

K210530 WOLF Thrombectomy System, 6FAug 27, 2021
184 days to decisionK210530 · Product code: **QEW** · Cardiovascular
Source: <https://www.510kdatabase.net/k210530/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Feb 24, 2021
Decision date	Aug 27, 2021
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Northwest Clinical Research Group, Inc.
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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