FDA 510(k) Premarket Notification

K012098 PRECLUDE PERICARDIAL MEMBRANE

CLEARED

Sep 20, 2001
77 days to decision

K012098 · Product code: **DXZ** · Cardiovascular
Source: https://www.510kdatabase.net/k012098/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfe, Polypropylene (DXZ)
Date received	Jul 5, 2001
Decision date	Sep 20, 2001
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**W.L. Gore & Associates, Inc.**
Location	Mchenry, IL, US
Contact	R. 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...