

K150257 PreludeEASE Hydrophilic Sheath IntroducerJun 19, 2015
136 days to decisionK150257 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k150257/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------|
| Decision | Substantially Equivalent - K |
| Submission type | Special |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Feb 3, 2015 |
| Decision date | Jun 19, 2015 |
| Days to decision | 136 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Merit Medical Systems, Inc. |
| Location | South Jordan, UT, US |
| Contact | Michaela Rivkowich |
| 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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