

K190634 Diamondback 360 Peripheral Orbital Atherectomy System, Stealth 360 Peripheral Orbital Atherectomy SystemJul 2, 2019
112 days to decisionK190634 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k190634/>**SUBMISSION DETAILS**

| | |
|-----------------------|-----------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Peripheral, Atherectomy (MCW) |
| Date received | Mar 12, 2019 |
| Decision date | Jul 2, 2019 |
| Days to decision | 112 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190634/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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