

K181940 GORE SEAMGUARD Bioabsorbable Staple Line ReinforcementAug 17, 2018
29 days to decisionK181940 · Product code: **OXC** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k181940/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Absorbable, Staple Line Reinforcement (OXC)
Date received	Jul 19, 2018
Decision date	Aug 17, 2018
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	W.L. Gore & Associates, Inc.
Location	McHenry, IL, US
Contact	Michael J. Titus
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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k181940/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 19, 2026