

**K132720 HEARTSPAN FIXED CURVE BRAIDED TRANSSEPTAL SHEATH**Feb 12, 2014  
166 days to decisionK132720 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k132720/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 30, 2013
Decision date	Feb 12, 2014
Days to decision	166 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	ALINA STUBBS
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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Device record: <https://www.510kdatabase.net/k132720/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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