

**K132397 GORE BIO-A WOUND MATRIX**May 7, 2014  
279 days to decisionK132397 · Product code: **QSZ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k132397/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Absorbable Synthetic Wound Dressing (QSZ)
Date received	Aug 1, 2013
Decision date	May 7, 2014
Days to decision	279 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---