

K162228 TorqVue Low Profile Delivery CatheterSep 9, 2016
32 days to decisionK162228 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k162228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 8, 2016
Decision date	Sep 9, 2016
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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