug 23, 2012
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aga Medical Corporation</b>
Location	Plymouth, MN, US
Contact	SHERRY KOLLMANN
510(k) history	2 submissions · 2 cleared · 2012-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121611/> 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