

**K120120 AMPLATZER TORQVUE 45X45 DELIVERY SHEATH  
AMPLATZER TORQVUE LA1 DELIVERY SHEATH AMPLATZER  
TORQVUE LA2 DELIVERY SHEATH**Mar 15, 2012  
58 days to decisionK120120 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k120120/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Jan 17, 2012
Decision date	Mar 15, 2012
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aga Medical Corporation</b>
Location	Plymouth, MN, US
Contact	RASHMI BHUSHAN
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/k120120/> 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