JUL - 7 2004

Section 9.0
510(k) SUMMARY
ACell UBM Surgical Mesh *ML* and *MLPlus*

Submitter Name:	ACell, Incorporated
Submitter Address:	10555 Guilford Road Suite 113 Jessup, Maryland 20790
Contact Person:	James R. DeFrancesco Chief Executive Officer
Phone Number: Fax Number:	410-715-1700 410-715-4511
Date Prepared:	April 30, 2004
Device Trade Name:	ACell UBM Surgical Mesh *ML* and *MLPlus*
Device Common Name:	Surgical mesh
Classification Name:	Mesh, Surgical (FTM; 21 CFR 878.3300)
Predicate Devices:	K040621; ACell, Inc., ACell UBM Surgical Mesh K992159; Cook Biotech, Inc., Surgisis™ Sling
Device Description:	The ACell UBM Surgical Mesh *ML* and *MLPlus* are composed of porcine collagen and are supplied sterile in sizes ranging from 16 cm^2 to 14x20 cm.
Intended Use:	The ACell UBM Surgical Mesh *ML* & *MLPLus* are intended for implantation to reinforce soft tissue where weakness exists in urological, gynecological, and gastroenterological anatomy including, but not limited to the following procedures: pubourethral support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor, bladder support, tissue repair, sacrocolposuspension, hernia and body wall repair, and esophageal repair. By providing pubourethral support, the ACell surgical mesh may be used for the treatment of urinary incontinence resulting from urethral hypermobility and intrinsic sphincter deficiency. The device is intended for one-time use.

Discussion of tests and test results:	The ACell Surgical Mesh *ML* and *MLPlus* were subjected to a number of tests to assess the biocompatibility and the performance of the materials. They passed the requirements of all tests and were shown to be safe and effective as surgical mesh devices as indicated.
Conclusion:	These devices, with respect to material composition, device characteristics and intended use, are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2004

ACell, Inc.
c/o Ms. Patsy J. Trisler, J.D., RAC
5610 Wisconsin Avenue, #304
Chevy Chase, Maryland 20815

Re: K041140
Trade/Device Name: ACell UBM Surgical Mesh ML and MLPlus
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: April 30, 2004
Received: April 30, 2004

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). 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) 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

510(k) Number (if known): K041140

Device Name: ACell UBM Surgical Mesh *ML* and *MLPlus*

Indications for Use:

The ACell UBM Surgical Mesh *ML* and *MLPlus* are intended for implantation to reinforce soft tissue where weakness exists in urological, gynecological, and gastroenterological anatomy including, but not limited to the following procedures: pubourethral support, urethral and vaginal prolapse repair, colon and rectal prolapse repair, reconstruction of the pelvic floor, bladder support, tissue repair, sacrocolposuspension, hernia and body wall repair, and esophageal repair. By providing pubourethral support, the ACell surgical mesh may be used for the treatment of urinary incontinence resulting from urethral hypermobility and intrinsic sphincter deficiency. The device is intended for one-time use.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

(Posted November 13, 2003)

510(k) Number K641140