February 1, 2018

Covidien (Sofradim Production)
℅ Ms. Mary Mellows
Regulatory Affairs Manager
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K172395
Trade/Device Name: Duatene™ Bilayer mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: January 2, 2018
Received: January 3, 2018

Dear Ms. Mellows:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172395

Device Name
Duatene™ Bilayer Mesh

Indications for Use *(Describe)*
Duatene™ Bilayer Mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists. It is indicated for the open repair of groin hernia defects.

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:	August 4, 2017
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:	Jose Marquez Regulatory Affairs Manager Covidien 60 Middletown Avenue North Haven, CT 06473, USA Telephone: (203) 492-7290 Fax: (203) 492-5029 Email: jose.a.marquez@medtronic.com
Name of device:	Duatene™ Bilayer 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:	Prolene™ (Polypropylene) Hernia System
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:	K984220
Manufacturer:	Ethicon
Reference 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
Manufacturer:	Sofradim Production

Reference Device:	Ultrapro™ Hernia System
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:	K071249
Manufacturer:	Ethicon

Reference Device:	Parietene™ Polypropylene Mesh (modified into Parietene™ Flat Sheet 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) Numbers:	K991400, K140941
Manufacturer:	Sofradim Production

Reason for 510(k) Submission:

To obtain market clearance for the Duatene™ Bilayer Mesh.

Device Description:

Duatene™ Bilayer Mesh is designed to be placed in an extraperitoneal site by open approach. Duatene™ Bilayer Mesh is a three-dimensional device made out of polypropylene monofilament textile knitted in one-piece.

The three-dimensional textile is composed of:

- a posterior textile layer which is circular or elliptic in shape (for preperitoneal placement)
- an anterior textile layer which is oblong in shape (for onlay placement)

The two textile layers are designed with differentiated knitting patterns, adapted to the function of each layer. The two layers are linked by crossing threads from both textiles.

The mesh is designed to be placed over the groin region to ensure long term reinforcement of soft tissues.

Intended Use:

Duatene™ Bilayer Mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists.

Indications for use:

Duatene™ Bilayer Mesh is intended for the reinforcement of abdominal wall soft tissue where a weakness exists. It is indicated for the open repair of groin hernia defects.

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

The subject Duatene™ Bilayer Mesh is substantially equivalent to the predicate device Prolene™ (Polypropylene) Hernia System (K984220) in terms of:

- Indications
- Design: bilayer mesh linked with connector and equivalent in regards of shapes and sizes of the reference devices Parietene™ Macroporous Mesh (K142091) and Ultrapro™ Hernia System (K071249)

- Polypropylene textile performance, including in regards of mechanical performance of the reference device Parietene™ Macroporous Mesh (K142091)

Materials: Duatene™ Bilayer Mesh has been evaluated and found compliant with ISO Standard 10993-1.

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

- *In vitro* (bench) tests have been performed in accordance with the *"Guidance for the Preparation of a Premarket Notification Application of a Surgical Mesh"* issued March 2, 1999 to evaluate the performance characteristics of the subject Duatene™ Bilayer Mesh in comparison with the predicate Prolene™ (Polypropylene) Hernia System (K984220).The following mesh characteristics were assessed:
  - Pore size
  - Thickness
  - Surface density
  - Bursting strength
  - Bursting distension
  - Breaking strength
  - Elongation at break
  - Tear strength
  - Suture pull-out strength

  The reference device Parietene™ Macroporous Mesh (K142091) is introduced in this submission to confirm that there are no issues associated with the mechanical differences identified in terms of bursting strength, bursting distension, breaking strength, elongation at break, tear strength and suture pull-out strength between the subject Duatene™ Bilayer Mesh and the predicate Prolene™ (Polypropylene) Hernia System (K984220) (refer to *section 21 Performance Testing - Bench*).

  Connector dimensions and breaking strength were compared between the subject device Duatene™ Bilayer Mesh and the predicate device Prolene™ (Polypropylene) Hernia System (K984220) and found to be substantially equivalent.

- *In vivo* pre-clinical tests on representative animal model were conducted in comparison with the predicate Prolene™ (Polypropylene) Hernia System (K984220) to evaluate the tissue integration. Results demonstrate that no difference was observed between the subject Duatene™ Bilayer Mesh and the predicate Prolene™ (Polypropylene) Hernia System (K984220) in terms of tissue integration.

- Stability study was conducted and the proposed device shelf

life was demonstrated.

- Biocompatibility evaluation was performed and confirmed that Duatene™ Bilayer Mesh and its constitutive components are compliant with ISO Standard 10993-1 for their intended patient contact profile. A chemical and toxicological assessment was performed. The biocompatibility data of the reference device Parietene™ Macroporous Mesh (K142091) has been leveraged for genotoxicity and systemic toxicity. Cytotoxicity, irritation, sensitization, acute systemic toxicity, pyrogen and implantation studies have been performed on the subject device.

- Usability tests were conducted and demonstrate that the subject Duatene™ Bilayer Mesh is safe and effective for the intended users, uses and use environments.

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Conclusion:
All testing demonstrate that the subject Duatene™ Bilayer Mesh is substantially equivalent to the predicate device, Prolene™ (Polypropylene) Hernia System (K984220).