

**K093301 TURBOHAWK PERIPHERAL PLAQUE EXCISION SYSTEM**Nov 6, 2009  
16 days to decisionK093301 · Product code: **MCW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k093301/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Oct 21, 2009
Decision date	Nov 6, 2009
Days to decision	16 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ev3, Inc.</b>
Location	Plymouth, MN, US
Contact	BRENDA JOHNSON
510(k) history	35 submissions · 26 cleared · 2003-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k093301/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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