

K211405 Prelude Guide SheathOct 4, 2021
151 days to decisionK211405 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k211405/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	May 6, 2021
Decision date	Oct 4, 2021
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Merit Medical Systems, Inc.
Location	South Jordan, UT, US
Contact	David Thomas
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...