

K041630 ORBITAL ATHERECTOMY SYSTEM FOR TREATMENT OF A-V SHUNT STENOSISJan 31, 2005
229 days to decisionK041630 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k041630/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Jun 16, 2004
Decision date	Jan 31, 2005
Days to decision	229 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cardiovascular Systems Incorporated
Location	Stoughton, WI, US
Contact	Gary Syring
510(k) history	2 submissions · 2 cleared · 2005-2013

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