

K110389 STEALTH 360 ORBITAL PAD SYSTEMMar 11, 2011
29 days to decisionK110389 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k110389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Feb 10, 2011
Decision date	Mar 11, 2011
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110389/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026