DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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March 18, 2015

Sofradim Production
% Ms. Mary Mellows
Surgical devices, a global business unit of Covidien
60 Middleton Avenue
North Haven, Connecticut 06473

Re: K143386
Trade/Device Name: ProGrip™ laparoscopic self-fixating mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: February 10, 2015
Received: February 11, 2015

Dear Ms. Mellows:

This letter corrects our substantially equivalent letter of March 13, 2015.

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

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)*
K143386

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)

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)*

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

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510(k) Summary

This 510(k) summary information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92.

Submitter Information

Name:	Sofradim Production (subsidiary of Covidien LLC)
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Establishment Registration:	9615742
Name of contact person:	Mary Mellows Covidien Senior Regulatory Specialist 60 Middletown Avenue North Haven, CT 06473
Phone:	203-492-5284
Date prepared:	November 25, 2014
Trade or proprietary name:	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:	Progrip™ Laparoscopic Self-Fixating Mesh (K142900)
Referenced devices noted in this submission:	Progrip™ Laparoscopic Self-Fixating Mesh (K120897) 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 additional sizes 13x9 cm, 16x12 cm and 16x14 cm to the Progrip™ Laparoscopic Self-Fixating Mesh product family (current size is 15x10 cm). These three sizes are being added to the product family to satisfy customer requirements.

These proposed sizes will result in the addition of 6 new reorder codes to the predicate product, Progrip™ Laparoscopic Self-Fixating Mesh (K142900):

1. The proposed size 13x9 will be available in two configurations:
    - Right anatomical mesh,
    - Left anatomical mesh
2. The proposed size 16x12 will be available in three configurations:
    - Right anatomical mesh,
    - Left anatomical mesh,
    - Rectangular mesh
3. The proposed size 16x14 will be available in one configuration:
    - Rectangular mesh

Device description:

Both the predicate and the proposed mesh are 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 incorporates a green band to facilitate 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:

Both the predicate and the proposed ProGrip™ Laparoscopic Self-Fixating Mesh are intended for the reinforcement of tissue during surgical repair.

No change to the intended use has been made in this submission.

Indications for use:

Both the predicate and the proposed ProGrip™ Laparoscopic Self-Fixating Mesh are indicated for the reinforcement of soft

tissues during repair of inguinal hernia defects by laparoscopic approach.

No change to the indication for use has been made in this submission.

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

Both the predicate and the proposed ProGrip™ Laparoscopic Self-Fixating Mesh are knitted monofilament polyester with monofilament polylactic acid resorbable grips on one side and an absorbable film made of collagen from porcine origin and glycerol, on the other side. The intended use and technology of the three additional sizes of ProGrip™ Laparoscopic Self-Fixating Mesh are identical to that of the predicate ProGrip™ Laparoscopic Self-Fixating Mesh.

Performance data:

The materials of the new ProGrip™ Laparoscopic Self-Fixating Mesh references are identical to the predicate ProGrip™ Laparoscopic Self-Fixating Mesh and therefore, the performance data submitted in the predicate ProGrip™ Laparoscopic Self-Fixating Mesh 510k (K142900) applies to the three additional sizes.

ProGrip™ Laparoscopic Self-Fixating Mesh new sizes are composed of biocompatible materials that are in compliance with ISO 10993-1 standard.

As materials and manufacturing processes have not changed, the stability data of the predicate ProGrip™ Laparoscopic Self-Fixating Mesh (K142900) is applicable for the additional sizes of ProGrip™ Laparoscopic Self-Fixating Mesh.

In addition to tests referenced in K142900, bench performance evaluations were completed to verify that the proposed additional sizes of ProGrip™ Laparoscopic Self-Fixating Mesh (16x12cm and 16x14cm) are compatible with 10mm and/or 12mm trocars. Mesh sizes 16x12cm and 16x14cm were chosen for testing due to their worst case configuration regarding trocar passage compared to 15x10cm size.
The tests performed were:

- Passage through 10mm and/or 12mm trocar
- Visual inspection after trocar passage
- Gripping point measurement and comparison with specification (≤27 gripping points for 16x12cm and16x14cm) after trocar passage.

Conclusion: Bench testing results demonstrate that the proposed additional sizes of Progrip™ Laparoscopic Self-Fixating Mesh are substantially equivalent to the predicate Progrip™ Laparoscopic Self-Fixating Mesh (K142900).