

**K091119 MODIFICATION TO THE CROSSER SYSTEM**May 15, 2009  
28 days to decisionK091119 · Product code: **PDU** · CardiovascularSource: <https://www.510kdatabase.net/k091119/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Apr 17, 2009
Decision date	May 15, 2009
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091119/> 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 21, 2026