

K131092 STEALTH 360 ORBITAL PAD SYSTEMJun 24, 2013
67 days to decisionK131092 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k131092/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Apr 18, 2013
Decision date	Jun 24, 2013
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardio Systems, Inc.
Location	Mchenry, IL, US
Contact	MAUREEN MCDONNELL
510(k) history	9 submissions · 9 cleared · 1979-2013

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