

**K013282 GORE INTRODUCER SHEATH**Dec 14, 2001  
73 days to decisionK013282 · Product code: **DBY** · Immunology  
Source: <https://www.510kdatabase.net/k013282/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fab, Rhodamine, Antigen, Antiserum, Control (DBY)
Date received	Oct 2, 2001
Decision date	Dec 14, 2001
Days to decision	73 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	R. LARRY PRATT
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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