

**K933541 GORE-TEX PERIODONTAL MATERIAL - TITANIUM  
REINFORCED CONFIGURATIONS**Nov 30, 1993  
132 days to decisionK933541 · Product code: **NPK** · Dental  
Source: <https://www.510kdatabase.net/k933541/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Synthetic, Intraoral (NPK)
Date received	Jul 21, 1993
Decision date	Nov 30, 1993
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>W.L. Gore &amp; Associates, Inc.</b>
Location	McHenry, IL, US
Contact	MARY EDWARDS
Website	<a href="http://www.gore.com/">http://www.gore.com/</a>
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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