

**K151260 ViperWire Advance Guide Wire, Diamondback 360
Peripheral Orbital Atherectomy System, Stealth 360 Orbital PAD**

Jun 10, 2015
29 days to decision

K151260 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k151260/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	May 12, 2015
Decision date	Jun 10, 2015
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardiovascular System, Inc.
Location	Saint Paul, MN, US
Contact	Kim Wallner
510(k) history	1 submissions · 1 cleared · 2015-2015

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k151260/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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