

K984197 FLUOROTEX SURGICAL MESHJan 7, 1999
45 days to decisionK984197 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k984197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Nov 23, 1998
Decision date	Jan 7, 1999
Days to decision	45 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k984197/> Data sourced from FDA 510(k) public records (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. - Generated June 30, 2026