APERTA, LLC

K093166

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510(k) Summary

As required by section 807.92(c).

DEC - 7 2009

Proprietary name: WITTMANN PATCH

Common name: ARTIFICIAL BUR FASCIA PROSTHESIS

Classification name: SURGICAL MESH

Predicate Devices:

We claim equivalence [807.92(a) (3)] with legally marketed devices:

1) In the United States: "STAR TEMPORARY WOUND COVER" (Trade name: WITTMANN PATCH) permitted for Osteogenics, Inc. on 11/18/1999 with the 510(k) approval Number K983753

2) in Europe) CE marketed product: ARTIFICIAL BUR FOR TEMPORARY ABDOMINAL CLOSURE (Trade name: WITTMANN PATCH) permitted for HIDIH-Surgical, Schloss Str. 13, D-55444 Dörrebach by TÜV Rhineland Product Safety GmbH for European Community authorities, Permission Number DD 600009914 001 and certificate number SX 600009921 0001

As required by section 807.92(c).

Description of the device

Like the predicate devices the Wittmann Patch is adjustable fascial expander prosthesis for temporary bridging abdominal wall incisions where primary closure is not possible and/or repeat abdominal entries are necessary. The device is used in life threatening conditions such as severe abdominal trauma and intra-abdominal infection with and without abdominal compartment syndrome to enable temporary closure of the incised abdominal cavity when direct fascial closure is not possible and would compromise perfusion of intra-abdominal organs. After 3-5 days use WP is usually no longer required and removed for final abdominal closure without any mesh in place

The device consists of two adhering sheets of biocompatible polymeric material. One sheet bears small hook like structures and the other a meshwork of loops. The two sheets are sutured to opposing fascial edges of an abdominal incision. The abdomen can be closed by pressing one sheet onto the other expanding the fascia (fascia prosthesis) to account for increased intraabdominal volume but at the same time it can be easily opened to inspect, control, and repair intraabdominal pathology. The artificial bur fascia prosthesis provides a temporary safe fascial closure of the abdominal cavity. Once the intraabdominal pathology improves and swelling diminishes it is possible to re-approximate opposing fascias remove the artificial and close the abdominal wound by final fascia-to-fascia suture.

Specification of all material components of the device

Like the predicate devices the Wittmann Patch consists of two sheets of knitted synthetic fibers with clinging elements on one surface which adhere to each other. The two thin mating meshes are equipped with either loops or hooks respectively. Both sheets are white measuring 20 cm x 40 cm each, and consist of woven polyamide fibers and an additional reinforced backing for the hook sheet.

The two sheets adhere to each other when pressed onto the other. High tangential shearing forces are required to separate the two sheets. Testing has demonstrated that separation of the two sheets would occur only with forces greater than those that would disrupt normal, intact fascia [Wittmann, DH, et al Eur J Surg, 159: 75-79, 1993.]. Peeling the top sheet away from the lower sheet opens the two sheets to access the abdominal cavity.

No component of the final device can be identified that is potentially toxic, carcinogenic or immunogenic (e.g., organic solvents, heavy metals, cross-linking reagents).

APERTA, LLC

510(k) Summary

As required by section 807.92(c).

Indications

1) Advanced intra-abdominal pathology requiring more than one abdominal operation.
2) As fascia expander prosthesis to temporarily close the abdominal cavity when regular abdominal closure is not possible because abdominal organs protrude due to massive swelling of tissues, e.g. abdominal compartment syndrome and other severe and life threatening abdominal pathology.
3) To prevent perfusion impairment of abdominal organs from increased intra-abdominal pressure.

Contraindications

Like the predicate device the Wittmann Patch is not designed or intended for use as a permanent implant. It has not been approved for use in more than five abdominal entries.

Warnings & Limitations

Like the predicate device the Wittmann Patch was not designed to be used as permanent implant. It is for single use only. This device can be sold only to, by, or on the order of a physician.

Non-clinical and clinical performance data

This 512 (k) application is based on the same clinical and non-clinical performance data as the predicate devices and the same conclusions are drawn and demonstrate that the device is as safe, as effective, and performs as well as or better than the predicate device . 807.92(b) (3)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APERTA, LLC
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Casey Key Nokomis, Florida 34275

DEC - 7 2009

Re: K093166
Trade/Device Name: Wittmann Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: September 18, 2009
Received: October 6, 2009

Dear Dr. Wittmann:

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 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

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): _____

Device Name: Wittmann Patch

It is intended to use the device:

1) Advanced intra-abdominal pathology requiring more than one abdominal operation to control the disease. As fascia expander prosthesis to temporarily close the abdominal cavity when regular abdominal closure is not possible because abdominal organs protrude due to massive swelling of tissues, e.g. abdominal compartment syndrome and other severe and life threatening abdominal pathology.
2) To prevent perfusion impairment of abdominal organs from increased intra-abdominal pressure.
3) Advanced intra-abdominal pathology requiring more than one abdominal operation to control the disease process.

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)

Daniel Krowfar MXM

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K093166