FDA 510(k) Premarket Notification

CLEARED

K251185 Recana Thrombectomy Catheter System (FG014. FG015, FG016, FG017, FG018, FG019, FG020)

Oct 22, 2025
189 days to decision

K251185 · Product code: **QEW** · Cardiovascular
Source: https://www.510kdatabase.net/k251185/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Apr 16, 2025
Decision date	Oct 22, 2025
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Intervene**
Location	Redwood City, CA, US
Contact	Eric Dooley
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Mark Smutka**
Contact	Mark Smutka

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