SECTION 4

JUN - 4 2004

510(K) SUMMARY

1. *Submitters Name, Address etc.:*

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: December, 2003

2. *Name of Devices:*

Trade Name: PeriPatch™ Sleeve[1]

Common Name: Processed bovine pericardial sleeve

Classification Name:
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
Glycar Pericardial Patch	Glycar Inc.	K963967	II
Supple Peri-Guard® Pericardium	BioVascular Inc.	K983162	II
Vascu-Guard	BioVascular Inc.	K942010	II
Supple Peri-Guard	BioVascular Inc	K921895	II

All of the above previously cleared products are composed of processed bovine pericardium and are all used for suture line staple reinforcement.

4. *Device Description:*

4a. *How the Device Works*

PeriPatch™ Sleeve

The PeriPatch™ Sleeve consists of one piece of glutaraldehyde fixed bovine pericardium that is sutured into a rectangular shaped tube. A picture can be seen in Figure 2, and an engineering drawing can be found in *Appendix C, Engineering Drawings.* It is intended for reinforcing surgical staples. These specially prepared sleeves are slipped over the forks of linear or endoscopic surgical staplers. Stapling is carried out according to the stapler manufacture's instructions. The suture is removed and the remaining pericardial tissue is withdrawn with the excised host tissue. The sleeves are intended for a number of resection techniques such as lung volume reductions, biopsies, lobectomies and other soft tissue repairs.

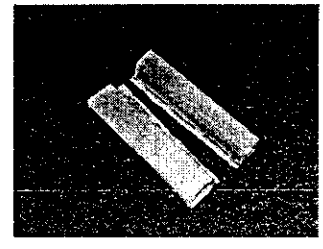

Figure 2 – PeriPatch™ Sleeve

The available PeriPatch™ Sleeve models and the surgical stapler that they are compatible with are listed in *Table 4.1* below.

[1] The PeriPatch™ Sleeve was originally called the StepSaver™ Cylinder, and marketed under that name in Europe (EC) and Canada. The name StepSaver™ Cylinder can be seen in validation reports as it was the name of the device during the validations. The StepSaver™ Cylinder and the PeriPatch™ Sleeve are the same device.

Table 4.1 Sleeve Sizes

Endoscopic	
Model	***Stapler***
G35-1, -2, -5	Auto Suture Endo GIA 30
E35-1, -2, -5	Ethicon EZ 35B
G45-1, -2, -5	Auto Suture Endo GIA 45
E45-1, -2, -5	Ethicon EZ 45B ,EZ 35G
G60-1, -2, -5	Auto Suture Endo GIA 60
E60-1, -2, -5	Ethicon Endopatch 60

Linear	
Model	***Stapler***
5c6-1, -2, -5	Auto Suture Endo GIA 60; Ethicon TLC 55
5c8-1, -2, -5	Auto Suture Endo GIA 80; Ethicon TLC 75
5c10-1, -2, -5	Auto Suture Endo GIA 90 (re-useable); Auto Suture Endo GIA 90 (disposable); 3M ILA 100

4b. *Scientific Concepts*

PeriPatch™ Sleeve

The PeriPatch™ Sleeve consists of one piece of glutaraldehyde fixed bovine pericardium that is sutured into a rectangular sleeve. It is intended for reinforcing surgical staples. These specially prepared sleeves are slipped over the forks of linear or endoscopic surgical staplers. Stapling is carried out according to the stapler manufacture's instructions. The suture is removed and the remaining pericardial tissue is withdrawn with the excised host tissue. The PeriPatch™ Sleeve's compatibility with common staplers is similar to predicate devices, see Table 4.2:

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

	Endoscopic					*Disposable Linear*					*Reusable Linear*	
	GIA ENDO 60	GIA ENDO 30	ENDOP ATH 60	ENDOP ATCH EZ 45	ENDOP ATH 35	GIA 80	TLC 75	ILA 75	GIA 60	TLC 55	GIA 90	ILA 100
Stapler Manufacturer	USSC	USSC	ETHICON	ETHICON	ETHICON	USSC	ETHICON	3M	USSC	ETHICON	USSC	3M
PeriPatch™ Sleeve	X	X	X	X	X	X	X		X	X		X
Peri-Strips® Sleeve	X	X	X	X		X	X	X			X	

X - compatible

The treatment and processing (relevant for the PeriPatch™ Sleeve) 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™ Sleeve * is considered to be similar to the Bio-Vascular predicate 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

* The PeriPatch™ Sleeve consists of a full sheet of processed bovine pericardial tissue. The Peri-Strip® Sleeve configuration consists of thin strips of bovine pericardium sutured to a polyethylene backing. Both devices are designed to fit a wide range of reusable, disposable and endoscopic staplers. This difference in the design of the two devices has no implications on the functionality or intended use of the device.

4c. *Physical & Performance Characteristics*

The PeriPatch™ Sleeve is designed to reinforce at suture lines and stapling sites and to repair the body's natural organs and function like natural tissue.

4d. *Safety & Effectiveness*

The device is designed and manufactured in such a way that, when used under the conditions and the purposes intended, it 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, References*). They have been in use for over 20 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(s) will treat, prevent, cure or mitigate and a description:

The PeriPatch™ Sleeve is intended for reinforcing staples and suture lines during a number of resection techniques – surgical repair of tissue deficiencies such as:

- Lung volume reductions
- Biopses
- Lobectomies
- Gastric banding
- Rectal and vaginal prolapse
- Urethral sling
- Other soft tissue repairs

6. *Technological Characteristics*

The device has the same technological characteristics as the predicate devices identified in Section 4–3. A comparison of the PeriPatch™ Sleeve 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™ Sleeve to the predicate devices

	PM Devices Inc.	PM Devices Inc.	Glycar Inc.	BioVascular	BioVascular	BioVascular	
Category	**PeriPatch™ Sleeve**	**K031948** (PeriPatch™ Sheet)	**K963967**	**K983162**	**K942010**	**K921895**	**Significance**
Indications for use	Surgical patch material to reinforce surgical staples during stapling procedures and for reinforcing suture lines for cardiovascular and general procedures. Resection techniques include: lung volume reduction, biopsies, lobectomies, gastric banding, rectal and vaginal prolapse, and urethral sling.	Surgical patch material to repair intracardiac defects: septal (atrial / ventrical) defects, great vessel and annulus repair & suture line reinforcement, repair of pericardial structures, soft tissue deficiencies, defects of abdominal and thoracic wall, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of pelvic floor, hernia(s), gastric banding.	Cardiac re-construction & repair, vascular patching, pericardial closure	Repair of pericardial structures, soft tissue deficiencies, defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, and hernias.	Peripheral vascular repair/ re-construction	For closure of the patient's pericardium & Peri-Strip sleeve configuration – reinforce staple lines during segmental resections	PeriPatch indications are same as (combined) K983162 and PeriPatch Sleeve indications are the same as K921895 indications for the Peri-Strip Sleeve SE
Materials	Bovine Pericardium	Bovine Pericardium	Same	Same	Same	Same	SE
Processing	Glutaralde-hyde cross-linking fixation	Glutaralde-hyde cross-linking fixation	Same	Same	Same	Same	SE
Shape	Rectangular shaped tube	Flat, square & Rectangular	Not determined at time of submission	Flat, square & Rectangular	Flat, Rectangular	Rectangular & Peri-Guard Sleeve, thin strips of bovine pericardium sutured to a polyethylene backing	SE
Sizes offered (cm)	See Table 4.1 & Table 4.2 Available to fit common staplers	1.5x8 4x4 4x6 6x8 10x16 1.5x16	Not determined at time of submission	4x4 6x8 8x14 10x16	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	SE
Packaging	Sealed, sterile container	Sealed, sterile container	Same	Same	Same	Same	SE
Tissue THK (mm)	0.58±0.17	0.58±0.17	Unknown	0.25	0.5±0.25	0.25	SE
Tensile Strength	1172±311 g/m²	1172±311 g/m²	Unknown	Unknown	1080±330 g/m²	Unknown	SE
Shrink Temp.	86.2°C	86.2°C	Unknown	Unknown	Unknown	Unknown	SE
Suture Retention (g)	969±114	969±114	Unknown	Unknown	1121±102	Unknown	SE
Elongation (%)	46.1±5.4	46.1±5.4	Unknown	Unknown	Unknown	Unknown	SE
Burst Strength (mmHg /psi)	8200 / 159	8200 / 159	Unknown	Unknown	7033 / 136	Unknown	SE
Storage Solution	0.2% Glutaralde-hyde / phosphate buffered solution (PBS)	0.2% Glutaralde-hyde / phosphate buffered solution (PBS)	Propylene oxide in water	Propylene oxide in water	Propylene oxide in water	Propylene oxide in water	SE
Rinse Instructions	Two 2 min. rinses	Two 2 min. rinses	Unknown	One 3 min. Rinse	One 3 min. rinse	One 3 min. Rinse	SE
Sterility Method &	Liquid Alcoholic	Liquid Alcoholic	Unknown	Same	Same	Same	SE

K033985

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2004

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

Re: K033985
Trade/Device Name: PeriPatch™ Sleeve Processed Bovine Pericardial Sleeve
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: May 5, 2004
Received: May 7, 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,

for Mark N. Melkerson

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

510(k) Number (if known) K033985

Device Name: PeriPatch™ Sleeve Processed Bovine Pericardial Sleeve

Indications For Use:

The PeriPatch™ Sleeve is intended for use as a surgical patch mesh material to reinforce surgical staples during stapling procedures and for reinforcing suture lines for cardiovascular and general procedures. Stapling is carried out according to the stapler manufacture's instructions. The sleeves are intended for staple reinforcement during a number of resection techniques such as lung volume reductions, biopsies, lobectomies, gastric banding, rectal and vaginal prolapse, and urethral sling.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Milhern

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

510(k) Number _____

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)