

**K182397 Diamondback 360 Peripheral Orbital Atherectomy  
System Exchangeable Series**Dec 13, 2018  
100 days to decisionK182397 · Product code: **MCW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k182397/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Sep 4, 2018
Decision date	Dec 13, 2018
Days to decision	100 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	Kris Miller
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/k182397/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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