K983162

510(K) SUMMARY

Submitted by:	Synovis Surgical Innovations 2575 University Avenue West St. Paul, MN 55114-1024 Tel: 651-796-7300 Fax: 651-642-9018
Contact Person:	Fonda Burley At address above
Device Trade Name:	Peri-Guard Repair Patch
Common Name:	Surgical Mesh
Classification Name:	Mesh, Surgical 21 CFR 878.3300
Product Code:	FTM, OYB
Predicate devices:	Peri-Guard K961811 and K842066 (Device acting as its own predicate)
Device Description:	Peri-Guard® Repair Patch (Peri-Guard) is a biologic tissue prepared from bovine pericardium cross-linked with glutaraldehyde. The pericardium is procured from cattle originating in the United States. Peri-Guard is chemically sterilized using ethanol and propylene oxide. Peri-Guard is treated with 1 molar sodium hydroxide for 60-75 minutes at 20-25°C.
Statement of Intended use:	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 binding, muscle flap reinforcement, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, and umbilical hernias).
Technological Comparisons:	The subject device is technologically identical to the predicate device. The only difference between these devices is that the subject device is treated with 1 molar sodium hydroxide (1 M NaOH) for 60-75 minutes at 20 -25 C.

Technology/Device Testing:	Cross-linked pericardium was treated with 1 molar sodium hydroxide (1 M 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 1 M NaOH treatment did not produce significant differences in biocompatibility or inflammation when comparing the treated versus non-treated pericardium. Product subjected to 1 M 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.

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Submitted by:	Synovis Surgical Innovations 2575 University Avenue West St. Paul, MN 55114-1024 Tel: 651-796-7300 Fax: 651-642-9018
Contact Person:	Fonda Burley At address above
Device Trade Name:	Supple Peri-Guard Pericardium
Common Name:	Surgical Mesh
Classification Name:	Mesh, Surgical 21 CFR 878.3300
Product Code:	FTM
Predicate devices:	Supple Peri-Guard K961810 and K921895 (Device acting as its own predicate)
Device Description:	Supple Peri-Guard® is prepared from bovine pericardium which is cross-linked with glutaraldehyde. The pericardium is procured from cattle originating in the United States. Supple Peri-Guard is chemically sterilized using ethanol and propylene oxide. Supple Peri-Guard has been treated with 1 molar sodium hydroxide for 60-75 minutes at 20-25°C. Supple Peri-Guard is packaged in a container filled with sterile, non-pyrogenic water containing propylene oxide. The contents of the unopened, undamaged container are sterile.
Statement of Intended use:	For use as a prosthesis for pericardial closure and soft tissue deficiencies which include: defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, and hernias (diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal and umbilical).
Technological Comparisons:	The subject device is technologically identical to the predicate device. The only difference between these devices is that the subject device is treated with 1 molar sodium hydroxide (1 M NaOH) for 60-75 minutes at 20 -25 C.

Technology/Device Testing:	**Cross-linked pericardium was treated with 1 molar sodium hydroxide (1 M 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 1 M NaOH treatment did not produce significant differences in biocompatibility or inflammation when comparing the treated versus non-treated pericardium. Product subjected to 1 M 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Bio-Vascular, Incorporated
% Ms. Dianna L. Geck
Regulatory Affairs Associate
2575 University Avenue
St. Paul, Minnesota 55114-1024

AUG 27 2012

Re: K983162
Trade/Device Name: Peri-Guard® Repair Patch
Supple Peri-Guard® Pericardium
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OXB
Dated: September 9, 1998
Received: September 10, 1998

Dear Ms. Geck:

This letter corrects our substantially equivalent letter of October 9, 1998.

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 (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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K983162

Device Name: Peri-Guard Repair Patch

Indications For Use:

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 binding, muscle flap reinforcement, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, and umbilical hernias).

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

Daniel Krone for MM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K983162

Indications for Use

510(k) Number (if known): K983162

Device Name: Supple Peri-Guard® Pericardium

Indications For Use:

For use as a prosthesis for pericardial closure and soft tissue deficiencies which include: defects of the abdominal and thoracic wall, gastric banding, muscle flap reinforcement, and hernias (diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal and umbilical).

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

David Krause for MM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K983162