JUL 30 1998

K982282

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant Name & Address: Bio-Vascular, Inc.
2575 University Avenue
St. Paul, MN 55114-1024
Fax: (612) 642-9018

Contact: Mary Frick
Senior Research Affairs Associate
Phone: (612) 603-3700

Date Prepared: June 29, 1998

Common or Usual Name: Dura-Guard®

Device Classification Name: Dural Repair Patch

Substantial Equivalence: Dura-Guard K973706

Device Description: Dura-Guard is a dural repair patch manufactured from bovine pericardium cross-linked with glutaraldehyde.

Statement of Intended Use: For use as a dural substitute for the closure of the dura mater during neurosurgery.

Summary/Comparison of Technological Characterisitics:
Cross-linked pericardium was treated with 1 molar sodium hydroxide (1M NaOH) for 60-75 minutes at 20 -25°C, rinsed with deionized (DI) water and neutralized with citrate solution, followed by a final DI water rinse. Sodium hydroxide treated and control (non-NaOH-treated) samples were subjected to shrink, suture, and thickness testing. Results showed no significant difference between the test and control samples. The test and control samples were subjected to bioburden, sterility, pH, pyrogen, and chemical residuals testing. Results showed no significant difference between the test and control samples. Samples of the NaOH-treated pericardium were also subjected to biocompatibility and animal testing. Results showed that the 1M NaOH treatment did not produce significant differences in biocompatibility or inflammation when comparing the treated versus non-treated pericardium.

Bio-Vascular believes that product subjected to 1M NaOH treatment performs in a manner substantially equivalent to the product not treated with 1M NaOH, and that the exposure to sodium hydroxide poses no additional questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 1998

Ms. Mary L. Frick
Senior Regulatory Affairs Associate
Bio-Vascular, Inc.
2575 University Avenue
St. Paul, Minnesota 55114

Re: K982282
Trade Name: Dura-Guard - Dural Repair Patch
Regulatory Class: II
Product Code: GXQ
Dated: June 29, 1998
Received: June 30, 1998

Dear Ms. Frick:

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): K98_____

Device Name: Dura-Guard - Dural Repair Patch

Indications for Use:
For use as a dural substitute for the closure of dura mater during neurosurgery.

(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 K982282

Prescription Use X
Per 21 CFR 801.109

OR

Over-The-Counter Use_____

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