FDA 510(k) Premarket Notification

CLEARED

K250013 VentiV 7Fr -12Fr MP Mechanical Thrombectomy System (VS7-MP60S, VS7-MP90S, VS8-MP60S, VS8-MP90S, VS8-MP100B, VS10-MP100B, VS11-MP60S, VS11-MP90S, VS12-MP100B, 7F-MP60S, 7F-MP90S, 8F-MP60S, 8F-MP100B, 10F-MP100B, 11F-MP60S, 11F-MP90S, 11P-MP60S, 11P-MP90S, 12F-MP100B, V30-ASP)

Mar 24, 2025
81 days to decision

K250013 · Product code: **QEZ** · Cardiovascular
Source: https://www.510kdatabase.net/k250013/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Aspiration Thrombectomy Catheter (QEZ)
Date received	Jan 2, 2025
Decision date	Mar 24, 2025
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Control Medical Technology, Inc. / Dba Ventiv Scientific**
Location	Salt Lake City, UT, US
Contact	Shawn Fojtik
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Peak Regulatory Consulting**
Contact	Spencer Walker

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