

K223872 Low Profile Companion SheathJan 19, 2023
27 days to decisionK223872 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k223872/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Dec 23, 2022 |
| Decision date | Jan 19, 2023 |
| Days to decision | 27 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Merit Medical Systems, Inc. |
| Location | South Jordan, UT, US |
| Contact | Kirk McIntosh |
| Website | https://www.merit.com |
| 510(k) history | 177 submissions · 169 cleared · 1988-2026 |

Merit Medical Systems, Inc. is a leading manufacturer of disposable medical devices for interventional, diagnostic, and therapeutic procedures. Based in South Jordan, the company serves hospitals and physicians worldwide. Merit Medical has established a strong FDA 510(k) regulatory record since its first clearance in 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances span cardiovascular devices, neurology, gastroenterology, and general surgery, demonstrating broad clinical expertise. The latest clearance in 2026 confirms the com...

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Device record: <https://www.510kdatabase.net/k223872/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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