

**K051267 GORE RESOLUT REGENERATIVE MATERIAL, GORE
RESOLUT XT REGENERATIVE MEMBRANE, GORE
OSSEOQUEST REGENERATIVE MEMBRANE**Jun 15, 2005
30 days to decisionK051267 · Product code: **NPK** · Dental
Source: <https://www.510kdatabase.net/k051267/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Synthetic, Intraoral (NPK)
Date received	May 16, 2005
Decision date	Jun 15, 2005
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	W.L. Gore & Associates, Inc.
Location	Mchenry, IL, US
Contact	JACQUELINE KALBACH
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...