K984197

Bridger Biomed, Inc.

2430 N. 7th Street, Ste. 4, Bozeman, MT 59715
ph: 1-406-586-7666 or fax: 1-406-586-5665

JAN 7 1999

5.10 (k) Summary

November 18, 1998

Contact Person: Bruce Ruefer
Classification Name: Surgical Mesh
Common Name: Surgical Mesh
Trade Name: FluoroTex™ Surgical Mesh

The FluoroTex Surgical Mesh is substantially equivalent to Gore-Tex® Soft Tissue Patch. GORE-TEX Soft Tissue Patch consists of a sheet of porous expanded polytetrafluoroethylene (ePTFE); FluoroTex Surgical Mesh consists of porous expanded polytetrafluoroethylene (ePTFE) reinforced with fluorinated ethylene propylene (FEP). The FluoroTex™ Surgical Mesh and the predicate device are intended for the repair of hernias and soft tissue.

Summary of Technological Characteristics

	GORE-TEX Soft Tissue Patch	FluoroTex Surgical Mesh
Dimensions	1 millimeter and 2 millimeter thickness in a variety of sizes.	1 millimeter and 2 millimeter thickness in a variety of sizes.
Porosity	pore size 10 to 30 microns	pore size 10 to 30 microns
Material Composition	100% ePTFE	ePTFE reinforced with FEP
Material Strength (Kg/cm, 1 millimeter thick material)	14.8 (1)	13.8 (2)
Suture Retention Strength (Kg/pin 1 millimeter thick material)	1.9 (1)	2.2 (2)

5.10 (k) Summary (page 2)

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Test Notes: (1) Reported in Gore literature; n=15; Standard ASTM methods.
(2) Tested at Bridger Biomed, Inc. labs; n=15; Standard ASTM methods.

CONCLUSION:

Mechanical and chemical tests, including material strength and chemical identification of the materials demonstrate that the FluoroTex Surgical Mesh and the Gore-Tex Soft Tissue Patch are substantially equivalent.

Bruce G. Ruefer

Bruce G. Ruefer, President

NOV 18, 1998

date

GORE-TEX is a Registered Trademark of W.L. Gore and Associates
FluoroTex is a Trademark of Bridger Biomed Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 7 1999

Mr. Bruce G. Ruefer
President
Bridger Biomed, Inc.
2430 North 7th Street, Suite 4
Bozeman, Montana 59715

Re: K984197
Trade Name: FluoroTex™ Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: November 18, 1998
Received: November 23, 1998

Dear Mr. Ruefer:

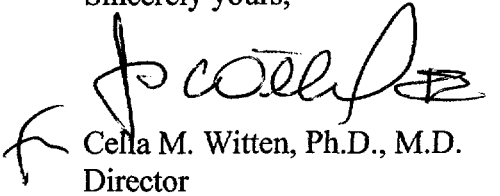
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K984197

Device Name: FluoroTex™ Surgical Mesh

Indications For Use:

The FluoroTex™ Surgical Mesh is intended to be used for the repair of soft tissue and the reconstruction of hernias.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative Devices
510(k) Number K984197

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)