

**K963619 GORE-TEX SOFT TISSUE PATCH,MYCROMESHA  
BIOMATERIAL,DUALMESH BIOMATERIAL,DUALMESH  
BIOMATERIAL WITH HOLES**Oct 25, 1996  
45 days to decisionK963619 · Product code: FTL · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k963619/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Sep 10, 1996
Decision date	Oct 25, 1996
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>W.L. Gore &amp; Associates, Inc.</b>
Location	Mchenry, IL, US
Contact	JOHN W NICHOLSON
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...