June 22, 2022

Sofradim Production
℅ Wing Ng
Regulatory Affairs Director
Covidien LLC.
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K220586
Trade/Device Name: Symbotex Composite Mesh, ProGrip Self-Gripping Polyester Mesh, Parietex Hydrophilic 2D 3D Anatomical Mesh, Versatex Monofilament Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: May 5, 2022
Received: May 23, 2022

Dear Wing Ng:

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,

for 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)*
K220586

Device Name
Symbotex™ Composite Mesh

Indications for Use *(Describe)*
Symbotex™ Composite Mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving primary abdominal wall and incisional hernia surgeries.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
K220586

Device Name
ProGrip™ Self-Gripping Polyester Mesh

Indications for Use *(Describe)*
ProGrip™ Self-Gripping Polyester Mesh is intended for the reinforcement of abdominal wall soft tissues where a weakness exists in procedure involving inguinal and incisional hernias 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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 08/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220586

Device Name
Parietex™ Hydrophilic 2D 3D Anatomical Mesh

Indications for Use *(Describe)*
Parietex™ hydrophilic 2-dimensional mesh, Parietex™ hydrophilic 3-dimensional mesh and Parietex™ hydrophilic anatomical mesh are intended for reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving inguinal and incisional hernia repairs.

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)

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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)*
K220586

Device Name
Versatex™ Monofilament Mesh

Indications for Use *(Describe)*
Versatex™ Monofilament Mesh is intended for reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving abdominal wall hernia repairs.

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)

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510(k) Summary

Date Prepared:	June 22, 2022
Submitter:	Sofradim Production (subsidiary of Covidien llc) 116, avenue du Formans 01600 Trevoux, France Telephone: +33 (0)4 74 08 90 00 Fax: +33 (0) 4 74 08 90 02
Contact:	Paula Paz Regulatory Operations Specialist 116, avenue du Formans 01600 Trevoux, France Phone: +33 (0)4 74 08 90 00 Email: paula.paz@medtronic.com
Name of device:	Symbotex™ Composite Mesh ProGrip™ Self-Gripping Polyester Mesh Parietex™ Hydrophilic 2D 3D Anatomical Mesh Versatex™ Monofilament Mesh
Trade/Proprietary name:	Surgical Mesh
Common name:	Mesh, Surgical, Absorbable, Abdominal Hernia
Classification name:	Panel number and product code: 79 FTL Regulation number: 21 CFR 878.3300
Predicate Device:	
Trade/Proprietary name:	Symbotex™ Composite Mesh ProGrip™ Self-Gripping Polyester Mesh Parietex™ Hydrophilic 2D 3D Anatomical Mesh Versatex™ Monofilament Mesh
Common name:	Surgical Mesh
Classification name:	Mesh, Surgical, Absorbable, Abdominal Hernia Panel number and product code: 79 FTL Regulation number: 21 CFR 878.3300
510(k) Number:	Symbotex™ Composite Mesh: K142908 ProGrip™ Self-Gripping Polyester Mesh: K142900 Parietex™ Hydrophilic 2D 3D Anatomical Mesh: K173796 Versatex™ Monofilament Mesh: K150091
Manufacturer:	Sofradim Production (subsidiary of Covidien llc) 116, avenue du Formans 01600 Trevoux, France

Reason for 510(k) Submission:

The purpose of this 510(k) is to notify the Agency of the update of Instructions for Use for the predicate devices Symbotex™ Composite Mesh (K142908), ProGrip™ Self-Gripping Polyester Mesh (K142900), Parietex™ Hydrophilic 2D 3D Anatomical Mesh (K173796) and Versatex™ Monofilament Mesh (K150091). These changes are made to comply with the requirements of the new European Regulation (EU) 2017/745, and, as part of continuous improvement, for improved readability and clarity and alignment with the state-of-the-art for surgical mesh implants.

Device Description

The purpose of this Special 510(k) is to notify the Agency the changes made on Instructions for Use. There is no change performed on the devices itself, and the device description is identical to those provided for predicate devices Symbotex™ Composite Mesh (K142908), ProGrip™ Self-Gripping Polyester Mesh (K142900), Parietex™ Hydrophilic 2D 3D Anatomical Mesh (K173796) and Versatex™ Monofilament Mesh (K150091).

<u>Symbotex™ Composite Mesh</u>

Symbotex™ Composite Mesh is made out of a three-dimensional monofilament polyester textile which is covered with an absorbable, continuous and hydrophilic film on one of its sides. This film is made up of collagen from porcine origin and glycerol. The collagen film is essentially degraded in less than 1 month.

For “Flat sheet” (SYM reorder codes): A dyed monofilament polyester (D&C Green No. 6)
marking is positioned on the center of the textile, on the opposite side of the film, and helps
center and orient the mesh.

For “Flat Sheet with sutures” (SYM-F reorder codes): Non-absorbable pre-placed sutures are
tied to the three-dimensional mesh. A dyed monofilament polyester (D&C Green No. 6) marking
is positioned on the center of the textile, on the opposite side of the film, and helps center and
orient the mesh.

For “With flap” (SYM-OS reorder codes): A dyed (D&C Green No. 6) bi-dimensional
monofilament polyester textile flap is attached to the three-dimensional reinforcement and helps
place and fix the mesh.

ProGrip™ self-gripping polyester mesh

The mesh and the overlapping flaps of the pre-cut versions are made of knitted monofilament polyester and have polylactic acid monofilament resorbable pins on one of the sides. These pins facilitate placing, positioning and fixation of the overlapping flap and the mesh to the surrounding tissue. A colored yarn marker on the medial edge of the pre-cut mesh helps orientation.

The monofilament polylactic acid pins are bioresorbable and contribute to the fixation of the mesh to surrounding tissue during at least 8 weeks. The polylactic acid pins degrade and resorb in vivo by hydrolysis and are metabolized by the body into CO_2 and H_2O.

Parietex™ Hydrophilic 2D 3D Anatomical Mesh

Two or three-dimensional multifilament polyester wall reinforcements.

The two-dimensional mesh, with rectangular pores, is available in two different textures: a standard version (TEC references) and a rigid version (TECR references). The textures and transparencies of this mesh make them particularly suitable for the treatment of parietal affections, in particular inguinal hernias, through laparoscopic approach.

The three-dimensional mesh (TET references) has hexagonal pores. The flexibility, porosity and low density of this mesh make it particularly suitable for the treatment of parietal affections, in particular incisional and inguinal hernias, through open approach.

The Parietex™ hydrophilic 2-dimensional mesh, hydrophilic 3-dimensional mesh and hydrophilic anatomical mesh has been adapted for various techniques of abdominal repair. The rectangular mesh is designed for the repair of inguinal and incisional hernias in a pre-peritoneal or pre-muscular approach. The pre-cut and slit mesh is suitable for the repair of inguinal hernias via anterior approach using the tension free technique. The folding mesh (in two-dimensional textile) is designed for the repair of direct or indirect inguinal hernias through a laparoscopic approach (trans-abdominal or pre-peritoneal or totally extra-peritoneal). Some codes have a slit for the passage of the cord.

The anatomical mesh is mainly designed for the repair of inguinal hernias via laparoscopic or posterior open procedures and is available for the left and/or right side.

	Versatex™ Monofilament Mesh Versatex™ Monofilament Mesh is made of macroporous three-dimensional monofilament polyester textile. Largest sizesinclude a green dyed monofilament polyester (D&C Green No. 6) marking that is positioned in the center of the textile to help center and orient the mesh.
Intended Use	Symbotex™ Composite Mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists. ProGrip™ Self-Gripping Polyester Mesh is intended for use in reinforcement of abdominal wall soft tissues where a weakness exists. Parietex™ Hydrophilic 2D 3D Anatomical Mesh is intended for reinforcement of abdominal wall soft tissue where a weakness exists. Versatex™ Monofilament Mesh is intended for reinforcement of abdominal wall soft tissue where a weakness exists.
Indications for use	Symbotex™ Composite Mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving primary abdominal wall and incisional hernia surgeries. ProGrip™ Self-Gripping Polyester Mesh is intended for use in reinforcement of abdominal wall soft tissues where a weakness exists in procedure involving inguinal and incisional hernias repair. Parietex™ Hydrophilic 2D 3D Anatomical Mesh is intended for reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving inguinal and incisional hernia repairs. Versatex™ Monofilament Mesh is intended for reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving abdominal wall hernia repairs.
Summary comparing the technological characteristics of the	In order to claim compliance with new European Medical Device Regulation 2017/745 (MDR), and, as part of continuous improvement, for improved readability and clarity and alignment

subject and predicate device:

with the state-of-the-art for surgical mesh implants, modifications of the predicate devices Symbotex™ Composite Mesh (K142908), ProGrip™ Self-Gripping Polyester Mesh (K142900), Parietex™ Hydrophilic 2D 3D Anatomical Mesh (K173796) and Versatex™ Monofilament Mesh (K150091). were made. These modifications have no impact on the substantially equivalence between the subject devices and the predicate devices in terms of indications and design for the following technological characteristics:

- Indications
- Labelling (labels)
- Design
- Raw materials
- Packaging
- Biocompatibility
- Stability
- Sterilization

Performance data:

The purpose of this Special 510(k) is to notify the Agency of the update of Instructions of Use for the currently marketed devices Symbotex™ Composite Mesh (K131969 and K142908), ProGrip™ Self-Gripping Polyester Mesh (K081050 and K142900), Parietex™ Hydrophilic 2D 3D Anatomical Mesh (K982532 and K173796) and Versatex™ Monofilament Mesh (K150091). These changes are made to comply with the requirements of the new European Regulation (EU) 2017/745 and as part of continuous improvement initiatives and IFUs portfolio homogenization. The changes made to the Instructions for Use are summarized below:

- Indications for use are reworded for Versatex™ Monofilament Mesh: minor wording changes and indication narrowed down as part of continuous improvement initiatives and IFUs portfolio homogenization. The indications of Symbotex™ Composite Mesh, ProGrip™ Self-Gripping Polyester Mesh and Parietex™ Hydrophilic 2D 3D Anatomical Mesh were not modified.
- For the four products, contraindications were reworded as part of continuous improvement initiatives and IFUs portfolio homogenization. They do not lead to new underlying risks.
- For the four products, possible complications were added or deleted as part of continuous improvement initiatives

and IFUs portfolio homogenization. They do not lead to new underlying risks.

- For the four products, additional information on trocar compatibility and fixation means compatibility were added as requested by the European Medical Devices Regulation (Regulation (EU) 2017/745).
- For the four products, minor wording improvements have been performed in the storage section.
- For the four products, a “Follow up” and “Magnetic Resonance Imaging (MRI) compatibility” section was added as requested by the European Medical Devices Regulation (Regulation (EU) 2017/745).

A Patient Implant Card (PIC) which is a small portable card is supplied with each permanent implantable product.

The following performance data is provided in support of the substantial equivalence determination:
In vitro (bench) tests have been performed to evaluate the trocar compatibility of the subject devices. The results demonstrate that the subject devices successfully met the established acceptance criteria.

The update of labeling for the currently marketed devices does not affect the safety and effectiveness of the products.

Conclusion:

The subject devices are substantially equivalent to the predicate devices Symbotex™ Composite Mesh (K142908), ProGrip™ Self-Gripping Polyester Mesh (K142900), Parietex™ Hydrophilic 2D 3D Anatomical Mesh (K173796) and Versatex™ Monofilament Mesh (K150091).