FDA 510(k) Premarket Notification

CLEARED

K063435 GORE DUALMESH PLUS BIOMATERIAL GORE MYCROMESH PLUS BIOMATERIAL

Nov 28, 2006
15 days to decision

K063435 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k063435/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Nov 13, 2006
Decision date	Nov 28, 2006
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**W.L. Gore & Associates, Inc.**
Location	Mchenry, IL, US
Contact	Michael Ivey
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...