

**K091029 CLEANER ROTATIONAL THROMBECTOMY SYSTEM  
(9 MM X 65 CM) AND (9 MM X 120 CM)**Feb 18, 2010  
314 days to decisionK091029 · Product code: **MCW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k091029/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Apr 10, 2009
Decision date	Feb 18, 2010
Days to decision	314 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rex Medical</b>
Location	Great Neck, NY, US
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	13 submissions · 11 cleared · 2003-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091029/>; 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 14, 2026