DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 29, 2017

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

Re: K163212
Trade/Device Name: Parietene Ds Composite Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: May 29, 2017
Received: June 5, 2017

Dear Ms. Mellows:

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 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" (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.

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,

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
See PRA Statement below.

510(k) Number *(if known)*

K163212

Device Name

Parietene™ DS Composite Mesh

Indications for Use *(Describe)*

Parietene™ DS Composite Mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists. It is indicated for the repair of ventral hernias or other abdominal fascial deficiencies that require the addition of a reinforcing material.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary of Safety and Effectiveness

Date Prepared:

November 14, 2016

Submitter:

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Name of device:

Trade/Proprietary name:	Parietene™ DS Composite Mesh
Common name:	Surgical Mesh
Classification name:	Mesh, Surgical, Polymeric • Panel number and product code: 79 FTL • Regulation number: 21 CFR 878.3300

Predicate Device:

Trade/Proprietary name:	Proceed™ Surgical Mesh
Common name:	Surgical Mesh
Classification name:	Mesh, Surgical, Polymeric • Panel number and product code: 79 FTL • Regulation number: 21 CFR 878.3300
510(k) Number:	K060713
Manufacturer:	Ethicon

Reason for 510(k) Submission: To obtain market clearance for the Parietene™ DS Composite Mesh.

Device Description: Parietene™ DS Composite Mesh is designed to be placed in an intraperitoneal site by a laparoscopic or open approach. The mesh is composed of a permanent macroporous polypropylene textile on one side and a fully absorbable synthetic film on the other side. The film is adhered to the textile using a binding agent localized on the textile fibers. A violet marking is positioned on the

mesh to help center and orient the mesh. Non-absorbable pre-placed sutures are tied to the mesh.

- The macroporous textile is knitted from a permanent monofilament polypropylene yarn.
- The synthetic film is made out of absorbable synthetic copolymer of glycolide, caprolactone, trimethylene carbonate, and lactide.
- The binding agent and the violet marking are made out of absorbable polycaprolactone. The D&C Violet No. 2 dye is used for the marking.
- The pre-placed sutures are made out of an isotactic crystalline stereoisomer of polypropylene (a synthetic linear polyolefin) and polyethylene. The Copper Phthalocyanine Blue is used to color the sutures.

The permanent macroporous textile is designed to be placed over the abdominal wall to ensure long term reinforcement of soft tissues, while the continuous absorbable film is designed to minimize tissue attachment to the mesh in case of direct contact with the viscera and is essentially degraded within 105 days by hydrolysis.

Intended Use: Parietene™ DS composite mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists.

Indications for use: Parietene™ DS composite mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists. It is indicated for the repair of ventral hernias or other abdominal fascial deficiencies that require the addition of a reinforcing material.

Summary comparing the technological characteristics of the subject and predicate device: The subject Parietene™ DS Composite Mesh is substantially equivalent to the predicate device Proceed™ Surgical Mesh (K060713) in terms of indications and design for the following technological characteristics:

- Polypropylene textile performance
- Minimizing tissue attachment layer
- Design: composite mesh with equivalent shapes and sizes

Materials: Parietene™ DS composite mesh and its constitutive components have been evaluated and found compliant with ISO Standard 10993-1.

Performance data: The following performance data is provided in support of the substantial equivalence determination:

In vitro (bench) tests have been performed in accordance with the *"Guidance for the Preparation of a Premarket Notification Application of a Surgical Mesh"* issued March 2, 1999 to evaluate the performance characteristics of the subject Parietene™ DS Composite Mesh in comparison with the predicate Proceed™ Surgical Mesh (K060713). 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

Knot-pull tensile strength and suture pull-out tests were performed on the pre-placed sutures of the subject Parietene™ DS Composite Mesh to demonstrate conformity to USP monograph for non-absorbable surgical suture and to assess the strength of the textile/suture assembly.

Trocar passage testing was conducted to demonstrate that the integrity of the mesh is preserved when used by laparoscopy.

- *In vivo* pre-clinical tests on representative animal models were conducted in comparison with the predicate Proceed™ Surgical Mesh (K060713) to evaluate the tissue integration and to demonstrate the minimizing tissue attachment performance in case of contact with viscera.

- Stability study was conducted and the proposed device shelf life was demonstrated.

- Biocompatibility tests were performed to confirm that Parietene™ DS Composite Mesh and its constitutive components are compliant with ISO Standard 10993-1 for their intended patient contact profile.

- Usability tests were conducted and demonstrate that the subject Parietene™ DS Composite Mesh is safe and effective for the intended users, uses and use environments.

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

Conclusion:
All testing demonstrates that the subject Parietene™ DS Composite Mesh is substantially equivalent to the predicate device, Proceed™ Surgical Mesh (K060713).