FDA 510(k) Premarket Notification

CLEARED

K062868 THE CROSSER CATHETER, MODEL CR1100 AND SYSTEM ELECTRONICS, MODEL FG1002-02

Jan 19, 2007
116 days to decision

K062868 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k062868/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 25, 2006
Decision date	Jan 19, 2007
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Flowcardia, Inc.**
Location	Sunnyvale, CA, US
Contact	Dustin Michaels
510(k) history	11 submissions · 11 cleared · 2005-2010