Section 5: 510(k) Summary

The safety and effectiveness of XYLOS™ Vessel Guard 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:	April 6, 2010
Proprietary Name:	XYLOS™ Vessel Guard
Common Name:	Vessel Guard
Regulatory Class:	Class II
Product Codes:	OMR
Predicate Device(s):	MTA™ Protective Sheet, K090778 Replication Medical Vessel Guard, K082782, and the predicates of Replication Medical Vessel Guard: PRECLUDE® Vessel Guard, K062161 PRECLUDE® IMA Sleeve, K960532

Device Description:

XYLOS™ Vessel Guard is a flexible, non-resorbable, implantable sheet composed of microbial-derived cellulose. The device is presented ready-to-use in a sterile double-pouched package. It is intended for one time use.

Indications for Use:

XYLOS™ Vessel Guard is indicated as a cover for vessels during anterior vertebral surgery.

Technological Characteristics and Substantial Equivalence:

XYLOS™ Vessel Guard is substantially equivalent to the previously cleared devices since it is biologically and chemically identical to MTA™ Protective Sheet (K090778), and therefore, has the equivalent biocompatibility properties of the MTA™ Protective Sheet.

Discussion of Performance Testing:

XYLOS™ Vessel Guard was subjected to biomechanical performance tests typical for vessel guard product (tensile strength and suture pull out testing). This testing demonstrated that XYLOS™ Vessel Guard is biomechanically equivalent to the predicate vessel guard device: Replication Medical Vessel Guard (K082782) and its predicates: PRECLUDE® IMA Sleeve, (K960532) and PRECLUDE® Vessel Guard (K061727). XYLOS™ Vessel Guard met the biomechanical performance test requirements, providing reasonable assurance of device performance for its intended use and supporting substantial equivalence.

Conclusion:

XYLOS™ Vessel Guard is substantially equivalent to the previously cleared devices since it is:

1. Biologically and chemically identical to MTA™ Protective Sheet (K090778), and therefore, XYLOS™ Vessel Guard has the equivalent biocompatibility properties of the MTA™ Protective Sheet, and
2. Biomechanically equivalent to Replication Medical Vessel Guard (K082782), as demonstrated via bench performance testing to its predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL - 7 2010

Xylos Corporation
c/o Joyce Elkins
Director, Quality Systems/Regulatory Affairs
838 Town Center Drive
Langhorne, PA 19047

Re: K100984
Trade/Device Name: XYLOS™ Vessel Guard
Regulation Number: 870.3470
Regulation Name: Intracardiac patch or pledget
Regulatory Class: II
Product Code: OMR
Dated: April 06, 2010
Received: April 08, 2010

Dear Ms. Joyce 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for reducing the incidence, severity, and extent of post-operative adhesion formation have not been established.

Furthermore, the indication for use as a cover for vessels following anterior vertebral surgery must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (301) 796-5540. 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 301-796-6075. 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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Christy Foreman

Christy Foreman
Acting Director
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure

Section 4: Indications for Use Statement

510(k) Number: ~~To be assigned~~> K100984

Device Name: XYLOS™ Vessel Guard

Indications for Use:

XYLOS™ Vessel Guard is indicated as a cover for vessels during anterior vertebral surgery.

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)

Page 1 of __1__

Donna R. Vachner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100984