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Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for Securian™ Tissue Reinforcement Matrix 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of Securian™ Tissue Reinforcement Matrix is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices.

Sponsor:	Xylos Corporation 838 Town Center Drive Langhorne, PA 19047
Contact:	Joyce Elkins 838 Town Center Drive Langhorne, PA 19047 Phone: 215-867-0220 ext. 642 Facsimile: 215-741-4804 joyce.elkins@xyloscorp.com
Date of Submission:	**December 19, 2008**
Proprietary Name:	Securian™ Tissue Reinforcement Matrix
Common Name:	Surgical Mesh
Regulatory Class:	Class II
Product Codes:	FTM
Predicate Device(s):	XYLOS® Surgical Mesh, K081882 / XYLOS Surgical Mesh, K023237 Ortho-Wrap® Bioresorbable Sheet, K072190 (Ortho-Wrap® Trademark of MAST Biosurgery, Inc.) Permacol™, K021056 (Permacol™ Biological Implant Trademark of Tissue Science Laboratories, PLC)

Device Description:

Securian™ Tissue Reinforcement Matrix is a sterile product composed of microbial-derived cellulose. The implantable device is presented in a sterile double-pouched package for

appropriate removal in preparation for surgery. The non-resorbable surgical mesh is used for trauma and reconstructive surgical procedures involving tendons or other soft tissues. Securian™ Tissue Reinforcement Matrix maintains the relative position and stability of soft tissues during the healing period.

Indications for Use:

Securian™ Tissue Reinforcement Matrix is indicated for the management and protection of soft tissue and tendon injuries in which there has been no substantial loss of tendon tissue. Securian™ Tissue Reinforcement Matrix minimizes tissue attachment to the device in case of direct contact with overlying tissues. Securian™ Tissue Reinforcement Matrix is also indicated for reinforcement of soft tissues repaired by sutures or suture anchors during tendon repair surgery including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Securian™ Tissue Reinforcement Matrix 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. Securian™ Tissue Reinforcement Matrix reinforces and protects healing soft tissues. The device is indicated for open and endoscopic procedures. Securian™ Tissue Reinforcement Matrix is intended for one-time use.

Technological Characteristics and Substantial Equivalence:

Securian™ Tissue Reinforcement Matrix is identical to previously cleared K081882 XYLOS Surgical Mesh. Therefore Securian™ Tissue Reinforcement Matrix has the same biocompatibility and performance characteristics to those cited in K081882. For this 510(k) submission, the device name is changed from "XYLOS® Surgical Mesh" K081882 to "Securian™ Tissue Reinforcement Matrix" and the 'Indications for Use' are modified from those cleared in K081882.

The Securian™ Tissue Reinforcement Matrix is substantially equivalent to legally marketed predicate devices and has the same intended uses and the same or similar indications, technological characteristics, and principles of operation as the predicate devices. Performance data demonstrate that Securian™ Tissue Reinforcement Matrix functions

equivalently to the predicate devices. Thus, Securian™ Tissue Reinforcement Matrix is substantially equivalent to the predicate devices.

Discussion of performance testing:

Securian™ Tissue Reinforcement Matrix was subjected to a panel of tests to demonstrate its equivalence to predicate devices. Additional performance testing was performed to support the modified 'Indications for Use' statement.

Securian™ Tissue Reinforcement Matrix met the test requirements, providing reasonable assurance of device performance for its intended use and supporting substantial equivalence.

Conclusion:

Securian™ Tissue Reinforcement Matrix is substantially equivalent to all the predicate devices. The modified 'Indications for Use' in this submission do not pose new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2009

Xylos Corporation
% Ms. Joyce Elkins
Director Regulatory Affairs/Quality
Assurance
838 Town Center Drive
Langhorne, Pennsylvania 19047

Re: K083823
Trade/Device Name: Securian™ Tissue Reinforcement Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTM
Dated: December 30, 2008
Received: January 5, 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.

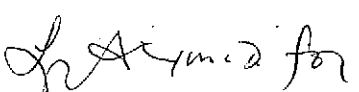
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K083823

Device Name: Securian™ Tissue Reinforcement Matrix

Indications For Use:

The Securian™ Tissue Reinforcement Matrix is indicated for the management and protection of soft tissue and tendon injuries in which there has been no substantial loss of tendon tissue. Securian™ Tissue Reinforcement Matrix minimizes tissue attachment to the device in case of direct contact with overlying tissues. Securian™ Tissue Reinforcement Matrix is also indicated for reinforcement of soft tissues repaired by sutures or suture anchors during tendon repair surgery including reinforcement of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Securian™ Tissue Reinforcement Matrix 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. Securian™ Tissue Reinforcement Matrix reinforces and protects healing soft tissues. The device is indicated for open and endoscopic procedures. Securian™ Tissue Reinforcement Matrix is intended for one-time use.

Prescription Use ___X__ AND/OR Over-The-Counter Use __X_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Daniel Kraus for MXM March 13, 2009

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

510(k) Number K083823