

**K082981 DIAMONDBACK 360 DEGREE ORBITAL
ATHERECTOMY SYSTEM WITH VIPERSLIDE LUBRICANT**Oct 31, 2008
25 days to decisionK082981 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k082981/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Oct 6, 2008
Decision date	Oct 31, 2008
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082981/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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