

K973178 FLUORO-TEX SURGICAL MEMBRANENov 24, 1997
91 days to decisionK973178 · Product code: **DXZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k973178/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Patch, Pledget And Intracardiac, Petp, Ptfе, Polypropylene (DXZ)
Date received	Aug 25, 1997
Decision date	Nov 24, 1997
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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