

K260942 AuST Steerable SheathApr 7, 2026
18 days to decisionK260942 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k260942/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Mar 20, 2026
Decision date	Apr 7, 2026
Days to decision	18 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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