K971726

APR 10 1998

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: May 7, 1997

Common or Usual Name: Cardiovascular patch

Device Classification Name: Intracardiac and Great Vessel Repair

Substantial Equivilance: Gore-Tex Cardiovascular Patch, Peri-Guard and Vascu-Guard

Device Description:
CV Peri-Guard™ - Cardiovascular Patch. CV Peri-Guard is composed of bovine pericardium, cross-linked with glutaraldehyde. Available in configurations ranging from 1 cm x 1 cm to 14 cm x 16 cm.

Statement of Intended Use:
CV Peri-Guard™ is intended for use as a patch for intracardiac, great vessel, valve repair and suture line buttressing (i.e. atrial septal defect (ASD) patch, atrial patch, aortic patch, valve annuloplasty, coronary graft buttress). May be used for repair of ventricular septal defect (VSD) using either a single patch or reinforced patch technique. May also be used in other applications exposed to peak systolic pressure using a reinforced patch technique (i.e. ventricular aneurysm patch, aortic graft suture line buttress).

Summary/Comparison of Technological Characteristics:
We maintain that CV Peri-Guard™ is substantially equivalent to the predicate devices and that the extended indication for use in intracardiac and great vessel repair does not pose new questions of safety and effectiveness. This claim of substantial equivalence is based upon the following elements.

1.Configuration
The additional sizes of CV Peri-Guard are configured for intracardiac and great vessel repair and are substantially equivalent to those sold by the predicate device.

2.Extension of Indications (Labeling)
Processed bovine pericardium and the material used in the predicate device have a history of being used in similar prosthetic applications. The material used in CV Peri-Guard is already indicated for pericardial closure and repair of soft tissue deficiencies. As summarized below and discussed earlier, we have shown that extension of these indications to include intracardiac and great vessel repair does not pose new questions of safety and effectiveness.

3.Physical/Mechanical Properties
The physical and mechanical properties critical for performance as an intracardiac and great vessel patch are substantially equivalent between CV Peri-Guard and the predicate device.

4.Biocompatibility
Processed bovine pericardium has a long history of biocompatibility. Peri-Guard has been marketed since 1982 with no indication of biocompatibility problems. The biocompatibility testing summarized herein is consistent with this clinical experience and the nonhemolytic nature of CV Peri-Guard is especially relevant to the intracardiac and great vessel repair indication under consideration in this premarket notification.

5.Calcification Studies
Peri-Guard has been evaluated in a proven model for calcification: the juvenile rat subcutaneous mode. Peri-Guard and Supple Peri-Guard have demonstrated clinical insignificant calcification and significantly less calcification that either a glutaraldehyde-treated control or a competitor's bovine pericardial patch product. Additionally, Peri-Guard has been evaluated clinically in the mitral valve annulus position, and other intracardiac patch positions, and has demonstrated no calcification related to the Peri-Guard patch up to a mean of 17 months post-op.

6.Canine Studies
A Canine implant study show that Supple Peri-Guard and ePTFE perform in a similar manner, in vivo.

7.Clinical Report
The clinical data, gathered under the Peri-Guard Retrospective study protocol, demonstrated that our bovine material performed safe and effectively, and in a substantially equivalent fashion to alternative intracardiac and great vessel patch materials.

8.History of Safety and Effectiveness
Peri-Guard (and thus CV Peri-Guard) processed bovine pericardium has been used widely as an implant material for well over two decades and has been shown to be safe and effective in a variety of medical applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

APR 10 1998

Re: K971726
CV Peri-Guard - Cardiovascular Patch
Regulatory Class: II (Two)
Product Code: DXZ
Dated: February 11, 1998
Received: March 23, 1998

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) 594-4648. 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" (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,

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): K971726

Device Name: CV Peri-Guard™

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)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971726

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)