

**K922452 GORE-TEX SOFT TISSUE PATCH PLUS**Sep 29, 1994  
856 days to decisionK922452 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k922452/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Mesh, Surgical, Polymeric (FTL)    |
| Date received         | May 26, 1992                       |
| Decision date         | Sep 29, 1994                       |
| Days to decision      | 856 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>W.L. Gore &amp; Associates, Inc.</b>                 |
| Location       | Mchenry, IL, US   |
| Contact        | THOM O&apos;HARA  |
| 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...

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