

K261492 FieldFlex Steerable SheathJun 5, 2026
30 days to decisionK261492 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k261492/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Introducer, Catheter (DYB) |
| Date received | May 6, 2026 |
| Decision date | Jun 5, 2026 |
| Days to decision | 30 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 | Lauren Marold |
| Website | https://centerpointsystems.com |
| 510(k) history | 13 submissions · 13 cleared · 2021-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k261492/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026