

K221655 Multiflex Steerable SheathNov 14, 2022
160 days to decisionK221655 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k221655/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jun 7, 2022
Decision date	Nov 14, 2022
Days to decision	160 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 P Douglas
510(k) history	2 submissions · 2 cleared · 2022-2026

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