

**K191419 Revolution Peripheral Atherectomy System,
Revolution Peripheral Atherectomy Guidewire**Sep 12, 2019
107 days to decisionK191419 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k191419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	May 28, 2019
Decision date	Sep 12, 2019
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191419/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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