

K212152 Prelude IDEal 9F Hydrophilic Sheath IntroducerJan 7, 2022
182 days to decisionK212152 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k212152/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jul 9, 2021
Decision date	Jan 7, 2022
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Merit Medical Systems
Location	South Jordan, UT, US
Contact	David Thomas
Website	http://www.merit.com/
510(k) history	1 submissions · 1 cleared · 2022-2022

Merit Medical Systems is a leading manufacturer of disposable medical devices used in interventional, diagnostic, and therapeutic procedures. Founded in 1987, the company serves hospitals and physicians worldwide with a manufacturing facility in South Jordan, Utah. Merit employs approximately 7,000 people globally and operates across multiple therapeutic areas including cardiology, radiology, oncology, critical care, and endoscopy. The company has received FDA 510(k) clearance from total submission. Merit's regulatory focus centers on Cardiovascular devices, with its clea...