

JUN 22 1998

K974251

X-Cell™ Wound Dressing : Revised EXHIBIT III-1 : Summary of safety and effectiveness information

EXHIBIT III-1 : X-CELL HYDROGEL WOUND DRESSING

510 (K) SUMMARY

Submitted By :

Eric Flann, Ph.D.

NTL Associates, Inc.

East Brunswick, NJ 08816

(908) 390-5656

May 29, 1998

Device Name : XYLOS : X-CELL WOUND DRESSING

(a) Intended Use

X-Cell™, a hydrogel wound dressing is a device intended to cover a wound or burn on a patient's skin to absorb wound exudate, and protect against abrasion, friction, desiccation, or external contamination. The moist environment has a cooling effect that may reduce pain.

(b) Biocompatibility

The results of the biocompatibility tests show the device to be safe for its intended purpose.

(c) Substantial Equivalence

The X-Cell™ hydrogel wound dressing is substantially equivalent to the NU-GEL hydrogel wound dressing (from Johnson & Johnson) and the Aquacel wound dressing (from ConvaTec) predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 1998

XYLOS Corporation
c/o Eric Flam, Ph.D.
NTL Associates, Inc.
29 Ainsworth Avenue
East Burnswick, New Jersey 08816

Re: K974251
Trade Name: X-Cell™ Wound Dressing
Regulatory Class: Unclassified
Product Code: MGQ
Dated: March 30, 1998
Received: April 1, 1998

Dear Dr. Flam:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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 following limitations:

1. This device may not be labeled for use on third degree burns.
2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.
3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.
4. This device may not be labeled as a treatment or a cure for any type of wound.

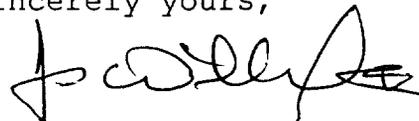
The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



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

X-Cell™ Wound Dressing : Revised APPENDIX IV-A

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510(k) Number (If known): K974251

Device Name: Xylos X-Cell™ wound dressing

Indications For Use:

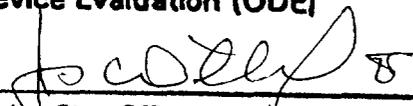
Prescription

X-Cell™ wound dressing may be used for the management of:

- Partial to Full thickness wounds (arterial, venous, pressure and diabetic ulcers);
- First and Second degree burns (severe sunburn, etc.);
- Post-operative surgical wounds;
- Donor sites;
- Dermal Lesions (cuts, abrasions, etc.)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974251

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)