ASPIDE Médical	PREMARKET NOTIFICATION 510(k) SURGICAL MESH: SURGIMESH®XB - SKIRTED	

510(k) Summary

JUN 26 2012

SURGIMESH®XB - Skirted

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

ASPIDE MEDICAL
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Contact Person: Mr. William Wiecek

Date Prepared: May 4, 2012

Name of Device and Name/Address of Sponsor

SURGIMESH®XB - Skirted

ASPIDE MEDICAL
246 allée Lavoisier
42350 LA TALAUDIERE (FRANCE)

Common or Usual Name

Polymeric Surgical Mesh

Classification Name

Surgical Mesh

Predicate Devices

(1) Apide Medical's SURGIMESH®XB (K072974);
(2) Aspide Medical's SURGIMESH®WN (K061445);
(3) Gore's DUALMESH (K992189); and
(4) Covidien's PARIETEX COMPOSITE OPEN ("PCO") SKIRT Mesh (K110816).

Intended Use / Indications for Use

The SURGIMESH® XB – Skirted mesh is used for the reinforcement of tissues during surgical repair.

The SURGIMESH®XB-Skirted is indicated for the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects. The silicone layer minimizes the tissue attachment to the mesh in the case of direct contact with the viscera.

Technological Characteristics

The SURGIMESH®XB – Skirted surgical mesh is a non-absorbable, synthetic mesh, made of non-knitted, non-woven fibers of polypropylene, one surface of which is coated with silicone. The use of SURGIMESH®XB – Skirted mesh provides reinforcement of soft tissues. On the opposite side, the silicone layer minimizes tissue attachment to the mesh in case of direct contact with the viscera. The SURGIMESH®XB – Skirted mesh is supplied sterile and is available in anatomic forms in order to meet individual surgeons' needs.

More specifically, the SURGIMESH® XB – Skirted mesh is composed of a layer of non-woven, non-knitted material made from polypropylene (i.e., SURGIMESH®XB), a skirted part made from polypropylene (i.e., SURGIMESH®WN) linked with the first layer by sewing a PVDF thread into the two parts with a layer of silicone (equivalent to SURGIMESH® XB product material).

Performance Data

Preclinical testing was conducted. Biocompatibility, product structure, and final product specifications were all tested. In all instances, the SURGIMESH®XB - Skirted functioned as intended and the results observed were as expected. Specifically, the company conducted the following performance testing:

- Biocompatibility testing in accordance with ISO 10993-1 standards were conducted and results demonstrated that the device is biocompatible per these standards;
- Sterilization validation testing in accordance with ISO 10993-7, ISO 11137-1, ISO 14937, and USP 28 and results demonstrated that the device is sterile per these standards;
- Product packaging testing in accordance with ISO 11607 and results demonstrated that the device packaging has the appropriate sealing characteristics;
- The device structure and product characterization testing was performed in accordance with ISO 5084, ISO 3801, ISO 9073-3, ISO 9073-4, ISO 9073-7, ISO 13934-1 and ISO 13938-1 and results demonstrated the SURGIMESH®XB - Skirted specifications are substantially similar to the identified predicate device specifications.

Substantial Equivalence

The SURGIMESH®XB - Skirted is substantially equivalent to: (1) Apide Medical's SURGIMESH®XB (K072974); (2) Aspide Medical's SURGIMESH®WN (K061445); (3) Gore's DUALMESH (K992189); and (4) Covidien's PARIETEX COMPOSITE OPEN ("PCO") SKIRT Mesh (K110816).

The SURGIMESH®XB - Skirted has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the SURGIMESH®XB – Skirted and its

predicate devices raise no new issues of safety or effectiveness. The SURGIMESH®XB - Skirted mesh's mechanical and material characteristics are substantially equivalent to its predicate devices. Thus, the SURGIMESH®XB – Skirted is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUN 26 2012

Aspide Medical
% Mr. John J. Smith
Partner, Hogan Lovells US LLP
555 Thirteenth St, NW
Columbia Square
Washington, District of Columbia 20004-1109

Re: K120025
Trade/Device Name: SURGIMESH®XB-Skirted mesh
Regulation Number: CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL, OXJ
Dated: June 19, 2012
Received: June 19, 2012

Dear Mr. Smith:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Eric D. Keith

for / Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120025

Device Name: SURGIMESH®XB – Skirted mesh

Indications for Use:

The SURGIMESH®XB – Skirted mesh is intended for use in the reinforcement of tissues during surgical repair.

The SURGIMESH®XB-Skirted is indicated for the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects. The silicone layer minimizes the tissue attachment to the mesh in the case of direct contact with the viscera

Prescription Use __X__ (Per 21 C.F.R. 801.109)	AND/OR	Over-The-Counter Use____ (Per 21 C.F.R. 807 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 for MM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120025