

K251051 AuST Steerable SheathApr 30, 2025
27 days to decisionK251051 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k251051/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Apr 3, 2025
Decision date	Apr 30, 2025
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	CenterPoint Systems, LLC
Location	West Valley City, UT, US
Contact	Conner Johnson
Website	https://centerpointsystems.com
510(k) history	12 submissions · 12 cleared · 2021-2026

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