

K220501 Pounce Thrombectomy SystemMar 23, 2022
29 days to decisionK220501 · Product code: **QEW** · CardiovascularSource: <https://www.510kdatabase.net/k220501/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Feb 22, 2022
Decision date	Mar 23, 2022
Days to decision	29 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

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