

**K211492 Pounce Thrombectomy System**Jul 30, 2021  
78 days to decisionK211492 · Product code: **QEW** · CardiovascularSource: <https://www.510kdatabase.net/k211492/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	May 13, 2021
Decision date	Jul 30, 2021
Days to decision	78 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Surmodics, Inc.</b>
Location	Eden Prairie, MN, US
Contact	Holly Ramirez
510(k) history	11 submissions · 11 cleared · 2018-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211492/> 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 26, 2026