

**K212351 Revolution Peripheral Atherectomy System**Dec 15, 2021  
139 days to decisionK212351 · Product code: **MCW** · CardiovascularSource: <https://www.510kdatabase.net/k212351/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Jul 29, 2021
Decision date	Dec 15, 2021
Days to decision	139 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rex Medical, L.P.</b>
Location	Great Neck, NY, US
Contact	Colin Valentis
510(k) history	8 submissions · 8 cleared · 2004-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212351/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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