

**K922905 FEP RINGED GORE-TEX STRETCH VASCULAR GRAFT**Nov 24, 1992  
161 days to decisionK922905 · Product code: **DSY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k922905/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent - SP
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Jun 16, 1992
Decision date	Nov 24, 1992
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>W.L. Gore &amp; Associates, Inc.</b>
Location	McHenry, IL, US
Contact	JAMES D LEWIS
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...

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k922905/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 19, 2026