

K220109 DIAMONDBACK 360 Peripheral Orbital Atherectomy System, DIAMONDBACK 360 Peripheral Orbital Atherectomy System, Exchangeable Series, Stealth 360 Peripheral Orbital Atherectomy SystemMar 1, 2022
47 days to decisionK220109 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k220109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Jan 13, 2022
Decision date	Mar 1, 2022
Days to decision	47 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220109/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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