

**K082063 PRELUDE SHORT SHEATH INTRODUCER**Oct 15, 2008  
86 days to decisionK082063 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k082063/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jul 21, 2008
Decision date	Oct 15, 2008
Days to decision	86 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	JERRIE HENDRICKSON
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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