

K260626 Multiflex Steerable Sheath 17.5FMar 26, 2026
28 days to decisionK260626 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k260626/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Feb 26, 2026
Decision date	Mar 26, 2026
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vizarmed, Inc.
Location	San Jose, CA, US
Contact	Jack Douglas
510(k) history	2 submissions · 2 cleared · 2022-2026

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