



Food and Drug Administration
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Silver Spring, MD 20993-0002

November 24, 2014

Sofradim Production
Ms. Mary Mellows
Senior Regulatory Specialist
60 Middletown Avenue
North Haven, Connecticut 06437

Re: K142908
Trade/Device Name: Parietex™ Lightweight Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: October 7, 2014
Received: October 8, 2014

Dear Ms. Mellows:

This letter corrects our substantially equivalent letter of November 14, 2014.

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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]); 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 [SELECT ONE: Part 801 [or, for IVDs only] Parts 801 and 809]), please contact the Division of Industry and Consumer Education 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 <i>See PRA Statement below.</i>
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510(k) Number (if known)

Device Name
Parietex™ Lightweight Mesh

Indications for Use (Describe)
Parietex™ lightweight mesh is indicated for inguinal and ventral hernia repair.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 <i>See PRA Statement below.</i>
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510(k) Number (if known)

Device Name
Parietex™ Composite Parastomal Mesh

Indications for Use (Describe)
The PARIETEX™ Parastomal Mesh is indicated for the reinforcement of soft tissues during surgical repair, and specifically for the repair of parastomal hernias.
The non-absorbable polyester mesh provides long term reinforcement of soft tissues.
The absorbable hydrophilic film minimizes tissue attachment to the mesh when in direct contact with the viscera.

Type of Use (Select one or both, as applicable)
 Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number (if known)

Device Name
Parietex™ Composite Ventral Patch

Indications for Use (Describe)
The Parietex™ composite ventral patch is used for the reinforcement of soft tissues during surgical repair. It is indicated for the treatment of ventral defects (primary and incisional hernias).
The three-dimensional non-absorbable monofilament polyester mesh provides long term reinforcement of soft tissues. The absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

Device Name

Symbotex™ Composite Mesh

Indications for Use (Describe)

Symbotex™ composite mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists in procedures involving primary abdominal wall and incisional hernia surgeries.

The non-absorbable three-dimensional polyester mesh provides long term reinforcement of soft tissues. On the opposite side, the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) summary

Submitter Information

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Establishment Registration: 9615742

Name of contact person: Mary Mellows
Senior Regulatory Specialist
60 Middletown Avenue
North Haven, CT 06473

Phone: 203-492-5284

Date prepared: October 3, 2014

Name of device:

Trade or proprietary name: Parietex™ Lightweight Mesh
Parietex™ Composite Parastomal Mesh
Parietex™ Composite Ventral Patch
Symbotex™ Composite Mesh

Common or usual name: Surgical Mesh

Classification name: Mesh, Surgical, Polymeric

Classification panel: General and Plastic Surgery (79)

Regulation: 21 CFR 878.3300

Product Code: FTL

Legally marketed devices to which equivalence is claimed:

Parietex™ Monofilament Polyester Mesh (K090858)
Parietex™ Composite Mono PM Mesh (K081126)
Parietex™ Composite Ventral Patch (K120506)
Symbotex™ Composite Mesh (K131969)

Reason for 510(k) Submission:

The purpose of this 510(k) is to notify the Agency of the addition of another formulation of raw material, polyester, from the yarn supplier who manufactures the monofilament yarns used in the proposed devices. Eventually the current polyester will no longer be available by the supplier.

Device description:

Parietex™ Lightweight Mesh

Non-absorbable synthetic surgical mesh made of two-dimensional monofilament polyester knitting.

Parietex™ Composite Parastomal Mesh

PARIETEX™ Parastomal Mesh is made from a monofilament polyester fabric, covered with an absorbable hydrophilic film. The meshes are available in two different designs. Both are round in shape.

The first design is made from a three-dimensional monofilament polyester fabric and has a circular opening in the center. It is completely covered on one side with an absorbable hydrophilic film made of collagen from porcine origin, polyethylene glycol and glycerol.

The second design is made from a three dimensional monofilament polyester fabric with a two-dimensional monofilament polyester central band. One side of the second design is completely covered with the hydrophilic film. On the opposite side, only the two dimensional central band is coated with the absorbable hydrophilic film.

On both designs the film extends 5 mm over the external edge of the reinforcement, and also extends around the internal edge of the circular opening if any.

Parietex™ Composite Ventral Patch

The Parietex™ composite ventral patch is a dual facing mesh composed of a non-absorbable three dimensional monofilament polyester textile for abdominal wall reinforcement covered by a bioabsorbable hydrophilic collagen film to minimize visceral attachment. A fixation system composed of four (4) flaps made out of monofilament polyester textile and two (2) removable handles completes the device. This fixation system and the three-dimensional reinforcement textile are assembled with absorbable poly(glycolide-co-L-lactide) (PGLA) expanders. This system facilitates placement and fixation of the mesh.

The fascial side of the mesh ensures abdominal wall reinforcement allowing complete tissue ingrowth. The visceral side of the mesh is composed of porcine origin collagen film, polyethylene glycol and glycerol. This film is absorbable, continuous and hydrophilic and juts out over the edge of the textile. This side physically separates the polyester textile from tissues and organs to minimize tissue attachment to the mesh in case of direct contact with viscera.

The four (4) flaps of the Parietex™ composite ventral patch which provide a dedicated fixation surface area are composed of a dyed (D&C Green no. 6) bidimensional monofilament polyester textile. These flaps also facilitate visualization during the semi-peripheral suture fixation.

Two (2) dyed (D&C Violet no. 2) PGLA expanders provide shape memory to the mesh and offer stability to facilitate insertion and proper deployment of the mesh through defect. The PGLA component is completely absorbed prior to one (1) year.

The device also presents two (2) removable handles (composed of colored tubes and yarns) that are attached to the extremity of the flaps to provide a means for proper positioning of the mesh. They are kept extra corporally during the procedure and discarded after the surgery.

The PGLA component and the hydrophilic film are fully absorbable which provide less long term foreign material in the body.

Symbotex™ Composite Mesh

Symbotex™ composite mesh is made out of a three-dimensional monofilament polyester textile, which is covered with an absorbable, continuous and hydrophilic film on one of its sides. This film is made up of collagen from porcine origin and glycerol. The collagen film is essentially degraded in less than 1 month.

For “Flat sheet” (SYM reorder codes): A dyed monofilament polyester (D&C Green No. 6) marking is positioned on the center of the textile, on the opposite side of the film, and helps center and orient the mesh.

For “Flat Sheet with sutures” (SYM-F reorder codes): Non-absorbable pre-placed sutures are tied to the three-dimensional mesh. A dyed monofilament polyester (D&C Green No. 6) marking is positioned on the center of the textile, on the opposite side of the film, and helps center and orient the mesh.

For “With flap” (SYM-OS reorder codes): A dyed (D&C Green No. 6) bi-dimensional monofilament polyester textile flap is attached to the three-dimensional reinforcement and helps place and fix the mesh.

Intended use of the device:

Parietex™ Lightweight Mesh

Parietex™ Lightweight Mesh is intended for the reinforcement of tissue during surgical repair.

No changes to the intended use have been made in this submission.

Parietex™ Composite Parastomal Mesh

Parietex™ Composite Parastomal Mesh is intended for the reinforcement of soft tissue during surgical repair.
No changes to the intended use have been made in this submission.

Parietex™ Composite Ventral Patch

Parietex™ Composite Ventral Patch is intended for the reinforcement of soft tissue during surgical repair.
No changes to the intended use have been made in this submission.

Symbotex™ Composite Mesh

Symbotex™ Composite Mesh is intended for reinforcement of soft tissue where a weakness exists.
No changes to the intended use have been made in this submission.

Indications for use:

Parietex™ Lightweight Mesh

Parietex™ lightweight mesh is indicated for inguinal and ventral hernia repair.
No changes to the indications for use have been made in this submission

Parietex™ Composite Parastomal Mesh

The PARIETEX™ Parastomal Mesh is indicated for the reinforcement of soft tissues during surgical repair, and specifically for the repair of parastomal hernias. The non-absorbable polyester mesh provides long term reinforcement of soft tissues. The absorbable hydrophilic film minimizes tissue attachment to the mesh when in direct contact with the viscera.
No changes to the indications for use have been made in this submission

Parietex™ Composite Ventral Patch

The Parietex™ composite ventral patch is used for the reinforcement of soft tissues during surgical repair. It is indicated for the treatment of ventral defects (primary and incisional hernias).
The three-dimensional non-absorbable monofilament polyester mesh provides long term reinforcement of soft tissues. The absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.
No changes to the indications for use have been made in this submission

Symbotex™ Composite Mesh

Symbotex™ composite mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists in procedures involving primary abdominal wall and incisional hernia surgeries.
The non-absorbable three-dimensional polyester mesh provides long term reinforcement of soft tissues. On the opposite side, the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.
No substantive changes to the indications for use have been made in this submission

Summary comparing the technological characteristics of the subject and predicate devices:

The proposed Parietex™ Lightweight Mesh, Parietex™ Composite Parastomal Mesh, Parietex™ Composite Ventral Patch, Symbotex™ Composite Mesh manufactured with another formulation of raw material, polyester, from the same yarn supplier as the current polyester are equivalent to predicate Parietex™ Monofilament Polyester Mesh (K090858), Parietex™ Composite Mono PM Mesh (K081126), Parietex™ Composite Ventral Patch (K120506), Symbotex™ Composite Mesh (K131969) in terms of the following technological characteristics:

- Indication
- Raw materials
- Performance characteristics
- Biocompatibility
- Stability
- Design

Performance data: This change consists of the addition of another formulation of raw material, polyester, for the subject devices.

Bench testing has been conducted in accordance with *FDA's Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh* issued March 2, 1999 to evaluate the performance characteristics of proposed devices.

Stability Studies have been conducted and the proposed devices shelf life has been demonstrated.

Biocompatibility studies have been conducted on the proposed polyester based devices in accordance with ISO 10993-1 for a permanent implant, a recognized standard by FDA (#2-156).

Conclusion: Bench testing and preclinical tests results demonstrate that proposed devices are substantially equivalent to the predicates Parietex™ Monofilament Polyester Mesh (K090858), Parietex™ Composite Mono PM Mesh (K081126), Parietex™ Composite Ventral Patch (K120506), Symbotex™ Composite Mesh (K131969).