

K821826 FEP-RINGED GORE-TEX@ VASCULAR GRAFTDec 29, 1982
190 days to decisionK821826 · Product code: **DYF** · Cardiovascular
Source: <https://www.510kdatabase.net/k821826/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Vascular Graft, Of Less Than 6mm Diameter (DYF)
Date received	Jun 22, 1982
Decision date	Dec 29, 1982
Days to decision	190 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...
