

**K131332 CARDIOSOLUTIONS PERCU-PRO STEERABLE
INTRODUCER**Jul 19, 2013
71 days to decisionK131332 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131332/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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