K131969 page 1/3

# 510(k) Summary

**Submitter Information**

| | |
|---|---|
| Name: | Sofradim Production (subsidiary of Covidien LLC) |
| Address: | 116, avenue du formans<br>01600 Trevoux,<br>France |
| Phone number | +33 (0)4 74 08 90 00 |
| Fax number: | +33 (0) 4 74 08 90 02 |
| Establishment Registration: | 9615742 |
| Name of contact person: | Clare Santulli<br>Manager, Regulatory Affairs<br>60 Middletown Avenue<br>North Haven, CT 06473<br>Phone: (203) 492-7635<br>Fax: (203) 492-5029 |

AUG 2 2 2013

| | |
|---|---|
| Date prepared: | August 20th, 2013 |
| **Name of device** | |
| Trade or proprietary name: | Symbotex™ Composite Mesh |
| Common or usual name: | Surgical Mesh |
| Classification name: | Mesh, Surgical, Polymeric |
| **Classification panel:** | General and Plastic Surgery (79) |
| **Regulation:** | 21 CFR 878.3300 |
| **Product Code:** | FTL |
| **Legally marketed devices to which equivalence is claimed:** | PARIETEX™ Composite Mesh (K040998)<br>PARIETEX™ Optimized Composite Mesh (K110663 and K110816)<br>PARIETEX™ Composite Ventral Patch (K120506)<br>PARIETEX™ Monofilament Polyester Mesh (K090858)<br>PARIETEX™ Composite Mono PM Mesh (K081126) |
| **Reason for 510(k) submission:** | To obtain market clearance of the Symbotex™ Composite Mesh(s). |
| **Device description:** | Symbotex™ Composite Mesh is made out of a three-dimensional (3D) 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.<br><br>Symbotex™ Composite Mesh will be proposed in 3 configurations: |

Symbotex™ Composite Mesh flat sheet (SYM): 3D textile mesh(s) of various sizes with a central green (dye D&C Green No6) marking to help surgeons center and orient the mesh.

Symbotex™ Composite Mesh flat sheet with sutures (SYMF): 3D textile mesh(s) of various sizes with a central green (dye D&C Green No6) marking and pre-placed Dermalon® sutures to help surgeons, place and fixate the mesh.

Symbotex™ Composite Mesh with flap (SYMOS): 3D textile mesh(s) of various sizes with a green (dye D&C Green No6) bi-dimensional (2D) monofilament polyester flap providing a dedicated fixation area.

**Intended use of the device:**

The Symbotex™ Composite Mesh is intended for the reinforcement of soft tissue where a weakness exists.

**Indications for use:**

Symbotex™ Composite Mesh is indicated for the reinforcement of soft tissue where a weakness exists such as the repair of the primary abdominal wall and incisional hernias.

The non-absorbable three-dimensional polyester mesh provides long term reinforcement of soft tissues. On the opposite side, the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.

**Summary comparing the technological characteristics of the subject and predicate devices:**

The proposed Symbotex™ Composite Mesh is equivalent to the predicate devices PARIETEX™ Composite Mesh (K040998), PARIETEX™ Optimized Composite Mesh (K110663 and K110816) in terms of design for the following technological characteristics:

- Indications
- 3D polyester textile performance characteristics
- collagen film performance
- assembly strength
- 2D polyester flap performance characteristics

The raw material of the proposed Symbotex™ Composite Mesh is equivalent to the predicate devices:
- PARIETEX™ Composite Ventral Patch (K120506) for the green polyester monofilament (D&C Green n°6) and 2D polyester monofilament textile,
- PARIETEX™ Monofilament Polyester Mesh (K090858) and PARIETEX™ Composite Mono PM Mesh (K081126) for the 3D polyester monofilament textile,
- PARIETEX™ Optimized Composite Mesh (K110663) for the hydrophilic film and Dermalon® suture.

**Performance data:**

Bench testing has been conducted in accordance with FDA's *Guidance for the Preparation of a Premarket Notification Application for Surgical Mesh* issued March 2, 1999 to evaluate the performance characteristics of the proposed Symbotex™ Composite Mesh. The following mesh characteristics were assessed: mesh thickness, pore size, surface density, bursting strength, bursting distension, breaking strength, elongation at break, tear strength, suturing strength, seam strength, suture assembly strength and trocar testing.

An *In-vivo* pre-clinical test on a representative animal model was conducted in comparison with the predicate PARIETEX™ Optimized Composite Mesh (K110663) to demonstrate the minimizing tissue attachment performance.

The results of the bench and preclinical tests demonstrate that the device is substantially equivalent to the predicates PARIETEX™ Composite Mesh (K040998) and PARIETEX™ Optimized Composite Mesh (K110663 and K110816).

Symbotex™ Composite Mesh is comprised of materials that have been evaluated for biocompatibility in accordance with ISO 10993-1 for a permanent implant, a recognized standard by FDA (#2-156).

Symbotex™ Composite Mesh shelf life has been demonstrated by stability testing on materials and components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

Sofradim Production
% Clare Santulli
Regulatory Affairs Manager
Surgical devices, a global business unit of Covidien
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K131969
Trade/Device Name: Symbotex™ Composite Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL, OXJ
Dated: June 26, 2013
Received: June 28, 2013

Dear Ms. Santulli:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jiyoung Dang -S

*on behalf of*
Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications For Use

510(k) Number (if known): K131969

**Device Name: Symbotex™ Composite Mesh**

Indications for Use:

The Symbotex™ Composite Mesh is intended for the reinforcement of soft tissue where a weakness exists such as the repair of the primary abdominal wall and incisional hernias.
The non-absorbable three-dimensional polyester mesh provides long term reinforcement of soft tissues. On the opposite side, the absorbable hydrophilic film minimizes tissue attachment to the mesh in case of direct contact with the viscera.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off
Division of Surgical Devices
510(k) Number: K131969