



March 9, 2018

Sofradim Production  
% Ms. Angela Arsdale  
Regulatory Affairs Manager  
Covidien  
60 Middletown Avenue  
North Haven, Connecticut 06473

Re: K173796

Trade/Device Name: Parietex Surgical Mesh (modified into Parietex Hydrophilic 2D, 3D, Anatomical Mesh), Parietex Composite Mesh (PCO and PCO-OS references), Parietex Optimized Composite Mesh (PCO-X, PCO-FX and PCO-OSX references)

Regulation Number: 21 CFR 878.3300

Regulation Name: Surgical Mesh

Regulatory Class: Class II

Product Code: FTL

Dated: January 8, 2018

Received: January 9, 2018

Dear Ms. Arsdale:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
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

## Indications for Use

510(k) Number (if known)  
K173796

Device Name  
Parietex™ Hydrophilic 2D, 3D, Anatomical Mesh

Indications for Use (Describe)  
Parietex™ Hydrophilic 2D, 3D, Anatomical Mesh is intended for the repair of inguinal and incisional hernias

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.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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## Indications for Use

510(k) Number (if known)  
K173796

Device Name  
Parietex™ Composite Mesh (PCO and PCO-OS references)

### Indications for Use (Describe)

Parietex™ Composite Mesh is used for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernias, abdominal wall repair and parietal (i.e. pertaining to the walls) reinforcement of tissues. 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)

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## Indications for Use

510(k) Number (if known)  
K173796

Device Name  
Parietex™ Optimized Composite Mesh (PCO-X, PCO-FX, and PCO-OSX references)

### Indications for Use (Describe)

Parietex™ Optimized Composite Mesh is used for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernias, abdominal wall repair and parietal (i.e. pertaining to the walls) reinforcement of tissues. The non-absorbable threedimensional 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)

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**510(k) Summary**

In accordance with 21 CFR 807.92, Covidien is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) number K173796 as of December 06, 2017.

**Date Prepared:** February 26, 2018

**Submitter:** Sofradim Production (subsidiary of Covidien llc)  
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**Name of device:** Parietex™ Hydrophilic 2D, 3D, Anatomical Mesh  
*Trade/Proprietary name:* Parietex™ Composite Mesh  
Parietex™ Optimized Composite Mesh  
*Common name:* Surgical Mesh  
*Classification name:* Mesh, Surgical, Polymeric  
Product code: FTL  
Regulation number: 21 CFR 878.3300

**Predicate Devices:** Parietex® Surgical Mesh (new names Parietex™ Hydrophilic 2D, 3D, Anatomical Mesh) (K982532)  
*Trade/Proprietary name (510(k) Number)* Parietex™ Composite Mesh (K040998, K050187)  
Parietex™ Optimized Composite Mesh (K110663, K110815, K110816)  
No reference devices were used in this submission.

*Common name:* Surgical Mesh  
*Classification name:* Mesh, Surgical, Polymeric  
Product code: FTL  
Regulation number: 21 CFR 878.3300  
*Manufacturer:* Sofradim Production  
116, avenue du Formans  
01600 Trevoux, France

**Device Description:**

**Parietex™ Hydrophilic 2D, 3D, Anatomical Mesh**

The two-dimensional mesh, with rectangular pores, is available in two different textures: a standard version (TEC references) and a rigid version (TECR references). The textures and transparencies of this mesh make them particularly suitable for the treatment of parietal affections, in particular inguinal hernias, through laparoscopic approach.

The three-dimensional mesh (TET references) has hexagonal pores. The flexibility, porosity and low density of this mesh make it particularly suitable for the treatment of parietal affections, in particular incisional and inguinal hernias, through open approach.

The Parietex™ hydrophilic 2-dimensional mesh, hydrophilic 3-dimensional mesh and hydrophilic anatomical mesh has been adapted for various techniques of abdominal repair. The rectangular mesh is designed for the repair of inguinal and incisional hernias in a pre-peritoneal or pre-muscular approach.

The pre-cut and slit mesh is suitable for the repair of inguinal hernias via anterior approach using the tension free technique.

The folding mesh (in two-dimensional textile) is designed for the repair of direct or indirect inguinal hernias through a laparoscopic approach (trans-abdominal or pre-peritoneal or totally extra-peritoneal). Some codes have a slit for the passage of the cord.

The anatomical mesh is mainly designed for the repair of inguinal hernias via laparoscopic or posterior open procedures and is available for the left and/or right side.

**Parietex™ Composite Mesh** is a composite mesh made out of a three-dimensional (3D) multifilament polyester textile for wall reinforcement, covered with an absorbable, continuous and hydrophilic film on one of its sides. This film is made up of collagen from porcine origin, polyethylene glycol and glycerol and juts out 5 mm over the edge of the reinforcement. For some references, a bi-dimensional (2D) multifilament polyester textile flap is attached to the 3D reinforcement and helps place and fixate the mesh (PCO-OS references).

**Parietex™ Optimized Composite Mesh** is made out of a three-dimensional (3D) multifilament polyester for wall reinforcement, 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 and juts out 5 mm over the edge of the reinforcement. The film is essentially degraded in less than 1 month. For some references, a bi-dimensional (2D) multifilament polyester textile flap is attached to the three-dimensional reinforcement and helps place and fixates the mesh (PCO-OSX references). For some references, one or many non-absorbable color monofilaments are tied (pre-placed sutures) to the three-dimensional mesh (PCO-FX references).

This change is a vendor change only, there are no changes to the material composition. Both the original material and the new materials are derived from the same base material.

**Intended Use:**

**Parietex™ Hydrophilic 2D, 3D, Anatomical Mesh** is intended for the reinforcement of tissue during surgical repair<sup>1</sup>.

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

**Parietex™ Optimized Composite Mesh** is intended for the reinforcement of tissue during surgical repair.

**Indications for use:**

**Parietex™ Hydrophilic 2D, 3D, Anatomical Mesh** is intended for the repair of inguinal and incisional hernias.

**Parietex™ Composite Mesh** is used for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernias, abdominal wall repair and parietal (i.e. pertaining to the walls) reinforcement of tissues. 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.

**Parietex™ Optimized Composite Mesh** is used for the reinforcement of tissues during surgical repair. It is indicated for the treatment of incisional hernias, abdominal wall repair and parietal (i.e. pertaining to the walls) reinforcement of tissues. 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.



**Summary comparing the technological characteristics of the subject and predicate device:** The proposed modified devices Parietex™ Hydrophilic 2D, 3D, Anatomical Mesh, Parietex™ Composite Mesh and Parietex™ Optimized Composite Mesh manufactured with the two new polyester (polyethylene terephthalate) multifilament yarns from the two new suppliers, are substantially equivalent to the predicate devices Parietex™ Hydrophilic 2D, 3D, Anatomical Mesh (K982532), Parietex™ Composite Mesh (K040998, K050187) and Parietex™ Optimized Composite Mesh (K110663, K110815, K110816) in terms of :

- Indications
- Material
- Performance characteristics
- Biocompatibility
- Stability
- Design

**Materials:** The biocompatibility of the proposed modified Parietex™ Hydrophilic 2D, 3D, Anatomical Mesh, Parietex™ Composite Mesh and Parietex™ Optimized Composite Mesh has been evaluated and found compliant with ISO Standard 10993-1:2009 (FDA recognition number #2-220).

**Performance data:** This change consists of the addition of two new polyester (polyethylene terephthalate) multifilament yarns from two new suppliers for the subject devices. These yarns are used to manufacture the textiles of the devices. The following performance data is provided in support of the substantial equivalence determination:

- *In vitro* (bench) tests have been performed in accordance with the FDA Guidance: “*Guidance for the Preparation of a Premarket Notification Application of a Surgical Mesh*” dated March 2, 1999 to evaluate the performance characteristics of the subject devices. The following mesh characteristics were assessed:
  - Pore size
  - Thickness
  - Surface density
  - Bursting strength
  - Bursting distension
  - Breaking strength
  - Elongation at break
  - Tear strength
  - Suture pull-out strength

Suture pull-out tests were performed on the pre-placed sutures of the proposed modified Parietex™ Optimized Composite Mesh (for PCO-FX references) to assess the

strength of the textile/suture assembly. Seam strength tests were performed on the textiles assemblies of the proposed modified Parietex™ Hydrophilic 2D and Anatomical Mesh (for TECR1410DP2 and TECT references), Parietex™ Composite Mesh and Parietex™ Optimized Composite Mesh (for PCO-OS, PCO-OSX references) to assess the strength of the textiles assembly.

- Stability studies were conducted and the shelf life of the proposed modified devices was demonstrated.
- Biocompatibility evaluation was performed and confirmed that the proposed modified Parietex™ Hydrophilic 2D, 3D, Anatomical Mesh, Parietex™ Composite Mesh and Parietex™ Optimized Composite Mesh are compliant with ISO Standard 10993-1:2009 (FDA recognition number #2-220) for their intended patient contact profile.

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

**Conclusion:**

All testing demonstrates that the proposed modified devices are substantially equivalent to the predicate devices Parietex™ Hydrophilic 2D, 3D, Anatomical Mesh (K982532), Parietex™ Composite Mesh (K040998, K050187) and Parietex™ Optimized Composite Mesh (K110663, K110815, K110816).