

K922627 GORE-TEX REGENERATIVE MATERIALJun 10, 1994
737 days to decisionK922627 · Product code: **NPK** · Dental
Source: <https://www.510kdatabase.net/k922627/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Synthetic, Intraoral (NPK)
Date received	Jun 3, 1992
Decision date	Jun 10, 1994
Days to decision	737 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	W.L. Gore & Associates, Inc.
Location	Mchenry, IL, US
Contact	MARY EDWARDS
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...
