FDA 510(k) Premarket Notification

K131332 CARDIOSOLUTIONS PERCU-PRO STEERABLE INTRODUCER

CLEARED

Jul 19, 2013
71 days to decision

K131332 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k131332/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	May 9, 2013
Decision date	Jul 19, 2013
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiosolutions, Inc.**
Location	Stoughton, MA, US
Contact	MICHELE LUCE
510(k) history	4 submissions · 4 cleared · 2010-2014