

K821717 GORE-TES EXPANDED PTFE PATCHJan 12, 1983
216 days to decisionK821717 · Product code: **DXZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k821717/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Jun 10, 1982
Decision date	Jan 12, 1983
Days to decision	216 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...
