

K930950 GORE-TEX CARDIOVASCULAR PATCH & SURGICAL MEMBRANEOct 22, 1993
241 days to decisionK930950 · Product code: **DXZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k930950/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Feb 23, 1993
Decision date	Oct 22, 1993
Days to decision	241 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k930950/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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