III 510(k) Summary

K061445

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SURGIMESH®WN

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

ASPIDE MEDICAL
Zone Industrielle La Chazotte
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Contact Person: Mr William WIECEK

FEB - 1 2007

Date Prepared: January 23, 2007

Name of Device and Name/Address of Sponsor

SURGIMESH®WN

ASPIDE MEDICAL
Zone Industrielle La Chazotte
Allée Joseph Cugnot
42350 LA TALAUDIERE (FRANCE)

Common or Usual Name

Polymeric Surgical Mesh

Classification Name

Surgical Mesh

Predicate Devices

(1) Tissue Science Laboratories' Permacol synthetic mesh (K992556)
(2) Davol, Inc.'s Bard Mesh (K033814)
(3) Mentor Corp.'s Obtape Mesh (K031767)

Intended Use / Indications for Use

The SURGIMESH®WN implant is recommended for reinforcement of hernia defects. The hernia repair could be, for example, inguinal hernia, femoral or crural hernia or ventral hernia. The SURGIMESH®WN implant is indicated for use via an extraperitoneal approach either by open or laproscopic surgery.

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Technological Characteristics

The SURGIMESH®WN consists of non-absorbable synthetic mesh, made of non-knitted, non-woven fibers of polypropylene. SURGIMESH®WN mesh is supplied sterile and is available in rectangular and anatomic forms in order to meet the individual patient's surgical needs.

Performance Data

Pre-clinical and clinical performance testing was conducted. Tissue integration, biocompatibility, product structure, and final product specifications were all tested, in addition to two clinical studies that were performed. In all instances, the SURGIMESH®WN functioned as intended and the results observed were as expected.

Substantial Equivalence

The SURGIMESH®WN is as safe and effective as: (1) Tissue Science Laboratories' Permacol synthetic mesh (K992556); (2) Davol, Inc.'s Bard Mesh (K033814); and (3) Mentor Corp.'s Obtape Mesh (K031767).

The SURGIMESH®WN 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®WN and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the SURGIMESH®WN is as safe and effective as: (1) Tissue Science Laboratories' Permacol synthetic mesh (K992556); (2) Davol, Inc.'s Bard Mesh (K033814); and (3) Mentor Corp.'s Obtape Mesh (K031767). The SURGIMESH®WN 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. Thus, the SURGIMESH®WN 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
Partner
Columbia Square
555 Thirteenth Street, NW
Washington, District of Columbia 20004-1109

FEB - 1 2007

Re: K061445
Trade/Device Name: SURGIMESH® WN
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: November 30, 2006
Received: November 30, 2006

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.

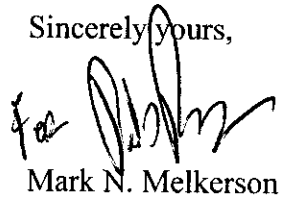
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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.

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 Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

K061445

Indications for Use Statement

510(k) Number (if known): K061445

Device Name: SURGIMESH® WN

Indications for Use:

The SURGIMESH®WN implant is recommended for reinforcement of hernia defects. The hernia repair could be, for example, inguinal hernia, femoral or crural hernia or ventral hernia. The SURGIMESH®WN implant is indicated for use via an extraperitoneal approach either by open or laproscopic surgery.

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 K061445

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