K092926

ACell, Inc.
8671 Robert Fulton Drive, Ste. B
Columbia, MD 21046
Toll Free: 800-826-2926
Phone: 410-715-1700
Fax: 410-715-4511
Website: www.acell.com

510(k) Summary

OCT 2 8 2009

Submitted by: ACell, Inc.
8671 Robert Fulton Drive, Suite B
Columbia, MD 21046

Contact Person: Rodney W. Bosley, Sr. Vice President
Phone: (410) 715-1700
Fax: (410) 715-4511

Date Prepared: September 21, 2009

Device Trade Name: ACell® MatriStem® Wound Sheet
Common/Usual Name: Wound Dressing
Proposed Classification: Dressing, Wound, Collagen
Unclassified, 79 KGN – General & Plastic Surgery

Device Description:

ACell® MatriStem® Wound Sheets are sterile, porcine-derived, lyophilized single or multi-layer extracellular matrix sheets available in various sizes with or without fenestrations or meshed.

Indications For Use:

ACell® MatriStem® Wound Sheet is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds. The device is intended for one-time use.

Predicate Device:

510(k) #	Device	Manufacturer
K021637	ACell® UBM Lyophilized Wound Dressing	ACell, Inc.

Substantial Equivalence:

ACell® MatriStem® Wound Sheets are identical to the predicate device with respect to fundamental scientific technology, materials, processing and intended use. The addition of multiple layers and fenestrations/meshes do not raise new issues of safety and effectiveness. MatriStem® Wound Sheets are substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

ACell, Inc.
% Mr. Rodney W. Bosley
Sr. Vice President
8671 Robert Fulton Drive, Suite B
Columiba, Maryland 21046

OCT 2 8 2009

Re: K092926
Trade/Device Name: ACell® MatriStem® Wound Sheet
Regulatory Class: Unclassified
Product Code: KGN
Dated: September 21, 2009
Received: September 23, 2009

Dear Mr. Bosley:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K092926

Device Name: ACell® MatriStem® Wound Sheet

Indications for Use:

ACell® MatriStem® Wound Sheet is intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns and skin tears) and draining wounds. The device is intended for one-time use.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krause for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092926