

K961811

510(K) SUMMARY

Submitted by: Synovis Surgical Innovations
2575 University Avenue West
St. Paul, MN 55114-1024
Tel: 651-796-7300
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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, DWV

Predicate devices: Peri-Guard K842066 (Device acting as its own predicate) and Supple Peri-Guard K923657

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 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: Peri-Guard is virtually identical to Supple Peri-Guard, differing only in elasticity (i.e., suppleness).

Technology/Device Testing: N/A; labeling clarification only



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Bio-Vascular, Incorporated
% Bruce A. MacFarlane, Ph.D.
Vice President of Regulatory Affairs & Quality Assurance
2575 University Avenue
Saint Paul, Minnesota 55114-1024

Letter dated: June 16, 2013

Re: K961811
Trade/Device Name: Peri-Guard® Repair Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OWV
Dated: May 08, 1996
Received: May 10, 1996

Dear Dr. MacFarlane:

This letter corrects our substantially equivalent letter of June 13, 1996

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact 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>. 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 -S

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

Enclosure

Indications for Use

510(k) Number (if known): K961811

Device Name: Peri-Guard Repair Patch

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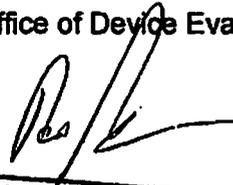
Prescription Use X
(Part 21 CFR 801 Subpart D)

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)



(Division Sign-Off)
Division of Surgical, Orthopedic, Page 1 of _____
and Restorative Devices

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