January 17, 2025

Sofradim Production
% Nancy Sauer
Regulatory Affairs Senior Director
Covidien LLC
200 Medtronic Dr
Lafayette, Colorado 80026

Re: K243315
Trade/Device Name: ProGrip™ Self-Gripping Polypropylene Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: October 18, 2024
Received: October 22, 2024

Dear Nancy Sauer:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2025.01.17 10:41:40 -05'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243315

Device Name

ProGrip™ Self-Gripping Polypropylene Mesh

Indications for Use *(Describe)*

ProGrip™ self-gripping polypropylene mesh is intended for use in reinforcement of abdominal wall soft tissue where weakness exists.
The ProGrip™ self-gripping polypropylene mesh rectangular and square shapes are 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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510(k) Summary

Date Prepared: January 16th, 2026

Submitter: Sofradim Production (subsidiary of Covidien llc)
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Name of device:

Trade/Proprietary name: Progrip™ self-gripping polypropylene 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: Progrip™ self-gripping polypropylene 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: K232373
Manufacturer: Sofradim Production (subsidiary of Covidien llc)
116, avenue du Formans
01600 Trevoux, France

Reference Device:

Trade/Proprietary name: Progrip™ self-gripping polyester 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: K220586
Manufacturer: Sofradim Production (subsidiary of Covidien llc)
116, avenue du Formans
01600 Trevoux, France

Device Description:	Progrip™ self-gripping polypropylene mesh is designed to allow extraperitoneal mesh placement for the repair of inguinal and ventral hernias. Progrip™ self-gripping polypropylene mesh is made of a non-absorbable knitted monofilament polypropylene textile with resorbable polylactic acid (PLA) monofilament grips on one side. Progrip™ self-gripping polypropylene mesh is available in different shapes and sizes. The monofilament polylactic acid grips facilitate placing and positioning the mesh, and they contribute to fixation of the mesh to the surrounding tissue for at least eight (8) weeks. The polylactic acid grips are bioresorbable. Over the time, they resorb in vivo by hydrolysis and are metabolized by the body into CO2 and H2O. Preclinical studies showed that the polylactic acid material is essentially resorbed in 36 to 50 months post-implantation. However, the resorption period depends on numerous factors including patient-related factors. Progrip™ self-gripping polypropylene mesh is a single use device, presented in a double sterile barrier packaging (two Tyvek® pouches). The packed device is terminally sterilized by Ethylene Oxide (EtO) and placed into a commercial box or envelope with the eIFU leaflet and Patient Implant Card (PIC). All the devices are packaged unitary in a commercial box or envelope (single pack configuration: 1 unit per commercial box or envelope).
Intended Use:	Reinforcement of soft tissue where weakness exists.
Indications for use:	ProGrip™ self-gripping polypropylene mesh is intended for use in reinforcement of abdominal wall soft tissue where weakness exists. ProGrip™ self-gripping polypropylene mesh rectangular and square shapes are indicated for inguinal and ventral hernia repair.
Summary comparing the technological characteristics of the subject and predicate device:	The subject device is substantially equivalent to Progrip™ self-gripping polypropylene mesh (K232373), which is the primary predicate device. The subject device, Progrip™ self-gripping polypropylene mesh has the following similarities to the primary predicate device Progrip™ self-gripping polypropylene mesh (K232373): • The intended use of the subject device is identical to the predicate device, i.e., reinforcement of soft tissue where a weakness exists • The mesh designs are the same: two-dimensional monofilament textile with monofilament absorbable grips on one side of the mesh for both the subject and the predicate devices

- Same materials
- Both devices present rectangular and square shapes with same sizes
- The choice of the fixation approach is left up to the surgeon for both devices
- The sterilization and packaging are the same between the subject device and the predicate device

The subject device incorporates the following changes compared to the predicate device:

- The subject device will be used by Minimally Invasive Surgery approach.
- The subject device will include electronic instruction for use
- Addition of 15*09cm rectangular sizes

This 510(k) also references the Progrip™ self-gripping polyester mesh (K220586). Progrip™ self-gripping polyester mesh (K220586) was selected because this legally marketed mesh is a mesh with grips already used by laparoscopic approach.

Performance data:

The following performance data is provided in support of substantial equivalence demonstration:

- **Performance testing - In vitro (bench) tests** has been performed:
    - to assess the compatibility with trocar passage using visual inspection method.
    - to compare the subject and predicate devices in accordance with the FDA Guidance "*Guidance for the Preparation of a Premarket Notification Application of a Surgical Mesh*" issued March 2, 1999. Results demonstrate that physical and mechanical performance of the subject are substantially equivalent to the predicate.
    - to compare the subject and reference devices in accordance with the FDA Guidance "*Guidance for the Preparation of a Premarket Notification Application of a Surgical Mesh*" issued March 2, 1999.
- During the development of ProGrip™ Self-Gripping Polypropylene Mesh for laparoscopic approach, **Human factors evaluation** was conducted. This usability evaluation was performed in different configurations to address usability risks identified:

- Simulated use evaluation in a cadaver model. In this model, surgeons prepared, introduced through trocar, deployed, placed and fixated the mesh in a cadaver to verify use of the product in contact with tissue.

- Simulated use evaluation in an abdominal simulator for trocar passage.

- The electronic Instruction For Use was also checked to verify whether it is clear and understandable.

The human factors engineering process applied to the ProGrip™ Self-Gripping Polypropylene Mesh complied with the requirements of IEC 62366-1: 2015 and associated FDA guidance documents.

Sterilization, shelf-life, shipping tests and biocompatibility are not impacted by the proposed change.
This premarket submission does not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Conclusion:
Comparison of the subject and predicate devices and labeling as well as the results of performance testing demonstrate that the subject Progrip™ self-gripping polypropylene mesh is substantially equivalent to the predicate device Progrip™ self-gripping polypropylene mesh (K232373).