

**K071427 DIAMONDBACK 360 DEGREE ORBITAL
ATHERECTOMY SYSTEM FOR TREATMENT OF A-V SHUNT
STENOSIS**Aug 30, 2007
99 days to decisionK071427 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k071427/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	May 23, 2007
Decision date	Aug 30, 2007
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k071427/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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