FDA 510(k) Premarket Notification

K070238 AMPLATZER RELIANT CATHETER DELIVERY SYSTEM

CLEARED

Feb 28, 2007
34 days to decision

K070238 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k070238/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jan 25, 2007
Decision date	Feb 28, 2007
Days to decision	34 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Aga Medical Corp.**
Location	Plymouth, MN, US
Contact	DAVID D COX
510(k) history	14 submissions · 14 cleared · 2000-2012