

JUL - 7 2000

K994032

Section 9

5.10 (k) Summary

Contact Person: Bruce Ruefer
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Bozeman, MT 59715
Ph: 406-58607666, Fax 406-586-5665

Date Prepared: July 7, 2000

Classification Name: PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE

Common Name: Cardiovascular Patch

Trade Name: Fluoro-Tex™ Cardiovascular Patch

Classification Code: DXZ

Device Predicates: Gore-Tex® Cardiovascular Patch
Impra® Cardiovascular Patch

Device Description: Fluoro-Tex Cardiovascular Patch consists of a sheet of porous expanded polytetrafluoroethylene (ePTFE) internally reinforced with fluorinated ethylene propylene (FEP).

Statement of Intended Use:

The Fluoro-Tex Cardiovascular Patch is intended for the repair of the cardiovascular system.

Substantial Equivalence:

The Fluoro-Tex Cardiovascular Patch is substantially equivalent to Gore-Tex® Cardiovascular Patch and IMPRA Cardiovascular Repair Patch. The predicate devices consist of a sheet of porous expanded polytetrafluoroethylene (ePTFE); The Fluoro-Tex Cardiovascular Patch and the predicate devices are intended for the repair of cardiovascular defects

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Discussion of Testing Performed:

1. The Fluoro-Tex Cardiovascular Patch was mechanically tested and compared to the predicate devices according to the following table:

	Gore-Tex [®] Cardiovascular Patch	IMPRA [®] Cardiovascular Patch	Fluoro-Tex [™] Cardiovascular Patch
Tensile Strength (kg/cm ²)	26.7, n=4	20.5, n=4	20.7, n=6
Suture Strength (kg/pin)	2.1, n=4	1.8, n=4	2.0, n=6
Burst Strength (psi)	Na	294, n=5	284, n=5

2. The Fluoro-Tex Cardiovascular Patch was tested and found biocompatible via cytotox, FTIR, and extensive in-house cleanliness testing. Full biocompatibility testing for this device was not done as the device is constructed of PTFE, a polymer known and demonstrated to be safe, biocompatible, non-reactive, and the same polymer from which the legally marketed predicate devices are made.

CONCLUSION:

Mechanical and chemical tests, including material strength and chemical identification of the materials demonstrate that the Fluoro-Tex[™] Cardiovascular Patch, the GORE-TEX[®] Cardiovascular Patch and the IMPRA[®] Cardiovascular Repair Patch are substantially equivalent

Bruce G. Ruefer, President

date



JUL - 7 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Bruce G. Ruefer
President
Bridger Biomed, Inc.
2430 N.7th Street, Ste. 4
Bozeman, MT 59715

Re: K994032
Fluoro-Tex Cardiovascular Patch
Regulatory Class: II (two)
Product Code: DXZ
Dated: April 6, 2000
Received: April 10, 2000

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 legally marketed predicate 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.

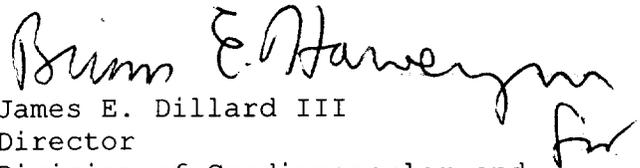
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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) 594-4648. 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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K994032

Device Name: Fluoro-Tex™ Cardiovascular Patch

Indications For Use: The Fluoro-Tex™ Cardiovascular Patch is intended to be used for the repair of the cardiovascular system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tom E. Hawey
Blair Shanker

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K994032

(Optional Format 3-10-98)