

**K133399 DIAMONDBACK 360 PERIPHERAL ORBITAL  
ATHERECTOMY SYSTEM**Nov 22, 2013  
16 days to decisionK133399 · Product code: **MCW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k133399/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Nov 6, 2013
Decision date	Nov 22, 2013
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardiovascular Systems Incorporated</b>
Location	Stoughton, WI, US
Contact	BLAIR BUTH
510(k) history	2 submissions · 2 cleared · 2005-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133399/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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