

K253730 RoVo Mechanical Thrombectomy SystemJan 21, 2026
58 days to decisionK253730 · Product code: **QEW** · CardiovascularSource: <https://www.510kdatabase.net/k253730/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Nov 24, 2025
Decision date	Jan 21, 2026
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Verge Medical, Inc.
Location	Campbell, CA, US
Contact	Michael Buck
510(k) history	2 submissions · 2 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Bridge City Regulatory, LLC
Contact	Rey Jacinto

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253730/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026