

**K252227 Pounce(TM) Sheath**Sep 24, 2025  
70 days to decisionK252227 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k252227/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jul 16, 2025
Decision date	Sep 24, 2025
Days to decision	70 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	Peter Bather
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/k252227/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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