

K203008 DIAMONDBACK 360 Peripheral Orbital Atherectomy System, DIAMONDBACK 360 Peripheral Orbital Atherectomy System, Exchangeable Series, Stealth 360 Peripheral Orbital Atherectomy SystemNov 19, 2020
49 days to decisionK203008 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k203008/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Oct 1, 2020
Decision date	Nov 19, 2020
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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