

510(k) SUMMARY—ACell™ Powder Wound Dressing

Submitter Name: ACell, Incorporated
Submitter Address: 10555 Guilford Road
Suite 113
Jessup, Maryland 20794

JUN 23 2006

Contact Person: James R. DeFrancesco
Chief Executive Officer

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Date Prepared: March 31, 2006

Device Trade Name: ACell™ Powder Wound Dressing

Device Common Name: Topical Wound Dressing
Classification Number: Unclassified, Pre-amendment
Classification Name: Dressing, Wound, Collagen
Product Code: KGN

Predicate Devices: K021637, ACell, Inc., ACell UBM Lyophilized Wound Dressing
K030921, Collagen Matrix, Inc., Collagen Topical Wound Dressing

Statement of Intended Use: The ACell™ Powder Wound Dressing is intended for the management of topical 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.

Device Description: The ACell™ Powder Wound Dressing is composed of porcine collagen from urinary bladder matrix. It is an absorbent, white to off-white, particulate that is lyophilized and to be used as a topical application. The product is sterile, for single use and is non-pyrogenic.

Comparison to the Predicate Devices: This device, with respect to material composition, device characteristics, and intended use, is substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2006

ACell, Incorporated
c/o Patsy J. Trisler, J. D., RAC
Regulatory Consultant
5600 Wisconsin Avenue, Suite 509
Chevy Chase, Maryland 20815

Re: K060888

Trade/Device Name: ACell Powder Wound Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: June 2, 2006
Received: June 2, 2006

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

Page 2 – Patsy J. Trisler, J.D., RAC

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark Melkerson", is written over the typed name. The signature is fluid and cursive.

Mark Melkerson

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

Applicant:
ACell, Inc.

ACell™ Powder Wound Dressing
Traditional 510(k) Premarket Notification

510(k) Number (if known):

K060888

Device Name:

ACell™ Powder Wound Dressing

Indications for Use:

The ACell™ Powder Wound Dressing is intended for the management of topical 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 x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K060888