

**K071350 DIAMONDBACK 360 DEGREE ORBITAL
ATHERECTOMY SYSTEM**Aug 22, 2007
100 days to decisionK071350 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k071350/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	May 14, 2007
Decision date	Aug 22, 2007
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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