K980548

MAY 13 1998

510(k) SUMMARY OF SAFETY AND EFFICACY

Bridger Biomed Dura-Patch™

Prepared by:	Bruce G. Ruefer, President
Date:	February 4, 1998
Classification Name:	Dura Substitute; 84GXQ
Common/Usual Names:	Dura Substitute
Proprietary Name:	Dura-Patch™ Dura Substitute
Establishment Reg. No.	9028940
Classification:	Class II
Performance Standards:	Not Applicable.
Substantial Equivalence:	The dura substitute manufactured by Bridger Biomed Inc., and is substantially equivalent to the dura substitute Preclude™ Dura Substitute, manufactured and marketed by W.L. Gore & Associates.
Product Description & Intended Use:	Dura-Patch™ Dura Substitute is a 100% ePTFE membrane, which is intended to be used as a replacement for dura tissue deficiencies.
Comparative Technological Characteristics:	Dura-Patch™ Dura Substitute is an inert and biocompatible 100% ePTFE membrane, strong enough to resist tears, supple enough to provide comfort, flexible, and is impermeable to CSF, as is the predicate device. Both devices also have a pore size of approximately 1 micron.
Safety & Efficacy:	Dura-Patch™ is composed of 100% expanded polytetrafluoroethylene or ePTFE. ePTFE is the most inert polymer known at this time. ePTFE has been found to pass

biocompatibility assays including U.S.P. Class VI, carcinogenicity studies, hemocompatibility studies, and others. ePTFE has been proven many times over to be non-reactive to body fluids and tissues making it a material of choice for biomaterial applications.

Usage of ePTFE as an implant material is well substantiated with over 4,000,000 long-term ePTFE devices implanted to date. In over 25 years of clinical use, and exposure to virtually all major tissue types, there have been no known adverse reactions to the material. Many configurations of ePTFE devices are marketed including; vascular grafts; soft tissue and cardiovascular patches; suture; pericardial, peritoneal and dura replacement membranes; periodontal implants and facial implant devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 1998

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

Re: K980548
Trade Name: Dura-Patch Model DP-XXX
Regulatory Class: II
Product Code: GXQ
Dated: February 10, 1998
Received: February 12, 1998

Dear Mr. Ruefer:

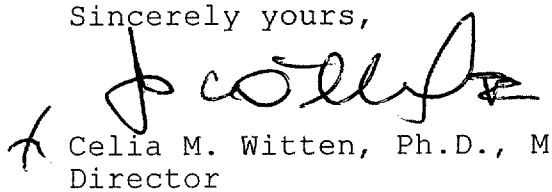
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

K980548

STATEMENT OF INDICATIONS FOR USE

The Bridger Biomed Dura-Patch™ is intended for replacement or repair of the dura.

Prescription Use Y
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980548