AUG 25 2011

Section 5: 510(k) Summary

Sponsor:	Xylos Corporation 838 Town Center Drive Langhorne, PA 19047
Contact:	Dr. Gonzalo Serafica 838 Town Center Drive Langhorne, PA 19047 Phone: 215-867-0220 ext. 612 Facsimile: 215-741-4804 al.serafica@xyloscorp.com
Date submitted:	June 3, 2011
Proprietary Name:	Xylos® Macro-Porous Surgical Mesh
Common Name:	Surgical Mesh
Regulation Classification:	878.3300
Classification Status:	Class II
Product Codes:	FTM
Predicate Device:	Xylos® Securian® Tissue Reinforcement Matrix (K083823) OrthADAPT Bioimplant (K071065), Pegasus Parietex Composite Mesh (K040998), Covidien Mersilene Mesh (Pre-amendment), Ethicon Inc.

Device Description:

Xylos® Macro-Porous Surgical Mesh is a flexible, non-resorbable implant composed of microbial-derived cellulose; there are no animal or human derived components in the device. Xylos® Macro-Porous Surgical Mesh is strong, conformable, biocompatible and includes macro-pores to facilitate tissue in-growth. The device is not subject to degradation or weakening by the action of tissue enzymes.

Indications for Use:

Xylos® Macro-Porous Surgical Mesh is intended to be used for implantation to reinforce and protect soft tissue including but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, hernias, suture-line reinforcement and other reconstructive procedures. This mesh may be used for the repair of hernia and other fascial deficiencies that require the addition of a reinforcing or bridging material to obtain the desired surgical result.

Xylos® Macro-Porous Surgical Mesh is also intended for the reinforcement of soft tissues repaired by sutures or suture anchors during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps or other tendons. Xylos® Macro-Porous Surgical Mesh is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Sutures used to repair the tear, and sutures or bone anchors used to attach the tissue to the bone provide biomechanical strength for the tendon repair.

Xylos® Macro-Porous Surgical Mesh is indicated for open and endoscopic procedures and is intended for one-time use only.

Technological Characteristics:

Xylos® Macro-Porous Surgical Mesh is a thin, conformable, non-resorbable surgical mesh intended for use in soft tissue and tendon repairs. Like its predicate devices, it is intended to be sutured in place and provide reinforcement for healing soft tissue and tendon. It is composed of microbial cellulose, a naturally occurring biopolymer hydrogel and contains no animal or human-derived materials. Xylos® Macro-Porous Surgical Mesh has the identical material composition to five previously cleared surgical devices: Xylos® Surgical Mesh (K081882), Xylos® Securian® Tissue Reinforcement Matrix (K083823), Xylos® Porous Surgical Mesh (K090880), Xylos® MTA® Protective Sheet (K090788) and Xylos® Vessel Guard (K100984). The material has demonstrated its biocompatibility via testing as defined in *ANSI/AAMI/ISO 10993 Biological evaluation of*

medical devices. It is not subject to degradation or weakening by the action of tissue enzymes. Macro-pores are incorporated into the device to facilitate tissue in-growth.

Xylos® Macro-Porous Surgical Mesh may be easily cut into any desired shape or size without fraying or unraveling. It is presented ready-to-use in a sterile double-pouched package.

Xylos® Macro-Porous Surgical Mesh is substantially equivalent in biocompatibility to Xylos® Securian® Tissue Reinforcement Matrix (K083823) because they have the identical material composition.

Performance Testing:

Xylos® Macro-Porous Surgical Mesh was subjected to mechanical performance tests typical for surgical mesh products (tensile strength, burst strength, and suture pull out strength). This testing demonstrated that Xylos® Macro-Porous Surgical Mesh is mechanically equivalent to the predicate devices: Pegasus' OrthADAPT Bioimplant (K071065), Ethicon's Mersilene Mesh (Pre-amendment), and Covidien's Parietex Composite Mesh (K040998). Further, animal study results show that Xylos® Macro-Porous Surgical Mesh possesses sufficient physical strength for the intended use.

Substantial Equivalence:

Xylos® Macro-Porous Surgical Mesh is substantially equivalent to the following previously cleared devices, Xylos® Securian® Tissue Reinforcement Matrix (K083823), Pegasus' OrthADAPT Bioimplant (K071065), Covidien's Parietex Composite Mesh (K040998) and Ethicon's Mersilene Mesh (Pre-amendment). Xylos® Macro-Porous Surgical Mesh has the same intended use and the same or similar indications, technological characteristics, and principles of operations as these predicate devices. Performance data demonstrates that Xylos® Macro-Porous Surgical Mesh is mechanically equivalent to Pegasus' OrthADAPT Bioimplant (K071065), Ethicon's Mersilene Mesh (Pre-amendment), and Covidien's Parietex Composite Mesh (K040998). Xylos® Macro-Porous Surgical Mesh is identical in material composition to Xylos® Securian® Tissue

Reinforcement Matrix (K083823) and therefore, substantially equivalent in regard to biocompatibility. Thus, Xylos® Macro-Porous Surgical Mesh is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G6
Silver Spring, MD 20993-0002

Xylos Corporation
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VP Technology and Intellectual Property
838 Town Center Drive
Langhorne, Pennsylvania 19047

AUG 25 2011

Re: K111584
Trade/Device Name: Xylos® Macro-Porous Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: August 12, 2011
Received: August 15, 2011

Dear Dr. Serafica:

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,

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

Enclosure

Section 4: Indications for Use Statement

510(k) Number: K111584

Device Name: Xylos® Macro-Porous Surgical Mesh

Indications for Use:

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Xylos® Macro-Porous Surgical Mesh is indicated for open and endoscopic procedures and is intended for one-time use only.

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)

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Daniel Kraine for MKM

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

510(k) Number K111584