

**K083214 AMPLATZER TORQVUE 45DEGREEX45DEGREE
DELIVERY SHEATH, MODELS 9-TV45X45-09F-100,
9-TV45X45-10F-100**May 12, 2009
193 days to decisionK083214 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k083214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Oct 31, 2008
Decision date	May 12, 2009
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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