

**K141801 HAWKONE DIRECTIONAL ATHERECTOMY SYSTEM**Oct 16, 2014  
105 days to decisionK141801 · Product code: **MCW** · CardiovascularSource: <https://www.510kdatabase.net/k141801/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Jul 3, 2014
Decision date	Oct 16, 2014
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Covidien, LLC</b>
Location	Mansfield, MA, US
Contact	JULIE UNDERDAHL
510(k) history	88 submissions · 85 cleared · 2010-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k141801/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 6, 2026