9/22/2022

Covidien
Jonas Gulmez
Senior Regulatory Affairs Specialist
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K220540
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: August 9, 2022
Received: August 11, 2022

Dear Jonas Gulmez:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Deborah Fellhauer RN, BSN
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220540

Device Name
Progrip™ Self-Gripping Polypropylene Mesh

Indications for Use *(Describe)*
Inguinal hernia repair via anterior tension-free 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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September 13, 2022

Submitter Information:
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(Cube:1-1-71)
Establishment Registration Number: 1282497

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Identification of Device:
Proprietary/Trade Name: ProGrip™ Self-Gripping Polypropylene Mesh
Regulatory Class: Class II
Classification Name: Mesh, Surgical, Polymeric
Regulations Number: 878.3300
Product Code: FTL
Review Panel: General and Plastic Surgery

Predicate Device:
Proprietary/Trade Name: ProGrip™ Self-Gripping Polypropylene Mesh
510(k) Number: K140941 (May 7, 2014)
Regulatory Class: Class II
Classification Name: Mesh, Surgical, Polymeric
Regulation Number: 878.3300
Product Code: FTL
Review Panel: General and Plastic Surgery

Device Description

Following device description of the proposed ProGrip™ self-gripping polypropylene mesh is identical to the predicate ProGrip™ Self-gripping Polypropylene Mesh (K140941). There is no design change included in this submission.

The proposed ProGrip™ self-gripping polypropylene mesh is available in 2 forms;
- Pre-cut, elliptic mesh with slit and self-gripping, overlapping flap. Right or left anatomical side.
- Rectangular mesh.

The mesh and the overlapping flaps of the pre-cut versions are made of knitted monofilament polypropylene with polylactic acid monofilament resorbable hooks on one of the sides. These hooks facilitate placing, positioning and temporary fixation of the overlapping flap and the mesh to the surrounding tissue. A colored yarn marker is placed on the medial edge of the pre-cut mesh to help with orientation.

The subject modified ProGrip™ self-gripping polypropylene mesh is different from the predicate ProGrip™ self-gripping polypropylene mesh (K140941) in labeling and new sterilizer facilities with the same ethylene oxide method. There is no change to the technology, engineering, or material specifications.

Indications for Use

Indications for use statement in the subject ProGrip™ self-gripping polypropylene mesh IFU was updated to align with the global IFU as shown below. Section 17 – Labeling in this submission contains further details and assessment for the indications for use and the other labeling changes.

Previous Indications for Use:

"Inguinal and Incisional hernia repair."

Proposed Indications for Use:

"Inguinal hernia repair via anterior tension-free approach."

Summary of Technological Characteristics

The subject device ProGrip™ Self-Gripping Polypropylene Mesh is substantially equivalent to the predicate device ProGrip™ Self-Gripping Polypropylene Mesh(K140941) in terms of:

- **Indications**: There are some insignificant changes made in the indications for use section to limit use that do not significantly affect safety and effectiveness of the device. Refer to Section 17 Labeling in this submission for further analysis.
- **Raw Materials**
- **Design**
- **Performance characteristics**
- **Biocompatibility**
- **Stability**
- **Sterility**: Two new sterilization facility were added with the same sterilization method (EO) with no change to the sterility assurance level (SAL) Section 15 – Sterilization and Stability section contains further assessment of this change.

Substantial Equivalence – Non-Clinical Evidence:

The following testing has been performed for the new sterilizer sites to demonstrate substantial equivalence to the predicate device.

Sterilization Validation

Validation studies demonstrated that the sterilization processes at new sterilization sites are capable of reliably and consistently sterilizing the ProGrip™ self-gripping polypropylene mesh product. The new sterilizers use the same sterilization method and achieve the same sterility assurance level as compared to the predicate device K140941. Therefore, sterilization process of the proposed ProGrip™ Self-Gripping Polypropylene Mesh is equivalent to the predicate ProGrip™ Self-Gripping Polypropylene Mesh (K140941). Section 15 Sterilization and Stability section contains further assessment for this change.

Aeration Validation

In order to improve Ethylene Oxide emissions, the new sterilizers use a dynamic aeration process rather than a static aeration process implemented at the current sterilizer. EtO residual evaluation is conducted in accordance with ISO 10993-7 – Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals. ProGrip™ Self-Gripping Polypropylene Mesh complies with the allowable limits of EtO residual: ≤ 4mg/device. As predicate ProGrip™ Self-Gripping Polypropylene Mesh, K140941. Section 15 Sterilization and Stability section contains further assessment for this change.

Biocompatibility

Consequently, the current biocompatibility assessments of the devices remain applicable as there is no material or manufacturing change for the Progrip™ Self-Gripping Polypropylene Mesh. EtO residual evaluation is conducted in accordance with ISO 10993-7 – Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals. ProGrip™ Self-Gripping Polypropylene Mesh complies with the allowable limits of EtO residual: ≤ 4mg/device The biological safety evaluation of the impacted devices has been found compliant with the biological safety requirements of ISO 10993-1. Therefore, introducing the new sterilization facilities has no biocompatibility impact for the Progrip™ Self-Gripping Polypropylene Mesh.

Stability

There are no changes to the design or materials of the device as a result of this 510(k) premarket notification. The minor differences in sterilization parameters have been shown to have no impact on the stability of the device. Progrip™ Self-Gripping Polypropylene Mesh packaging sealing, and over all packaging integrity remain as is. Please see Section 15 for further assessment for stability.

Product Performance

There are no changes to the design or materials of the device as described in this submission. Product performance remains unchanged. The new sterilizers will maintain the same sterilization, method, and sterility assurance level. The minor differences in sterilization parameters will not impact device performance. Please see Section 15 for further assessment for product performance.

Substantial Equivalence –Clinical Evidence:

Clinical evidence was not necessary to show substantial equivalence.

Conclusion:

The information provided in this 510(k) demonstrates that the proposed ProGrip™ Self-Gripping Polypropylene Mesh is substantially equivalent to its predicate ProGrip™ Self-Gripping Polypropylene Mesh, K140941 for new sterilizers and labeling change.