April 23, 2025

Sofradim Production
% Nancy Sauer
Official Correspondent
Covidien llc
200 Medtronic Dr
Lafayette, Colorado 80026

Re: K250869
Trade/Device Name: Parietene™ Macroporous Mesh (PPM5050)
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: March 13, 2025
Received: March 24, 2025

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

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)*
K250869

Device Name
Parietene™ Macroporous Mesh (PPM5050)

Indications for Use *(Describe)*
Parietene™ macroporous mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving abdominal wall 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)

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 -K250869

Date Prepared:	April 18, 2025
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:	Nancy Sauer Regulatory Affairs Senior Director 200 Medtronic Dr. Lafayette, CO 80026 Phone: 720-361-5290 Email: nancy.k.sauer@medtronic.com
Name of device:	Parietene™ macroporous Mesh
Trade/Proprietary name:	Surgical Mesh
Common name:	Mesh, Surgical, Polymeric
Classification name:	Panel number and product code: 79 FTL Regulation number: 21 CFR 878.3300
Predicate Device:	Parietene™ macroporous Mesh
Trade/Proprietary name:	Surgical Mesh
Common name:	Mesh, Surgical, Polymeric
Classification name:	Panel number and product code: 79 FTL Regulation number: 21 CFR 878.3300
510(k) Number:	K142091, K223218
Manufacturer:	Sofradim Production (subsidiary of Covidien llc) 116, avenue du Formans 01600 Trevoux, France
Reference Device:	PROLENE® Soft Polypropylene Mesh
Trade/Proprietary name:	Surgical Mesh
Common name:	Mesh, Surgical, Polymeric
Classification name:	Panel number and product code: 79 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
Reason for 510(k) Submission:	To obtain market clearance for the new size (50cm x 50cm) of Parietene™ macroporous Mesh

Device Description:

Parietene™ macroporous mesh is designed for extraperitoneal mesh placement only, for the repair of abdominal wall hernias by laparoscopic or open approach.

Parietene™ macroporous mesh is a non-absorbable synthetic surgical mesh made of two-dimensional (2D) monofilament polypropylene knitted textile.

Parietene™ macroporous mesh is offered in square flat sheet version (50cm x 50cm).

The non-absorbable textile is designed to ensure long term reinforcement of soft tissues. The macroporous textile provides strength required to withstand biomechanical stresses throughout the healing period, while allowing for tissue ingrowth. As the textile integrates, host tissue ingrowth is intended to provide strength to the repair.

The detailed composition listed below refers to the estimated maximum amount of each material and substance to which a patient can be exposed when 1 unit of the largest size of Parietene™ macroporous mesh is implanted (i.e. PPM5050). This amount could be less if the mesh is trimmed by the practitioner prior to implantation.

Mesh composition: monofilament polypropylene yarn (up to 11.5 g)

Intended Use:

Parietene™ macroporous mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists.

Indications for use:

Parietene™ macroporous mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists, in procedures involving abdominal wall hernias repair.

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

The modified device Parietene™ macroporous Mesh is substantially equivalent to the predicate device Parietene™ macroporous Mesh (K142091, K223218) in terms of indications and design for the following technological characteristics:

- The intended use
- Surgical approach
- Shape: both devices present a square shape
- Textile design: monofilament polypropylene knitted textile
- Material – polypropylene
- Mechanical performance

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

- The subject device presents larger mesh sizes compared to the predicate device (50cm x 50cm)

This 510(k) also references the PROLENE® Soft Polypropylene Mesh (K172089) as a reference device. PROLENE® Soft Polypropylene Mesh (K172089) was selected because this legally marketed mesh includes the size 50cm x 50cm.

Performance data:

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

- **Performance testing** - **In vitro (bench) tests** have been performed on modified or predicate device (representative of modified device) and include:
    - the evaluation of the trocar compatibility of Parietene™ macroporous Mesh size 50 cm x 50 cm. The results demonstrate that the subject device successfully met the established acceptance criteria and is substantially equivalent to the predicate device.
    - Bench performance testing for the Parietene™ macroporous Mesh fabric showed comparable results to i reference device Prolene™ Soft polypropylene mesh, which includes a 50cm X 50cm size Bench performance tests were based on requirements set in the FDA guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions" issued on April 26, 2019 and included bursting strength and deflection, uniaxial tensile maximum force and elongation at maximum force (Warp and Weft) and tear strength (Warp and Weft).
- **Biocompatibility:** biocompatibility evaluation was performed for the modified Parietene™ macroporous 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 modified device meets the criteria for biocompatibility set forth in the FDA guidance and ISO standard.
- **Sterilization:** sterilization process has been validated in means of adoption rationale accordance with ISO 11135 (2014) and AAMI TIR28 (2016) standards.
- **Literature and MAUDE database review:** literature review of reference and predicate devices also supported the conclusion of substantial equivalence. Review of MAUDE database for the reference device showed a low number of mesh failures, also supporting the substantial equivalence.

Conclusion:

Comparison of the subject and predicate device and labeling as well as the results of performance testing demonstrates that the subject device Parietene™ macroporous mesh is substantially equivalent to the predicate device Parietene™ macroporous Mesh (K142091, K223218).