FDA 510(k) Premarket Notification

K121611 AMPLATZER TORQVUE FX

CLEARED

Aug 23, 2012
83 days to decision

K121611 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k121611/

SUBMISSION DETAILS

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

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