

**K081944 MODIFICATION TO DIAMONDBACK 360 DEGREE  
ORBITAL ATHERECTOMY SYSTEM**Aug 14, 2008  
37 days to decisionK081944 · Product code: **MCW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k081944/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Jul 8, 2008
Decision date	Aug 14, 2008
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cardio Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	DAVID D BROOKE
510(k) history	9 submissions · 9 cleared · 1979-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081944/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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