

K000185 GORE-TEX DUALMESH PLUS BIOMATERIAL (1 MM & 2MM)Feb 14, 2000
25 days to decisionK000185 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k000185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Jan 20, 2000
Decision date	Feb 14, 2000
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	W.L. Gore & Associates, Inc.
Location	McHenry, IL, US
Contact	R. LARRY PRATT
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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