

K170668 HeartSpan Steerable Sheath IntroducerApr 5, 2017
30 days to decisionK170668 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k170668/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Mar 6, 2017
Decision date	Apr 5, 2017
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Merit Medical Systems, Inc.
Location	South Jordan, UT, US
Contact	Alina Stubbs
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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170668/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026