Section 6: 510(k) Summary

MAY 27 2009

510(k) Summary

Applicant:
Xylos Corporation
Joyce Elkins
838 Town Center Drive
Langhorne, PA 19047

US Contact:
Xylos Corporation
Joyce Elkins
838 Town Center Drive
Langhorne, PA 19047
Phone: 215-867-0220 ext. 642
Facsimile: 215-741-4804
joyce.elkins@xyloscorp.com

Manufacturing/ Distribution Address:
Xylos Corporation
838 Town Center Drive
Langhorne, PA 19047

Establishment Registration Number: N/A

Date submitted:
March 30, 2009
(Section 6: 510(k) Summary was revised and re-submitted on May 18, 2009)

Proprietary Name: Xylos® Porous Surgical Mesh

Common Name: Surgical Mesh

Classification Status: Class II

Product Codes: FTM

Predicate Device: Xylos Surgical Mesh (K081882)

Device Description:

Xylos® Porous Surgical Mesh is a sterile, non-resorbable product composed of

solvent-dehydrated, microbial-derived cellulose. The implantable unit is presented in sterile double-pouched packages for appropriate removal in preparation for surgery.

Processing: The microbial derived cellulose undergoes a strict quality controlled procedure that involves thorough cleaning and dehydration. The process leaves no harmful residue. Assurance of sterility is maintained with the validated dose range of gamma irradiation having no adverse effect on the biomechanical property of the device.

Indications for Use:

Xylos® Porous Surgical Mesh is intended for implantation to reinforce soft tissue including, but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, prolapse repair, reconstruction of the pelvic floor, hernias, suture-line reinforcement and reconstructive procedures. Xylos® Porous Surgical Mesh is intended for one-time use.

Summary of Technological Characteristics:

The process modification to the Xylos Surgical Mesh since its previous clearance in K081882 is an additional processing step increasing porosity of the finished product. In addition, the name was changed to Xylos® Porous Surgical Mesh in this submission to distinguish it from Xylos Surgical Mesh. These modifications do not affect the safety or performance of the device and do not change the intended use of the Xylos Surgical Mesh.

Summary of Nonclinical Testing:

The verification and validation tests that were performed confirmed that the Xylos® Porous Surgical Mesh met the acceptance criteria. Therefore the device should perform as intended.

Substantial Equivalence Discussion:

As shown in the verification and validation testing, the additional perforation processing step of the Xylos® Porous Surgical Mesh does not change the intended use nor affect the safety and effectiveness as compared to the Xylos Surgical Mesh previously cleared in K081882.

Conclusion:

The modified Xylos® Porous Surgical Mesh has the following similarities to the Xylos Surgical Mesh previously cleared in K081882:

- has the same indicated use,
- has the same operating principle,
- incorporates the same basic device design and physical properties,
- is manufactured identically except for an additional perforation process prior to packaging, and
- incorporates the same materials.

Therefore the modification to the Xylos® Porous Surgical Mesh can be found substantially equivalent to the Xylos Surgical Mesh cleared in K081882.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2009

Xylos Corporation
% Ms. Joyce Elkins
Director RA/QA
838 Town Center Drive
Langhorne, Pennsylvania 19047

Re: K090880
Trade/Device Name: Xylos® Porous Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: May 11, 2009
Received: May 13, 2009

Dear Ms. Elkins:

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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090880

Section 5: Indications for Use Statement

Indications for Use

510(k) Number (if known): K090880

Device Name: Xylos® Porous Surgical Mesh

Indications for Use: This device is intended for implantation to reinforce soft tissue including, but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, prolapse repair, reconstruction of the pelvic floor, hernias, suture-line reinforcement and reconstructive procedures. The device is intended for one-time use.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 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 MKM

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

510(k) Number K090880

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