12/02/2022

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

Re: K223218
Trade/Device Name: Parietene™ Macroporous Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: October 13, 2022
Received: October 17, 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,

Deborah A. Fellhauer -S

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)*
K223218

Device Name
Parietene™ Macroporous Mesh

Indications for Use *(Describe)*
Parietene™ macroporous mesh is intended for the repair of hernias or other fascial deficiencies that require the addition of a reinforcing material.

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.

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510(k) Summary

Date Prepared:	November 30, 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:	Jhony Mallet Regulatory Affairs Senior Specialist 116, avenue du Formans 01600 Trevoux, France Phone: +33 (0)4 74 08 90 00 Email: jhony.mallet@medtronic.com

Name of device:

Trade/Proprietary name:	Parietene™ Macroporous Mesh
Common name:	Surgical Mesh
Classification name:	Mesh, Surgical, Polymeric
Panel:	General and Plastic Surgery (79)
Product code:	FTL
Regulation number:	21 CFR 878.3300

Predicate Device:

Trade/Proprietary name:	Parietene™ Macroporous Mesh (K142091)
Common name:	Surgical Mesh
Classification name:	Mesh, Surgical, Polymeric
Panel:	General and Plastic Surgery (79)
Product code:	FTL
Regulation number:	21 CFR 878.3300
510(k) Number:	K142091
Manufacturer:	Sofradim Production (subsidiary of Covidien llc) 116, avenue du Formans 01600 Trevoux, France

Device Description: The Parietene™ Macroporous Mesh is a non-absorbable synthetic surgical mesh made of bi-dimensional monofilament polypropylene textile. The Parietene™ Macroporous mesh is offered in a flat sheet and pre-cut mesh. The pre-cut mesh facilitates the repair of inguinal hernias via the anterior approach using a tension free technique.

	Parietene™ Macroporous Mesh is a single use device, presented sterile and unitary packaged in a single pouch and provided in a commercial box or sleeve with the labels and instructions for use. The device can be packaged in single pack (1 unit per sleeve) or multipack (3 or 6 units per box).
Intended Use:	Parietene™ Macroporous Mesh is intended for the reinforcement of soft tissue where weakness exists during surgical repair.
Indications for use:	Parietene™ Macroporous Mesh is indicated for the repair of hernias or other fascial deficiencies that require the addition of a reinforcing material.
Summary comparing the technological characteristics of the subject and predicate device:	Parietene™ Macroporous Mesh was initially designed to be used via open or laparoscopic approach. In order to provide the user with information related to trocar compatibility during laparoscopic surgeries of the Parietene™ Macroporous Mesh (K142091), modifications of the IFU are proposed. It includes minor changes to the IFU which are implemented since clearance of K142091 but did not exceed the threshold for a new 510(k). These modifications have no impact on the substantially equivalence between the subject device and the predicate device in terms of indications and design for the following technological characteristics: • Indications • Design • Raw materials • Packaging • Biocompatibility • Stability • Sterilization
Performance data:	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 Parietene™ Macroporous Mesh. The results demonstrate that the subject device successfully met the established acceptance criteria and is substantially equivalent to the predicate device. Sterility, shelf-life/stability, biocompatibility end points, and other performance testing data are leveraged from the predicate device since there is no change in the materials and manufacturing processes except in the instructions for use.

Conclusion:	Covidien believes that the subject device is substantially equivalent to the predicate device Parietene™ Macroporous Mesh (K142091).