

K984526 ACUSEAL CARDIOVASCULAR PATCHApr 8, 1999
108 days to decisionK984526 · Product code: **DXZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k984526/>**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 | Dec 21, 1998 |
| Decision date | Apr 8, 1999 |
| Days to decision | 108 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | W.L. Gore & Associates, Inc. |
| Location | Mchenry, IL, US |
| Contact | TIMOTHY J RYNN |
| 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...
