FDA 510(k) Premarket Notification

K830806 VASCULAR GRAFT/BIFURCATED/FEP-RINGED

CLEARED

Aug 13, 1983
152 days to decision

K830806 · Product code: **DXZ** · Cardiovascular
Source: https://www.510kdatabase.net/k830806/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfe, Polypropylene (DXZ)
Date received	Mar 14, 1983
Decision date	Aug 13, 1983
Days to decision	152 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...