

K152694 Diamondback 360 Peripheral Orbital Atherectomy SystemOct 21, 2015
30 days to decisionK152694 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k152694/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Sep 21, 2015
Decision date	Oct 21, 2015
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardiovascular Systems, Inc.
Location	Saint Paul, MN, US
Contact	Kim Wallner
510(k) history	26 submissions · 26 cleared · 2007-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k152694/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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