K023237

510(k) Summary

DATE PREPARED:
09SEP2002

MAR 1 8 2003

SUBMITTED BY:
XYLOS Corporation
41 University Drive, Suite 400
Newtown, PA 18940

CONTACT PERSON:
Patsy J. Trisler, J.D., RAC
Senior Director, Medical Device Consulting
PharmaNet, Inc.
815 Connecticut Avenue, NW, Suite 800
Washington, D.C. 20006
202-835-1346 (direct dial)
609-520-8107 (fax)

DEVICE:

Classification Name:	Mesh, Surgical
Common/Usual Name:	Surgical Mesh
Proprietary Name:	XYLOS™ Surgical Mesh

DEVICE CLASSIFICATION:

Product Code/Classification Number:	FTM (878.3300)
Regulatory Class:	II

PREDICATE DEVICES:
Bio-Vascular, Inc. Peri-Guard® Pericardium K983162
Ethicon, Inc. Prolene Polypropylene Mesh, Nonabsorbable K962530
XYLOS™ XCell® Wound Dressing K974251

STATEMENT OF SUBSTANTIAL EQUIVALENCE:
XYLOS™ Surgical Mesh is substantially equivalent to the predicate devices, having similar intended use, technological characteristics, and performance.

INTENDED USE:
XYLOS™ 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. The device is intended for one-time use.

DEVICE DESCRIPTION:
XYLOS™ Surgical Mesh is prepared from microbial derived cellulose that undergoes chemical processing inclusive of solvent dehydration. Units are cut in various sizes to meet surgical needs. Each unit is double-pouched, labeled, and gamma sterilized. The sterilized surgical mesh exhibits excellent tensile strength, suture retention and consistent thickness.

PERFORMANCE DATA:
XYLOS™ Surgical Mesh functions as intended when subjected to safety, biocompatibility, toxicity, pyrogenicity, sterility and mechanical strength testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2003

Xylos Corporation
c/o Ms. Patsy J. Trisler, J.D., RAC
Senior Director, Medical Device Consulting
PharmaNet, Inc.
815 Connecticut Avenue NW, Suite 800
Washington, D.C. 20006

Re: K023237
Trade/Device Name: XYLOS™ Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTM
Dated: February 5, 2003
Received: February 7, 2003

Dear Ms. Trisler:

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 Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use FORM

510(k) Number (if known) K023237

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.**

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-Counter-Use** ____
(Per 21CFR 801.109) Optional Format 1-2-96

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

510(k) Number K023237