May 21, 2026

Sofradim Production
Ng Wing
Sr Regulatory Affairs Dir
116, avenue du Formans
01600 Trévoux, France

Re: K253956
Trade/Device Name: ProGrip™ advanced self-gripping polypropylene mesh (ADG1510, ADG2015, ADG3020, ADG4030)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: April 22, 2026
Received: April 22, 2026

Dear Ng Wing:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K253956

Device Name
ProGrip™ advanced self-gripping polypropylene mesh (ADG1510, ADG2015, ADG3020, ADG4030)

Indications for Use *(Describe)*
ProGrip™ advanced self-gripping polypropylene mesh is intended for use in reinforcement of abdominal wall soft tissues where weakness exists. It is indicated for use in the extraperitoneal space during ventral hernia repair procedures, utilizing either conventional laparoscopic or robotic-assisted surgical techniques.

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 (K253956)

| | |
|---|---|
| **Date Prepared:** | May 20, 2026 |
| **Submitter:** | Sofradim Production (subsidiary of Covidien llc)<br>116, avenue du Formans<br>01600 Trevoux, France<br>Telephone: +33 (0)4 74 08 90 00<br>Fax: +33 (0) 4 74 08 90 02 |
| **Contact:** | Anne Bertron<br>Regulatory Affairs Principal Specialist<br>116, avenue du Formans<br>01600 Trevoux, France<br>Phone: +33 (0)4 74 08 90 00<br>Email: anne.bertron@medtronic.com |
| **Name of device:** | |
| *Trade/Proprietary name:* | ProGrip™ advanced self-gripping polypropylene mesh |
| *Common name:* | Surgical Mesh |
| *Classification name:* | Mesh, Surgical, Polymeric<br>Product code: FTL<br>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<br>Product code: FTL<br>Regulation number: 21 CFR 878.3300 |
| *510(k) Number:* | K243315 |
| *Manufacturer:* | Sofradim Production (subsidiary of Covidien llc)<br>116, avenue du Formans<br>01600 Trevoux, France |
| **Reference Device 1:** | |
| *Trade/Proprietary name:* | Progrip™ Laparoscopic Self-Fixating Mesh |
| *Common name:* | Surgical Mesh |
| *Classification name:* | Mesh, Surgical, Polymeric<br>Product code: FTL<br>Regulation number: 21 CFR 878.3300 |
| *510(k) Number:* | K143386 |
| *Manufacturer:* | Sofradim Production (subsidiary of Covidien llc)<br>116, avenue du Formans<br>01600 Trevoux, France |

**Reference Device 2:**

| | |
|---|---|
| *Trade/Proprietary name:* | Progrip™ self-gripping polyester mesh |
| *Common name:* | Surgical Mesh |
| *Classification name:* | Mesh, Surgical, Polymeric<br>Product code: FTL<br>Regulation number: 21 CFR 878.3300 |
| *510(k) Number:* | K220586 |
| *Manufacturer:* | Sofradim Production (subsidiary of Covidien llc)<br>116, avenue du Formans<br>01600 Trevoux, France |

**Device Description:**

ProGrip™ advanced self-gripping polypropylene mesh (ADG1510, ADG2015, ADG3020, ADG4030) is designed for use in the extraperitoneal space during ventral hernia repair procedures, utilizing either conventional laparoscopic or robotic-assisted surgical techniques. The mesh is a sterile non-pyrogenic device made of a non-absorbable, bi-dimensional, monofilament polypropylene textile with monofilament polylactic acid, resorbable grips on one side and an absorbable, continuous, collagen-based film on the other side. This film is made of collagen from porcine origin and glycerol and is identical to that present in Reference Device 1. A colored yarn (D&C Blue No.6) marker, identical to that present in Reference Device 2, is present on the center of the mesh.

ProGrip™ advanced self-gripping polypropylene mesh is available in rectangular shape with rounded corners and in different sizes.

The monofilament polylactic acid grips facilitate positioning of the mesh, and they contribute to fixation of the mesh to the surrounding tissue for at least 8 weeks. The polylactic acid grips are bioresorbable. Over 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 between 36- and 50- months post-implantation. However, the resorption period depends on numerous factors including patient-related factors.

The colored yarn (D&C Blue No.6) marker present on the center of the textile helps for centering and orientation of the mesh. The absorbable collagen-based film facilitates mesh handling and deployment and is essentially degraded in 2 weeks. However, the resorption period depends on numerous factors including patient-related factors.

**Intended Use:**

ProGrip™ advanced self-gripping polypropylene mesh is intended for use in reinforcement of abdominal wall soft tissues where weakness exists.

**Indications for use:**

ProGrip™ advanced self-gripping polypropylene mesh is intended for use in reinforcement of abdominal wall soft tissues where weakness exists. It is indicated for use in the extraperitoneal space during ventral hernia repair procedures, utilizing either conventional laparoscopic or robotic-assisted surgical techniques.

**Summary comparing the technological characteristics of the subject and predicate device:**

The subject device ProGrip™ advanced self-gripping polypropylene mesh is substantially equivalent to the predicate device Progrip™ self-gripping polypropylene mesh (K243315).

| | ProGrip™ advanced self-gripping polypropylene mesh (K253956)<br>**Subject device** | ProGrip™ self-gripping polypropylene mesh (K243315)<br>**Predicate device** | Comparison assessment |
|---|---|---|---|
| **Intended Use** | Reinforcement of soft tissues where a weakness exists | Reinforcement of soft tissues where a weakness exists | **Same** |
| **Indications for use** | It is indicated for use in the extraperitoneal space during ventral hernia repair procedures, utilizing either conventional laparoscopic or robotic-assisted surgical techniques. | The ProGrip™ self-gripping polypropylene mesh rectangular and square shapes are indicated for inguinal and ventral hernia repair. | **Similar** |
| **Method of Insertion** | Conventional laparoscopic or robotic-assisted surgical techniques | Open or robotic-assisted surgical techniques | **Different** |
| **Location of Mesh placement** | Extraperitoneal | Extraperitoneal | **Same** |
| **Grips Feature** | Yes | Yes | **Same** |
| **Collagen Film** | Yes | No | **Different** |
| **Materials** | Non-absorbable Textile: polypropylene (PP)<br>Absorbable grips: Polylactic Acid (PLA) | Non-absorbable Textile: polypropylene (PP)<br>Absorbable grips: Polylactic Acid (PLA) | **Same** |
| | Colored marking: polyester yarn marker dyed with D&C blue no. 6. | / | **Different** |
| | Absorbable film: collagen from porcine origin and glycerol | / | **Different** |
| **Shape** | Flat Sheet<br>Rectangular with rounded corner | Flat Sheet<br>Rectangular | **Same** |
| **Sizes** | 15 x 10 cm<br>20 x 15 cm<br>30 x 20 cm<br>40 x 30 cm<br><br>The mesh may be recut as needed | 15x09cm<br>15x15cm<br>20x15cm<br>30x20 cm<br>30x30cm<br>40x30cm<br><br>The mesh may be recut as needed | **Same** |
| **Texture** | Two-dimensional monofilament textile with monofilament absorbable grips on one side and an absorbable collagen-based film on the other side.<br><br>Pore size (mm): 1.7 ± 0.1 x 1.7 ± 0.1 | Two-dimensional monofilament textile with monofilament absorbable grips on one side of the mesh<br><br>Pore size (mm): 1.6 ± 0.1 x 0.6 ± 0.0 | **Different** |
| **Sterilization** | Ethylene Oxide | Ethylene Oxide | **Same** |
| **Packaging** | Polypropylene tray, Tyvek® envelope, Foil pouch, dessiccant<br>(single sterile barrier system) | Sealed Tyvek® pouches//polyester/polyethylene<br><br>(double sterile barrier system) | **Different** |

The main differences between the proposed and predicate devices consist in (1) the presence of the collagen film to facilitate mesh handling and deployment, (2) the addition of a yarn marker, (3) a difference in mesh pore size and (4) a packaging design change. Any differences in the technological characteristics were tested and the results demonstrate that there are no new questions of safety and effectiveness.

**Materials:** ProGrip™ advanced self-gripping polypropylene mesh has been evaluated and found compliant with ISO Standard 10993-1.

**Performance data:** The performance of ProGrip™ advanced self-gripping polypropylene mesh has been evaluated through bench tests and *in vivo* studies. These studies demonstrate that the subject device and predicate device Progrip™ self-gripping polypropylene mesh (K243315) have substantially equivalent performance characteristics. The following performance data is provided:

- Bench tests have been performed in accordance with the FDA Guidance *"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 device ProGrip™ advanced self-gripping polypropylene mesh in comparison with the predicate Progrip™ self-gripping polypropylene mesh (K243315). Results demonstrate that physical and mechanical performance of the subject are substantially equivalent to the predicate.

- In vitro (bench) tests were performed to assess the mesh compatibility with trocar insertion using visual inspection method.
- Gripping performances were assessed in two models: ex-vivo testing and animal testing. The peel strengths were found equivalent between subject and predicate devices in these two models.
- *In vivo* testing was performed in comparison with predicate Progrip™ self-gripping polypropylene mesh (K243315) to evaluate:
    - The strength at the mesh-tissue interface at 2 and 8 weeks after implantation.
    - The impact of the mesh including collagen-based film and PLA grips on the quality of the mesh tissue integration and ingrowth at 2 and 8 weeks after implantation.
    - The mesh collagen-based film degradation at 2 and 8 weeks after implantation.

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

- Biocompatibility evaluation was performed and confirmed that ProGrip™ advanced self-gripping polypropylene mesh is compliant with ISO Standard 10993-1 for its intended patient contact profile.

- Usability tests were conducted 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 Instructions for Use was also checked to verify whether it is clear and understandable.

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

**Conclusion:**
All testing demonstrates that the subject device ProGrip™ advanced self-gripping polypropylene mesh is substantially equivalent to the predicate device, Progrip™ self-gripping polypropylene mesh (K243315).