FDA 510(k) Premarket Notification

CLEARED

K253730 RoVo Mechanical Thrombectomy System

Jan 21, 2026
58 days to decision

K253730 · Product code: **QEW** · Cardiovascular
Source: 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