

**K111388 DIAMONDBACK 360\* ORBITAL ATHERECTOMY  
SYSTEM, STEALTH 360\* ORBITAL PAD SYSTEM**Jul 26, 2011  
70 days to decisionK111388 · Product code: **MCW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k111388/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	May 17, 2011
Decision date	Jul 26, 2011
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardiovascular Systems, Inc.</b>
Location	Saint Paul, MN, US
Contact	MEGAN M BRANDT
510(k) history	26 submissions · 26 cleared · 2007-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111388/> 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 18, 2026