

K241362 Pounce XL Thrombectomy System (PTS-1011-7F135)Sep 11, 2024
120 days to decisionK241362 · Product code: **QEW** · CardiovascularSource: <https://www.510kdatabase.net/k241362/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	May 14, 2024
Decision date	Sep 11, 2024
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241362/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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