K973706

Bio-Vascular, Inc.

DEC 24 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant Name & Address: Bio-Vascular, Inc., 2575 University Ave.,St. Paul, MN 55114-1024

Contact: Barbara Atzenhoefer, Regulatory Affairs Manager

Date Prepared: September 26, 1997

Common or Usual Name: Dura-Guard®

Device Classification Name: Dural Repair Patch

Substantial Equivilance: Dura-Guard K950956

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 dura mater during neurosurgery.

Summary/Comparison of Technological Characteristics:
Product samples were subjected to various antibiotic treatments. Both control and test samples were subjected to burst strength, suture retention, ultimate tensile and shrink temperature testing. Results showed no significant difference between the test and control articles. Biocompatibility testing also showed no significant difference between the test and control articles. BVI believes that product subjected to antibiotics perform in a manner substantially equivalent to product not subjected to antibiotics, and that the exposure to antibiotics poses no additional questions of safety or effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 24 1997

Ms. Barbara Atzenhoefer
Regulatory Affairs Manager
Bio-Vascular, Inc.
2575 University Avenue
Saint Paul, Minnesota 55114-1024

Re: K973706
Trade Name: Dura-Guard - Dura Repair Patch
Regulatory Class: II
Product Code: GXQ
Dated: September 26, 1997
Received: September 29, 1997

Dear Ms. Atzenhoefer:

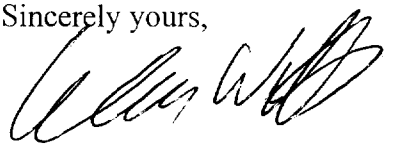
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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): K97 3706

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)

Prescription Use X OR Over-The-Counter Use_____
Per 21 CFR 801.109

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973706