

K802095 GORE-TEX VASCULAR GRAFTOct 10, 1980
38 days to decisionK802095 · Product code: **DSY** · Cardiovascular
Source: <https://www.510kdatabase.net/k802095/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Sep 2, 1980
Decision date	Oct 10, 1980
Days to decision	38 days
Third-party review	No

APPLICANT

Company	W.L. Gore & Associates, Inc.
Location	Mchenry, IL, US
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...