

**K210586 Diamonback 360 Peripheral Orbital Atherectomy System, Diamondback 360 Stealth Orbital Atherectomy system**Sep 14, 2021  
200 days to decisionK210586 · Product code: **MCW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k210586/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Feb 26, 2021
Decision date	Sep 14, 2021
Days to decision	200 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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