

K220568 Diamondback 360 Peripheral Orbital Atherectomy System, Stealth 360 Peripheral Orbital Atherectomy System, Diamondback 360 Peripheral Orbital Atherectomy System Exchangeable SeriesApr 27, 2022
58 days to decisionK220568 · Product code: **MCW** · Cardiovascular
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Feb 28, 2022
Decision date	Apr 27, 2022
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cardiovascular Systems, Inc.
Location	St Paul, MN, US
Contact	Kris Miller
510(k) history	1 submissions · 1 cleared · 2022-2022

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