

**K120086 CARIOSOLUTIONS PERCU-PRO STEERABLE  
INTRODCER 65CM CARIOSOLUTIONS PERCU-PRO  
STEERABLE INTRODUCER 80CM**Apr 24, 2012  
104 days to decisionK120086 · Product code: **DRA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k120086/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Steerable (DRA)
Date received	Jan 11, 2012
Decision date	Apr 24, 2012
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardiosolutions</b>
Location	West Bridgewater, MA, US
Contact	MICHELE LUCEY
510(k) history	1 submissions · 1 cleared · 2012-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120086/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 14, 2026