

K940906 GORE-TEX CARDIOVASCULAR PATCHMay 18, 1994
83 days to decisionK940906 · Product code: **DXZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k940906/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ) |
| Date received | Feb 24, 1994 |
| Decision date | May 18, 1994 |
| Days to decision | 83 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | W.L. Gore & Associates, Inc. |
| Location | Mchenry, IL, US |
| Contact | R. LARRY PRATT |
| 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...
