

**K070644 GORE SEAMGUARD STAPLE LINE REINFORCEMENT
MATERIAL FOR CIRCULAR STAPLERS**Apr 2, 2007
25 days to decision

K070644 · Product code: FTL · General & Plastic Surgery

Source: <https://www.510kdatabase.net/k070644/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Mar 8, 2007
Decision date	Apr 2, 2007
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	W.L. Gore & Associates, Inc.
Location	McHenry, IL, US
Contact	BARBARA L SMITH
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...

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