

K940062 DIASTAT VASCULAR ACCESS GRAFTMay 2, 1994
116 days to decisionK940062 · Product code: **DSY** · Cardiovascular
Source: <https://www.510kdatabase.net/k940062/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | PT |
| Submission type | Traditional |
| Device classification | Prosthesis, Vascular Graft, Of 6mm And Greater Diameter (DSY) |
| Date received | Jan 6, 1994 |
| Decision date | May 2, 1994 |
| Days to decision | 116 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | W.L. Gore & Associates, Inc. |
| Location | McHenry, IL, US |
| Contact | JAMES D LEWIS |
| 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...
