SECTION 4 K040835 510(K) SUMMARY

1/4

1. *Submitters Name, Address etc.*:

JUN 1 5 2004

PM Devices Inc.
2135 – 13700 Mayfield Place
Richmond, British Columbia
V6V 2E4, CANADA
Ph: 604.270-4344 Fx: 604.270-4384
www.pmdevices.com
Contact: Britta Dombovari
Date: March 2004

2. *Name of Devices*: Trade Name: PeriPatch™ Sheet

Common Name: Processed bovine pericardial patch

Classification Name:
Currently: Intracardiac Patch or Pledget –Class II-Product Code: DXZ
Expanded Indications: Mesh, surgical, polymeric –Class II–Product Code: FTM

3. *Predicate Devices*: Legally marketed devices which PM Devices Inc. claims substantial equivalence:

Predicate Device	*Manufacture*	*510(k) #*	*Class*
PeriPatch™ Sheet	PM Devices Inc.	K031948	II
Supple Peri-Guard® Pericardium	BioVascular Inc.	K983162	II
Glycar Pericardial Patch	Glycar Inc.	K963967	II
Vascu-Guard	BioVascular Inc.	K942010	II
Supple Peri-Guard	BioVascular Inc	K921895	II
Hancock Pericardial Patch	Extrcorpeal	K830863	II

All of the above previously cleared products are composed of processed bovine pericardium and are all used as a mesh material for surgical repair of pericardial structures and soft tissue deficiencies.

4. *Device Description*:

4a. *How the Device Works*

PeriPatch™ Sheet

The PeriPatch™ Sheet is a quadrilateral shaped xenograft patch made from a sheet of glutaraldehyde fixed bovine pericardium selected for even thickness. It is designed to repair the body's natural organs and functions like natural tissue. It is intended for intra-cardiac repair procedures. A picture of a patch can be seen in Figure 1 – PeriPatch Sheet, and the engineering drawing can be found in *Appendix C, Engineering Drawings*. It is identical to other marketed bovine pericardial patches. Extensive quality control procedures assure a consistent, high quality product for clinical use.

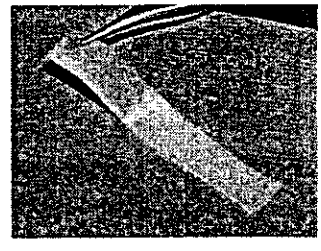

Figure 1 – PeriPatch Sheet

The PeriPatch Sheet is available in 6 sizes (*Table 4.1 – page 4-2*), but can also be trimmed to specific size depending on the procedure.

Table 4.1 PeriPatch Sheet Model Numbers & Dimensions

Model	1.5P8	1.5P16	4P4	4P6	6P8	10P16
Size (cm)	1.5 x 8	1.5 x 16	4 x 4	4 x 6	6 x 8	10 x 16

4b. *Scientific Concepts*

PeriPatch Sheet

The PeriPatch Sheet is manufactured from glutaraldehyde fixed bovine pericardium, this is the same material used for the predicate devices. Physical configuration of the PeriPatch sheet is similar to predicate patches, see Table 4.2 below:

Table 4.2: Comparison of PeriPatch Sheet sizes available to current predicate devices.

PeriPatch Sheet Models (DXZ/FTM) *	1.5P8	1.5P16	4P4	4P6	6P8	10P16
PeriPatch Sheet Sizes (DXZ/FTM)	1.5cmx8cm	1.5cmx16cm	4cmx4cm	4cmx6cm	6cmx8cm	10cmx16cm
*Bio-Vascular Supple Peri-guard Patch***	N/A	N/A	4cmx4cm	N/A	6cmx8cm	10cmx16cm
*Bio-Vascular Vascu-Guard****	1.5cmx8cm	N/A	N/A	N/A	N/A	N/A

* PeriPatch Sheet (DXZ) – K031948
** Bio-Vascular Supple Peri-guard Patch – K981895
*** Bio-Vascular Vascu-Guard – K942010

The treatment and processing (relevant for the PeriPatch Sheet) for cross-linking bovine pericardial tissue with glutaraldehyde is well described in the literature (*Appendix A, Literature*), and similar to those used in predicate devices, and has been validated (*Appendix D, Validations*). Sterilization is performed using a liquid alcoholic sterilant which is similar to the predicates and validated to be effective (*Appendix D, Validations*). The finished devices are packaged and labeled in a similar manner as the predicates (*Section 6, Proposed Labeling; Appendix E, Predicate Device Labeling*).

The PeriPatch Sheet is considered to be similar to the PeriPatch Sheet and Bio-Vascular predicates because:

- Same raw material – Bovine Pericardium
- Same intended medical use
- Operates using the same fundamental scientific technology
- Similar shapes & sizes
- Similar method of processing
- Similar method of sterilization
- Similar packaging and labelling

4c. *Physical & Performance Characteristics*

The PeriPatch Sheet is designed to repair the body's natural organs and function like natural tissue.

4d. *Safety & Effectiveness*

The devices are designed and manufactured in such a way that, when used under the conditions and the purposes intended, they will not compromise the clinical condition or the

safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

The safety and effectiveness of bovine pericardial patches used for reconstruction and repair are well characterized in the literature (*Appendix A, Literature*). They have been in use for over 25 years and have proven to be effective in achieving the desired result and well tolerated by host tissue.

5. *Intended use of the Device*

Below is a list of the diseases or conditions that the device will treat, prevent, cure or mitigate and a description:

The PeriPatch Sheet has been approved for the following intended use:

- Surgical patch material for cardiac and vascular reconstruction and repair.

The intended expanded indications for use would include:

- *... soft tissue deficiency repair and reinforcing the suture line during general surgical procedures.*

6. *Technological Characteristics*

The devices have the same technological characteristics as the predicate devices identified in Section 4–3. A comparison of the PeriPatch Sheet to the predicate devices can be found in Table 4.3 on the next page. As shown in the table, the applicant device is substantially equivalent to the predicates technological characteristics.

Table 4.3 - Similarities of the PeriPatch Sheet to the predicate devices

CATEGORY	PM Devices Inc.	PM Devices Inc.	BioVascular	Glycar Inc.	BioVascular	BioVascular	Extracorporeal	
Device / K - number	**PeriPatch (DXZ & FTM)**	**PeriPatch (DXZ) K031948**	**K983162**	**K963967**	**K942010**	**K921895**	**K830863**	**Significance**
Indications for use	The PeriPatch Sheet is intended for use as a surgical patch material for: cardiac and vascular reconstruction and repair, *soft tissue deficiency repair and reinforcing the suture line during general surgical procedures.*	The PeriPatch Sheet is intended for use as a surgical patch material for: cardiac and vascular reconstruction and repair.	Repair of pericardial structures, soft tissue deficiencies, defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, rectal and vaginal pro-lapse, reconstruction of the pelvic floor, and hernias.	Cardiac re-construction & repair, vascular patching, pericardial closure	Peripheral vascular repair/ re-construction	For closure of the patient's pericardium & Peri-Strip sleeve configuration – reinforce staple lines during segmental resections	Pericardial closure	PeriPatch indications are same as (combined) K031948 and K983162. SE
Materials	Bovine Pericardium	Same	Same	Same	Same	Same	Same	SE
Processing	Glutaraldehyde cross-linking	Same	Same	Same	Same	Same	Same	SE
Shape	Flat, square & Rectangular	Same	Same	Not determined at time of submission	Same	Rectangular & Peri-Guard Sleeve, thin strips of bovine pericardium sutured to a polyethylene backing.	Same	SE
Sizes offered (cm)	1.5x8 1.5x16 4x4 4x6 6x8 10x16	Same	4x4 6x8 8x14 10x16	Not determined at time of submission	1.5x8 1.5x9 1.5x10 2x8 2x9 2x10 2.5x8 2.5x9 2.5x10	4x4 6x8 8x14 10x16 Peri-Guard Sleeves are available in sizes to fit common staplers	5x12	SE
Packaging	Sealed, sterile container	Same	Same	Same	Same	Same	Same	SE
Tissue THK (mm)	0.58±0.17	Same	0.25	Unknown	0.5±0.25	0.25	0.35	SE
Tensile Strength	1172±311 g/m²	Same	Unknown	Unknown	1080±330 g/m²	Unknown	4360±1600 g	SE
Shrink Temp.	86.2°C	Same	Unknown	Unknown	Unknown	Unknown	83.6°C	SE
Suture Retention (g)	969±114	Same	Unknown	Unknown	1121±102	Unknown	1280±108	SE
Elongation (%)	46.1±5.4	Same	Unknown	Unknown	Unknown	Unknown	31.2±6.0	SE
Burst Strength (mmHg /psi)	8200 / 159	Same	Unknown	Unknown	7033 / 136	Unknown	Unknown	SE
Storage Solution	0.2% Glutaralde-hyde / phosphate buffered solution (PBS)	Same	Propylene oxide in water	Propylene oxide in water	Propylene oxide in water	Propylene oxide in water	Same	SE
Rinse Instructions	Two 2 min. rinses	Same	One 3 min. Rinse	Unknown	One 3 min. rinse	One 3 min. Rinse	Three 2 min. rinse	SE
Sterility Method	Liquid Alcoholic	Same	Same	Unknown	Same	Same	Same	SE

K040835

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 5 2004

Ms. Britta Dombovari
Regulatory Affairs/Quality Assurance
PM Devices, Inc.
2135-13700 Mayfield Place
Richmond, British Columbia
V6V 2E4 Canada

Re: K040835
Trade/Device Name: PeriPatch™ Sheet
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: March 29, 2004
Received: March 31, 2004

Dear Ms. Dombovari:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040835

Device Name: PeriPatch™ Sheet – Processed Bovine Pericardial Pat

Indications For Use:

The PeriPatch sheet is intended for use as a surgical patch material for: cardiac and vascular re-construction and repair, soft tissue deficiency repair and reinforcing the suture line during general surgical procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040835