K024054

XYLOS™ XCell® Antimicrobial Dressing
510(k) Summary

DATE PREPARED: 13FEB03

MAR 0 7 2003

SUBMITTED BY:

XYLOS Corporation
838 Town Center Drive
Langhorne, PA 19407

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:	Dressing
Common/Usual Name:	Wound Dressing
Proprietary Name:	XYLOS™ XCell® Antimicrobial Wound Dressing

DEVICE CLASSIFICATION:

Product Code/Classification Number:	FRO
Regulatory Class:	Unclassified

PREDICATE DEVICES:

Kendall Kerlix Antimicrobial Gauze K990530 NAD
ConvaTec Aquacel Ag Absorbent Antimicrobial Wound Dressing K013814 FRO
Maersk Medical Arglaes AB Antimicrobial Barrier Film Dressing K990810 MGP
XYLOS™ XCell® Wound Dressing K974251 MGQ
XYLOS™ XCell® Wound Dressing K011379 Exempt NAE

STATEMENT OF SUBSTANTIAL EQUIVALENCE:

XYLOS™ XCell® Antimicrobial Wound Dressing is substantially equivalent to the predicate devices, having similar intended use, technological characteristics, and performance.

INTENDED USE:

Indications (From Labeling): The XCell® Antimicrobial Wound Dressing is intended for use on partial and full-thickness wounds as an effective barrier to resist microbial colonization within the dressing and reduce microbial penetration through the dressing. The XCell® Antimicrobial Wound Dressing is intended to cover a wound or burn on a patient's skin to absorb areas of wound exudates and to provide a moist wound environment that supports the autolytic debridement of areas of the wound that are necrotic. The dressing may be used on minimally exuding, non-exuding and dry wounds as stated in the Instructions-for-use. The wound dressing also protects against abrasion, desiccation, and external contamination. The moist environment has a cooling effect that may reduce pain. Under the supervision of a health care professional, the XCell® Antimicrobial Wound Dressing is intended for the local management of exuding wounds, including infected and non-infected pressure ulcers, venous ulcers, diabetic ulcers, arterial ulcers, donor sites and other bleeding surface wounds, dermal lesions, trauma injuries or incisions, superficial cuts, minor scalds and burns, minor skin irritations, lacerations and abrasions. The device is intended for one-time use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 7 2003

Xylos Corporation
c/o Patsy Trisler
PharmaNet, Inc.
815 Connecticut Avenue, N.W.
Suite 800
Washington, D.C. 20006

Re: K024054
Trade/Device Name: Xylos™ Xcell® Antimicrobial Wound Dressing
Regulation Name: Hydrogel wound dressing with a drug
Regulatory Class: Unclassified
Product Code: MGQ
Dated: December 5, 2002
Received: December 9, 2002

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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) K024054

Device Name: **XYLOS™ XCell® Antimicrobial Wound Dressing**

Indications for Use: The XCell® Antimicrobial Wound Dressing is intended for use on partial and full-thickness wounds as an effective barrier to resist microbial colonization within the dressing and reduce microbial penetration through the dressing. The XCell® Antimicrobial Wound Dressing is intended to cover a wound or burn on a patient's skin to absorb areas of wound exudates and to provide a moist wound environment that supports the autolytic debridement of areas of the wound that are necrotic. The dressing may be used on minimally exuding, non-exuding and dry wounds as stated in the Instructions-for-use. The wound dressing also protects against abrasion, desiccation, and external contamination. The moist environment has a cooling effect that may reduce pain.

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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 X **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 K024054