

**K253407 NeVa PV Thrombectomy Device**Nov 24, 2025  
55 days to decisionK253407 · Product code: **QEX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k253407/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Coronary Mechanical Thrombectomy With Aspiration (QEX)
Date received	Sep 30, 2025
Decision date	Nov 24, 2025
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253407/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026