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510(k) SUMMARY

Aspide Medical's SURGIMESH®XB

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

AUG 18 2008

ASPIDE MEDICAL
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Contact Person: Mr. William WIECEK

Date Prepared: August 8, 2008

Name of Device and Name/Address of Sponsor

SURGIMESH®XB

ASPIDE MEDICAL
Impasse George SAND
246 Allée LAVOISIER
42350 LA TALAUDIERE (FRANCE)

Common or Usual Name

Polymeric Surgical Mesh

Classification Name

Surgical Mesh
Product Code: FTL
Regulation Number: 21 C.F.R. 878.3300

Predicate Devices

(1) ASPIDE MEDICAL SURGIMESH®WN (K061445)
(2) Sofradim Production's Parietex Composite mesh (K040998)
(3) AMS triangle silicone-coated sling (K002721)
(4) Gore-Tex® DualMesh® PLUS Biomaterial with Holes (K010228)
(5) Davol Inc., Bard® Soft Mesh (K033814)
(6) Davol Inc., Bard Composix® L/P Mesh (K061754)

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Intended Use / Indications for Use

The SURGIMESH®XB is intended to be used for the reinforcement of tissues during surgical repair.

The SURGIMESH®XB is indicated for use in: 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 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 SURGIMESH®XB mesh is supplied sterile and is available in anatomic forms in order to meet the individual patient's surgical needs. The use of SURGIMESH®XB 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.

Performance Data

The SURGIMESH®XB mesh's mechanical and material characteristics are substantially equivalent to its predicate devices. The biocompatibility results show that the material used in the design and manufacture of the device is non-toxic and non-sensitizing to biological tissues when used as intended

Substantial Equivalence

The SURGIMESH®XB is as safe and effective as the (1) the ASPIDE MEDICAL SURGIMESH®WN; (2) the Sofradim Production's Parietex Composite mesh; (3) the AMS triangle silicone-coated sling; (4) the Gore-Tex® DualMesh® PLUS Biomaterial with Holes; (5) the Davol Inc., Bard® Soft Mesh; and (6) the Duvol Inc., Bard® Composix® L/P Mesh. The SURGIMESH®XB has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the SURGIMESH®XB and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the SURGIMESH®XB is as safe and effective as (1) the ASPIDE MEDICAL SURGIMESH®WN; (2) the Sofradim Production's Parietex Composite mesh; (3) the AMS triangle silicone-coated sling; (4) the Gore-Tex® DualMesh® PLUS Biomaterial with Holes; (5) the Davol Inc., Bard® Soft Mesh; and (6) the Davol Inc., Bard® Composix® L/P Mesh. Thus, the SURGIMESH®XB is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aspide Medical
% Hogan & Hartson, LLP
Mr. Howard M. Holstein, Esq.
Columbia Square
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

AUG 18 2008

Re: K072974
Trade/Device Name: SURGIMESH®XB
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: August 8, 2008
Received: August 8, 2008

Dear Mr. Holstein:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K072974

Indications for Use Statement

510(k) Number (if known): K072974

Device Name: SURGIMESH®XB

Indications for Use:

The SURGIMESH®XB 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__	AND/OR	Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D)		(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)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072974