

**K180416 ViperWire Advance Guide Wire, Stealth 360 Orbital Peripheral Atherectomy Device (PAD), DIAMONDBACK 360 Peripheral Atherectomy System**Apr 17, 2018  
61 days to decisionK180416 · Product code: **MCW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k180416/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Feb 15, 2018
Decision date	Apr 17, 2018
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Cardiovascular Systems, Inc.</b>
Location	Saint Paul, MN, US
Contact	Susan Wolf
510(k) history	26 submissions · 26 cleared · 2007-2022

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180416/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 30, 2026