

**K160254 GORE DrySeal Flex Introducer Sheath**May 12, 2016  
101 days to decisionK160254 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k160254/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Feb 1, 2016
Decision date	May 12, 2016
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>W.L. Gore &amp; Associates, Inc.</b>
Location	Mchenry, IL, US
Contact	Mary Townsend
Website	<a href="http://www.gore.com/">http://www.gore.com/</a>
510(k) history	163 submissions · 148 cleared · 1980-2025

W.L. Gore & Associates, Inc. is a global materials science company specializing in advanced medical devices. The company operates with a manufacturing facility in McHenry, US. The company has received FDA 510(k) clearances from total submissions since its first clearance in 1980. Cardiovascular devices represent a dominant category, including vascular grafts and balloon catheters. Recent clearances also span general surgery, plastic surgery, and gastroenterology applications. The latest FDA 510(k) clearance in 2025 reflects ongoing regulatory activity. W.L. Gore & Associa...

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