

K080994 AMPLATZER TORQVUE EXCHANGE SYSTEMMay 16, 2008
39 days to decisionK080994 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k080994/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Apr 7, 2008
Decision date	May 16, 2008
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Aga Medical Corp.
Location	Plymouth, MN, US
Contact	MICHELLE NIVALA
510(k) history	14 submissions · 14 cleared · 2000-2012

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