October 24, 2025

Medtronic - Sofradim Production
Paula Paz
Senior Regulatory Affairs Specialist
116 Avenue du Formans
Trévoux, 01600
France

Re: K253125
Trade/Device Name: Parietene™ Flat Sheet Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: September 25, 2025
Received: September 25, 2025

Dear Paula Paz:

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 Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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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)*
K253125

Device Name
Parietene™ Flat Sheet Mesh

Indications for Use *(Describe)*
Parietene™ flat Sheet 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.

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:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

(K253125)

Date Prepared: October 24th, 2025

Submitter: Sofradim Production (subsidiary of Covidien llc)
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Regulatory Affairs Senior Specialist
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Phone: +33 (0)4 74 08 90 00
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Name of device:

Trade/Proprietary name:	Parietene™ Flat Sheet Mesh
Common name:	Surgical Mesh
Classification name:	Mesh, Surgical, Polymeric
	Panel number and product code: 79 FTL
	Regulation number: 21 CFR 878.3300

Predicate Device:	Parietene™ Flat Sheet Mesh
Trade/Proprietary name:	Surgical Mesh
Common name:	Mesh, Surgical, Polymeric
Classification name:	Panel number and product code: 79 FTL
510(k) Number:	Regulation number: 21 CFR 878.3300
Manufacturer:	K140941
	Sofradim Production (subsidiary of Covidien llc) 116, avenue du Formans 01600 Trevoux, France

Reason for Special 510(k) Submission: To update labeling to improve clarity only. All other performance and biocompatibility testing are leveraged from the predicate device.

Device Description: Parietene™ Flat Sheet Mesh is a Monofilament polypropylene mesh.

Intended Use: Parietene™ flat Sheet Mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists.

Indications for use: Parietene™ flat Sheet 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™ flat Sheet Mesh is substantially equivalent to the predicate device Parietene™ flat Sheet Mesh (K140941) in terms of indications and design for the following technological characteristics:

- The intended use
- Surgical approach
- Shape and sizes
- Textile design: monofilament polypropylene knitted textile
- Material – polypropylene
- Mechanical performance

Performance data:

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

- **Performance testing:** A summary of in-vitro (bench) tests that have been performed to evaluate the trocar compatibility of Parietene™ Flat Sheet Mesh. The results demonstrate that the subject device successfully met the established acceptance criteria and is substantially equivalent to the predicate device. As this Special 510(k) submission is intended only to update the labeling for improved clarity, most of the performance and biocompatibility testings are leveraged from its own predicate device.

This premarket submission did not rely on the assessment of clinical performance data to demonstrate 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™ Flat Sheet Mesh is substantially equivalent to the predicate device Parietene™ Flat Sheet Mesh (K140941).