

**K122190 PRELUDE 7F SHORT SHEATH INTRODUCER**Aug 17, 2012  
24 days to decisionK122190 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k122190/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Jul 24, 2012
Decision date	Aug 17, 2012
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Merit Medical Systems, Inc.</b>
Location	South Jordan, UT, US
Contact	DAN CLARK
Website	<a href="https://www.merit.com">https://www.merit.com</a>
510(k) history	178 submissions · 170 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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