

K161361 HawkOne Directional Atherectomy SystemOct 14, 2016
151 days to decisionK161361 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k161361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	May 16, 2016
Decision date	Oct 14, 2016
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Vascular, Inc.
Location	Plymouth, MN, US
Contact	Rupali Gupta
510(k) history	5 submissions · 5 cleared · 2016-2018

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