

**K210911 WOLF Thrombectomy System, 14F**Oct 19, 2021  
204 days to decisionK210911 · Product code: **QEW** · CardiovascularSource: <https://www.510kdatabase.net/k210911/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Mar 29, 2021
Decision date	Oct 19, 2021
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Devoro Medical, Inc.</b>
Location	Fremont, CA, US
Contact	Michael P Wallace
510(k) history	5 submissions · 5 cleared · 2020-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Northwest Clinical Research Group, Inc.</b>
Contact	Roberta Hines

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210911/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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