

K120346 CLEANER ROTATIONAL THROMBECTOMY SYSTEMJun 1, 2012
119 days to decisionK120346 · Product code: **MCW** · CardiovascularSource: <https://www.510kdatabase.net/k120346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Feb 3, 2012
Decision date	Jun 1, 2012
Days to decision	119 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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