K983602

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

NOV 12 1998

Applicant Name & Address: Bio-Vascular, Inc.
2575 University Avenue
St. Paul, MN 55114-1024
Fax: (651) 642-9018

Contact: Dianna L. Geck
Regulatory Affairs Associate
Phone: (651) 603-3700

Date Prepared: September 9, 1998

Common or Usual Name: CV Peri-Guard™ Cardiovascular Patch

Device Classification Name: Intracardiac patch or pledget

Substantial Equivalence: CV Peri-Guard K971726

Device Description: CV Peri-Guard is prepared from bovine pericardium which is cross-linked with glutaraldehyde.

Statement of Intended Use: CV Peri-Guard is intended for use as a patch material for intracardiac defects, great vessel, septal defect and annulus repair, and suture-line buttressing.

Summary/Comparison of Technological Characteristics:
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.

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant Name & Address: Bio-Vascular, Inc.
2575 University Avenue
St. Paul, MN 55114-1024
Fax: (651) 642-9018

Contact: Dianna L. Geck
Regulatory Affairs Associate
Phone: (651) 603-3700

Date Prepared: September 9, 1998

Common or Usual Name: Vascu-Guard® Peripheral Vascular Patch

Device Classification Name: Intracardiac patch or pledget

Substantial Equivalence: Vascu-Guard K942010

Device Description: Vascu-Guard is prepared from bovine pericardium which is cross-linked with glutaraldehyde.

Statement of Intended Use: Vascu-Guard is intended for peripheral vascular reconstruction including the carotid, renal, iliac, femoral, profunda, and tibial blood vessels and arteriovenous access revisions.

Summary/Comparison of Technological Characteristics:
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.

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant Name & Address: Bio-Vascular, Inc.
2575 University Avenue
St. Paul, MN 55114-1024
Fax: (651) 642-9018

Contact: Dianna L. Geck
Regulatory Affairs Associate
Phone: (651) 603-3700

Date Prepared: September 9, 1998

Common or Usual Name: Supple Peri-Guard® Pericardium

Device Classification Name: Mesh, surgical, polymeric

Substantial Equivalence: Supple Peri-Guard K961810, K921895

Device Description: Supple Peri-Guard is prepared from bovine pericardium which is cross-linked with glutaraldehyde.

Statement of Intended Use: Supple Peri-Guard is intended for the repair of pericardial structures and for use as a prosthesis for the surgical repair of soft tissue deficiencies which include: defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, and umbilical hernias).

Summary/Comparison of Technological Characteristics:
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

NOV 12 1998

Ms. Dianna L. Geck
Regulatory Affairs Associate
Bio-Vascular, Inc
2575 University Avenue
Saint Paul, MN 55114-1024

Re: K983602
Various Tissue Patches
Regulatory Class: II
Product Code: DXZ
Dated: October 9, 1998
Received: October 13, 1998

Dear Ms. Geck:

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. Any promotional or advertisement materials referring to the sodium hydroxide treatment must contain the language agreed upon regarding reducing infectivity.

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) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K98 3602

Device Name: CV Peri-Guard™ Cardiovascular Patch

Indications for Use:
CV Peri-Guard is intended for use as a patch material for intracardiac defects, great vessel, septal defect and annulus repair, and suture-line buttressing.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983602

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

510(k) Number (if known): K98_____

Device Name: Vascu-Guard® Peripheral Vascular Patch

Indications for Use:
Vascu-Guard is intended for peripheral vascular reconstruction including the carotid, renal, iliac, femoral, profunda, and tibial blood vessels and arteriovenous access revisions.

(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 Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number _____

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

510(k) Number (if known): K98 3162

Device Name: Supple Peri-Guard® Pericardium

Indications for Use:
Supple Peri-Guard is intended for repair of pericardial structures and for use as a prosthesis for the surgical repair of soft tissue deficiencies which include: defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, and umbilical hernias).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

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