

K013250 GORE-TEX VASCULAR GRAFTOct 26, 2001
28 days to decisionK013250 · Product code: **DSY** · Cardiovascular
Source: <https://www.510kdatabase.net/k013250/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Sep 28, 2001
Decision date	Oct 26, 2001
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary
Other names	GORE-TEX STRETCH VASCULAR GRAFT

APPLICANT

Company	W.L. Gore & Associates, Inc.
Location	Mchenry, IL, US
Contact	TIMOTHY J RYNN
Website	http://www.gore.com/
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...