

K251312 Vesalio Peripheral SystemOct 24, 2025
179 days to decisionK251312 · Product code: **QEZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k251312/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aspiration Thrombectomy Catheter (QEZ)
Date received	Apr 28, 2025
Decision date	Oct 24, 2025
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vesalio, Inc.
Location	San Diego, CA, US
Contact	Sharon Shachar
510(k) history	4 submissions · 3 cleared · 2025-2026

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