DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 28, 2014

Sofradim Production
% Ms. Mary Mellows
Surgical Devices, a global business unit of Covidien
60 Middletown Avenue
North Haven, Conneticut 06473

Re: K142900
Trade/Device Name: ProGrip™ Self-Gripping Polyester Mesh
Parietex™ Plug and Patch System
ProGrip™ Laparoscopic Self-Fixating Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: October 3, 2014
Received: October 6, 2014

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" (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
See PRA Statement below.

510(k) Number *(if known)*
K142900

Device Name
Parietex™ Plug and Patch System

Indications for Use *(Describe)*
Parietex™ Plug and Patch System is indicated for the reinforcement of soft tissues during repair of groin hernia defects by open approach

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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
K142900

Device Name
ProGrip™ Laparoscopic Self-Fixating Mesh

Indications for Use *(Describe)*
ProGrip™ Laparoscopic Self-Fixating Mesh is indicated for the reinforcement of soft tissues during repair of inguinal hernia defects by laparoscopic approach

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

Indications for Use

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

510(k) Number *(if known)*
K142900

Device Name
ProGrip™ Self-Gripping Polyester Mesh

Indications for Use *(Describe)*
ProGrip™ Self-Gripping Polyester Mesh is indicated for inguinal and incisional hernias 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.

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510(k) Summary

Submitter Information

Name:	Sofradim Production (subsidiary of Covidien LLC)
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Fax number:	+33 (0) 4 74 08 90 02
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:	ProGrip™ Self-Gripping Polyester Mesh Parietex™ Plug and Patch System ProGrip™ Laparoscopic Self-Fixating 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™ Progrip™ Mesh (K103682)
Parietex™ Plug and Patch (K101519)
Progrip™ Laparoscopic Self-Fixating Mesh (K123479)

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:

ProGrip™ Self-Gripping Polyester Mesh

The mesh and the overlapping flaps of the pre-cut versions are made of knitted monofilament polyester and have polylactic acid monofilament resorbable pins on one of the sides. These pins facilitate placing, positioning and fixation of the overlapping flap and the mesh to the surrounding tissue. A colored yarn marker on the medial edge of the pre-cut mesh helps orientation.
The monofilament polylactic acid pins are bioresorbable and contribute to the fixation of the mesh to surrounding tissue during at least 8 weeks. The polylactic acid pins degrade and resorb in vivo by hydrolysis and are metabolized by the body into CO^2 and H_2O.

Parietex™ Plug and Patch System

The Parietex™ Plug and Patch System is a kit composed of:

- a pre-cut patch made from monofilament polyester
- a semi-resorbable disk which is a bi-component made of polyester monofilament and polylactic acid.

ProGrip™ Laparoscopic Self-Fixating Mesh

The mesh is made of knitted monofilament polyester with monofilament polylactic acid resorbable grips on one side and a resorbable film made of collagen from porcine origin and glycerol, on the other side. The grips allow positioning and fixation of the mesh to the surrounding tissue, while the collagen film facilitates mesh handling and deployment. The mesh presents a green band (polyester dyed with D&C green no. 6) to facilitate their orientation.
The monofilament polylactic acid grips are bioresorbable and provide the fixation of the mesh to surrounding tissue for at least 8 weeks. The polylactic acid grips degrade and resorb in vivo by hydrolysis and are metabolized by the body into CO_2 and H_2O.

Intended use of the device:

ProGrip™ Self-Gripping Polyester Mesh

ProGrip™ Self-Gripping Polyester Mesh is intended for the reinforcement of tissue during surgical repair.
No changes to the intended use have been made in this submission.

Parietex™ Plug and Patch System

Parietex™ Plug and Patch System is intended for the reinforcement of soft tissues during surgical repair.

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

ProGrip™ Laparoscopic Self-Fixating Mesh

ProGrip™ Laparoscopic Self-Fixating Mesh is intended for the reinforcement of tissue during surgical repair.

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

Indications for use:

ProGrip™ Self-Gripping Polyester Mesh

ProGrip™ Self-Gripping Polyester Mesh is indicated for inguinal and incisional hernias repair.

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

Parietex™ Plug and Patch System

Parietex™ Plug and Patch System is indicated for the reinforcement of soft tissues during repair of groin hernia defects by open approach.

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

ProGrip™ Laparoscopic Self-Fixating Mesh

ProGrip™ Laparoscopic Self-Fixating Mesh is indicated for the reinforcement of soft tissues during repair of inguinal hernia defects by laparoscopic approach.

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

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

The proposed ProGrip™ Self-Gripping Polyester Mesh, Parietex™ Plug and Patch System and ProGrip™ Laparoscopic Self-Fixating Mesh manufactured with another formulation of raw material, polyester, from the same yarn supplier as the current polyester are equivalent to predicate Parietex™ Progrip™ Mesh (K103682), Parietex™ Plug and Patch (K101519) and Progrip™ Laparoscopic Self-Fixating Mesh (K123479) 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™ Progrip™ Mesh (K103682), Parietex™ Plug and Patch (K101519) and Progrip™ Laparoscopic Self-Fixating Mesh (K123479).