

**K994032 FLUORO-TEX CARDIOVASCULAR PATCH**Jul 7, 2000  
224 days to decisionK994032 · Product code: **DXZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k994032/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Nov 26, 1999
Decision date	Jul 7, 2000
Days to decision	224 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Bridger Biomed, Inc.</b>
Location	Bozeman, MT, US
Contact	BRUCE G RUEFER
510(k) history	7 submissions · 7 cleared · 1997-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k994032/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 30, 2026