

K231828 Pounce™ SheathSep 7, 2023
78 days to decisionK231828 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k231828/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jun 21, 2023
Decision date	Sep 7, 2023
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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