

K955532 DIASTAT VASCULAR ACCESS GRAFTMar 11, 1996
97 days to decisionK955532 · Product code: **DSY** · Cardiovascular
Source: <https://www.510kdatabase.net/k955532/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - ST
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY)
Date received	Dec 5, 1995
Decision date	Mar 11, 1996
Days to decision	97 days
Third-party review	No

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...
