

K821158 FED RINGED-TEX VASCULAR GRAFTMay 18, 1982
21 days to decisionK821158 · Product code: **DSY** · Cardiovascular
Source: <https://www.510kdatabase.net/k821158/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY) |
| Date received | Apr 27, 1982 |
| Decision date | May 18, 1982 |
| Days to decision | 21 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | W.L. Gore & Associates, Inc. |
| Location | Mchenry, IL, US |
| 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...