

**K182835 WOLF Thrombectomy Device**Mar 27, 2019  
169 days to decisionK182835 · Product code: **QEW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k182835/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Oct 9, 2018
Decision date	Mar 27, 2019
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>880 Medical, LLC</b>
Location	Fremont, CA, US
Contact	Micheal P. Wallace
510(k) history	1 submissions · 1 cleared · 2019-2019

**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](https://accessdata.fda.gov)

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