Section 6: 510(k) Summary

JUL 11 2008

510(k) Summary

Applicant: Xylos Corporation
Gerry Ann Oster
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Langhorne, PA 19047

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

Establishment Registration Number: N/A

Date submitted: 02JULY2008

Proprietary Name: XYLOS Surgical Mesh

Common Name: Surgical Mesh

Classification Status: Class II

Product Codes: FTM

Predicate Device: **XYLOS Surgical Mesh (K023237)**

Device Description:

The XYLOS Surgical Mesh will function as a non-absorbable surgical biomaterial that enables rapid fixation by tissue incorporation. The device incorporates a microporous structure that ensures early fixation to host tissue with minimal foreign body response. The

double-pouched, sterile, single use unit is designed to allow maintenance of the sterile field prior to implantation. The material is conducive to cutting to size with sterile surgical instruments to avoid excessive tension on the suture line.

Indication 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.

Summary of Technological Characteristics:

The modifications to the XYLOS Surgical Mesh since its previous clearance in K023237 include a change to the processing conditions that has led to slight changes in certain physical properties of the mesh as well as a change to rehydrate the mesh before packaging with a wetting solution. These minor differences 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:

Based on the Risk Analysis, the verification and validation tests that were performed and the acceptance criteria applied for each are listed in Section 10.

Substantial Equivalence Discussion:

The changes to the chemical processing and the slight change in physical properties of the XYLOS Surgical Mesh do not change the intended use nor do they affect the safety and effectiveness as compared to the XYLOS Surgical Mesh previously cleared in K023237.

Conclusion:

The modified XYLOS Surgical Mesh has the following similarities to the XYLOS Surgical Mesh previously cleared in K023237:

- has the same indicated use,
- uses the same operating principle,
- incorporates the same basic device design and physical properties,
- incorporates the same materials.

Therefore the modification to the XYLOS Surgical Mesh can be found substantially equivalent to the XYLOS Surgical Mesh cleared in K023237.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Xylos Corporation
% Ms. Gerry Ann Oster
838 Town Center Drive
Langhorne, Pennsylvania 19047

JUL 11 2008

Re: K081882
Trade/Device Name: XYLOS Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: July 2, 2008
Received: July 3, 2008

Dear Ms. Oster:

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

Section 5: Indications for Use Statement

Indications for Use

510(k) Number (if known): K081882

Device Name: XYLOS 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)

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

510(k) Number K081882

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