Bridger Biomed, Inc.

2430 N. 7th Street, Ste. 4, Bozeman, MT 59715

K973178 NOV 24 1997

5.10(k) Summary

20 August, 1997

Contact Person: Bruce Ruefer

Classification Name: Surgical Membrane

Common Name: Surgical Membrane

Trade Name: Fluoro-Tex™ Surgical Membrane

The Bridger Biomed Fluoro-Tex™ Surgical Membrane is substantially equivalent to Gore-Tex® Surgical Membrane. Both devices consist of a sheet of porous expanded polytetrafluoroethylene (ePTFE), approximately 0.1 millimeters thick. The Fluoro-Tex™ Surgical Membrane and the predicate device are intended for the repair or replacement of the peritoneum.

Summary of Technological Characteristics

	Gore-Tex® Surgical Membrane	**Fluoro-Tex™ Surgical Membrane**
Dimensions	nominal 0.1 millimeter sheet	nominal 0.1 millimeter sheet
Porosity	pore size less than 3.0 microns	pore size less than 3.0 microns
Material Composition	expanded polytetrafluoroethylene (ePTFE)	expanded polytetrafluoroethylene (ePTFE)

Non-clinical mechanical and chemical tests, including material strength and suture retention strength, and chemical identification of the materials demonstrate that the Fluoro-Tex™ Surgical Membrane and the Gore-Tex® Surgical Membrane are substantially equivalent, and that Fluoro-Tex™ Surgical Membrane is safe and effective for its intended use.

ph: 1-406-586-7666 or fax 1-406-586-5665

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

NOV 24 1997

Re: K973178
Trade Name: Fluoro-Tex™ Surgical Membrane
Regulatory Class: II
Product Code: DXZ
Dated: August 20, 1997
Received: August 25, 1997

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 requirements , 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,

Mark N Melkerson

for 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

Statement of Indications for Use

Fluoro-Tex™ Surgical Membrane is an implant material which is intended to be used for the repair or replacement of the peritoneum and pericardium.

Mark N Miller

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973178

for EMW

Prescription Use X
(Per 21 CFR 801.109)

Over-the-Counter Use _____