January 18, 2024

Sofradim Production
℅ Nancy Sauer
Regulatory Affairs Senior Director
Covidien llc
200 Medtronic Drive
Lafayette, Colorado 80026

Re: K232373
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: December 18, 2023
Received: December 18, 2023

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.

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: 2024.01.18 15:36:39 -05'00'

Tek 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232373

Device Name
ProGrip™ Self-Gripping Polypropylene Mesh

Indications for Use *(Describe)*
ProGrip™ Self-Gripping Polypropylene Mesh is intended to be used for the reinforcement of abdominal wall soft tissues where weakness exists in procedures involving inguinal and ventral hernia repair 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.

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510(k) Summary

Date Prepared: Jan 17, 2024

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 Product code: FTL Regulation number: 21 CFR 878.3300

Predicate Device:

Trade/Proprietary name:	Progrip™ self-gripping polyester mesh
Common name:	Surgical Mesh
Classification name:	Mesh, Surgical, Polymeric Product code: 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

Reference Device:

Trade/Proprietary name:	PROLENE® Soft Polypropylene Mesh
Common name:	Surgical Mesh
Classification name:	Mesh, Surgical, Polymeric Product code: FTL Regulation number: 21 CFR 878.3300
510(k) Number:	K172089

Manufacturer:	Ethicon, Inc. a Johnson & Johnson company P.O. Box 151 Route 22 West Somerville, NJ 08876-0151

Reference Device:

Trade/Proprietary name:	Progrip™ self-gripping polypropylene mesh
Common name:	Surgical Mesh
Classification name:	Mesh, Surgical, Polymeric Product code: FTL Regulation number: 21 CFR 878.3300
510(k) Number:	K220540
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 by open approach.

Progrip™ self-gripping polypropylene mesh is a sterile non-pyrogenic device 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 non-absorbable textile is designed to ensure long term reinforcement of soft tissues.

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 CO_2 and H_2O. 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 envelope with the Instructions for Use (IFU) and Patient Implant Card (PIC). All the devices are packaged unitary in a commercial envelope (single pack configuration: 1 unit per commercial 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, in procedures involving inguinal and ventral hernia repair by open approach.

Summary comparing the technological characteristics of the subject and predicate device: The subject device is substantially equivalent to Progrip™ self-gripping polyester mesh (K220586), which is the primary predicate device.

	Progrip™ self-gripping polypropylene mesh K232373 (subject device)	**Progrip™ self-gripping polyester mesh (K220586) (predicate device)**	**Comparison**
Intended Use	Reinforcement of soft tissue where a weakness exists	Reinforcement of soft tissue where weakness exists.	**Same**
Classification	FTL, per 21 CFR 878.3300	FTL, per 21 CFR 878.3300	**Same**
Indications for use	Inguinal and ventral hernias repair	Inguinal and incisional hernias repair	**Different**
Method of Insertion	Open	Open and Laparoscopic (conventional and robotically assisted approach)	**Equivalent**
Location of placement	Extraperitoneal	Extraperitoneal	**Same**
Defect Closure	Recommended	Recommended	**Same**
Materials	Surgical mesh, textile based, knitted, monofilament, synthetic made of polypropylene and polylactic acid yarns	Surgical mesh, textile based, knitted, monofilament, synthetic made of polyester and polylactic acid yarns *only for elliptic (precut) codes*: polyester yarn marker dyed with D&C blue no. 6.	**Different**
Shape	Rectangular and square	Rectangular and square Elliptic	**Equivalent**
Sizes	Rectangular and square: 15x15cm 20x15cm 30x20 cm 30x30cm 40x30cm The mesh may be recut as needed.	- Rectangular: 15x9 cm 15x15 cm 20x15 cm 30x15 cm - Elliptic, slit with overlapping flap left side/right side: 12x8 cm The mesh may be recut as needed.	**Different**

Texture	Two-dimensional monofilament textile with monofilament absorbable grips on one side of the mesh	Two-dimensional monofilament textile with monofilament absorbable grips on one side of the mesh	**Same**
Pore size	1.6±0,1mm and 0.6±0,0mm	1.6±0,1mm and 0.6±0,1mm	**Same**
Fixation instructions	The technique used to fixate the mesh (suture and/or tacks) is left up to the surgeon. Compatibility with other fixation devices may not have been established. Using means of fixation other than those for which compatibility is established may lead to mesh damage. If tacks are used to fixate the mesh, the use of Covidien™ fixation devices is recommended. It is suggested to fixate the mesh at a distance of approximately 1 cm from the edge of the mesh. The textile self-gripping feature makes it possible to position the mesh without fixation, depending on the size of the defect, the hernia position and the quality of the anatomical structures.		**Same**
Sterilization	Ethylene Oxide	Ethylene Oxide	**Same**
Packaging	Sealed Tyvek®// polyester/polyethylene pouch (double sterile barrier system)	Sealed Tyvek®// polyester/polyethylene pouch (double sterile barrier system)	**Same**

The subject device and predicate device have the same intended use and nearly identical indications for use, differing only in the addition of primary ventral hernia repair for the subject device. Differences in the technological characteristics between the subject and predicate devices do not raise new questions of safety or effectiveness. Performance testing has demonstrated substantial equivalence for biocompatibility, mechanical properties such as strength, human factors evaluation, sterilization, packaging, transport and shelf life.

This 510(k) also references the PROLENE® Soft Polypropylene Mesh (K172089) and the Progrip™ self-gripping polypropylene mesh (K220540). PROLENE® Soft Polypropylene Mesh (K172089) was selected because this legally marketed mesh includes large sizes (up to 50x50cm). Progrip™ self-gripping polypropylene mesh (K220540) was selected because this legally marketed mesh presents the same base materials as the subject device.

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

- **Sterilization:** the sterilization process has been validated in accordance with ISO 11135 (2014) and AAMI TIR28 (2016) standards.

- **Shelf-life**: the 5-year shelf life has been demonstrated for the subject device.

- **Shipping test:** shipping test was performed in accordance with the ASTM D4169 (2022) standard.

- **Biocompatibility:** biocompatibility evaluation was performed for the subject Progrip™ self-gripping polypropylene mesh in accordance with the FDA guidance "*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" issued September 4, 2020, and international standard ISO 10993-1 (2018). The subject device meets the criteria for biocompatibility set forth in the FDA guidance and ISO standard.

- **Performance testing - In vitro (bench) tests** has been performed to compare the subject and predicate 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.

- **Human factors evaluation** was conducted. A comparison of the critical tasks of the subject device and the predicate device was performed. The critical tasks are the same and there are no critical tasks introduced and no existing critical tasks have been impacted. Therefore, human factors data are not needed to demonstrate substantial equivalence.

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 polyester mesh (K220586).