

DEC 10 1998

K 983833

ATTACHMENT 8

**510(K) SUMMARY FOR THE WESTAIM CORPORATION'S
ACTICOAT® COMPOSITE WOUND DRESSING**

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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The Westaim Corporation
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Date Prepared: March 1, 1998

Name and Device and Name/Address of Sponsor

Acticoat® Composite Wound Dressing

Sponsor

Westaim Biomedical Division
The Westaim Corporation
10102 – 114 Street
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Common or Usual Name

Composite wound dressing

Classification Name

Wound dressing

Predicate Devices

The Company's Acticoat® Composite Wound Dressing, covered by this submission, is substantially equivalent to other legally marketed wound dressings. Specifically, Acticoat® Composite Wound Dressing is substantially equivalent The Westaim Corporation's Acticoat® Antimicrobial Barrier Dressing (K955453) and Bioderm's Composite Wound Dressing. The wound contact layer is also substantially equivalent to the Conformant 2® Wound Dressing.

Intended Use

The Acticoat[®] Composite Wound Dressing is an effective barrier to bacterial penetration. The barrier function of the dressing may help reduce infection in partial and full thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, donor sites, and surgical wounds. Acticoat[®] dressings may be used over debrided and grafted partial thickness wounds

Technological Characteristics and Substantial Equivalence

A. Description of the Acticoat[®] Composite Wound Dressing

Acticoat[®] Composite Wound Dressing is a 3-ply dressing consisting of an absorbent rayon core with an upper layer of polyurethane film and a lower layer of silver-coated high density polyethylene mesh designed to be a barrier against microbial infections of a wound. The silver in the coating is an alloy of silver and oxygen. The coating is highly porous, and the film has enhanced solubility in water-based fluids. Additionally, the performance characteristics of the Acticoat[®] Composite Wound Dressing are similar to those found in untreated gauze-based dressings in the areas of absorptivity and moisture content, abrasion resistance, adhesion, and tensile strength.

B. Substantial Equivalence of the Acticoat[®] Composite Wound Dressing

The predicate devices also provide the same or similar functions, characteristics, and accessories as described above for the Acticoat[®] Composite Wound Dressing. The dressings have the same intended use and are recommended for the same indications (e.g., ulcers, trauma wounds, surgical wounds, abrasion, lacerations, and donor sites).

Like the subject composite wound dressing the Acticoat[®] Antimicrobial Barrier Dressing consists of an absorbent material and the dressing releases silver ions into and around the wound site when activated by moisture. Both products are provided sterile to the user, and both have an antimicrobial effect. Additionally, both dressings are non-toxic, non-irritating, and non-sensitizing. Similar to the subject device, the silver coated dressing is gas permeable and has a soft, pliable, cushioning texture.

Both the subject dressing and its predicates are effective over similar periods of time (i.e., between dressing changes). Additionally, the dressings are secured to the wound site via traditional dressing methods such as tape, gauze, or elastic bandage. The predicate dressings, like the composite wound dressings, also have been shown to have low adhesivity to the wound site.

Although there are some differences between the Acticoat® Composite Wound Dressing and its predicates, these differences are minor and raise no new questions of safety or effectiveness. First, the Bioderm device is described as a similar 3-ply gauze bandage without the silver coating on the lower layer of HDPE. Similarly, the Acticoat® Antimicrobial Barrier Dressing is described as a device similar to the subject dressing but lacks the occlusive polyurethane film and is not as absorptive. The labelling for all of the devices indicate that the frequency of dressing changes should be determined, in part, by the amount of wound exudate and general condition of the wound. The predicate silver coated dressing is also sterilized by gamma irradiation as is the subject composite wound dressing. These few differences in technological characteristics between the Acticoat® Composite Wound Dressing and its predicate devices are minor and do not present any new issues of safety or effectiveness.

Performance Data

The Acticoat® Composite Coated Dressing was subjected to the following performance tests:

- Silver dissolution
- Absorptivity and moisture content
- Drop penetration and vapour transmission
- Tensile strength
- Biocompatibility studies (including skin irritation, sensitization and cytotoxicity)
- Silver ion exposure levels
- *In vitro* studies of antimicrobial activity

In all instances, the Acticoat® Composite Wound Dressing is both effective for its intended use and functions in a substantially equivalent manner to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Westaim Biomedical, Inc.
c/o Jonathan S. Kahan
Regulatory Counsel for The Westaim Corporation
Hogan and Hartson L.L.P.
555 Thirteenth Street NW
Washington, DC 20004

Re: K983833
Trade Name: Acticoat® Composite Wound Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: October 30, 1998
Received: October 30, 1998

Dear Mr. Kahan:

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 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 (the Act). You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (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.

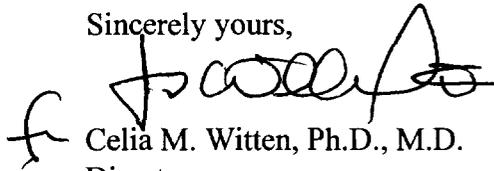
The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, 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 (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP 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/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a large, stylized initial 'C' on the left.

Celia M. Witten, Ph.D., M.D.

Director

Division of General and
Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K983833

HOGAN & HARTSON L.L.P.

510(k) Number (if known): K983833

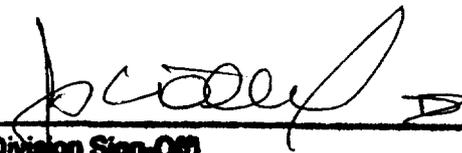
Device Name: Acticoat® Composite Wound Dressing

Indications For Use:

The Acticoat® Composite Wound Dressing is an effective barrier to bacterial penetration. The barrier function of the dressing may help reduce infection in partial and full thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, donor sites, and surgical wounds. Acticoat® dressings may be used over debrided and grafted partial thickness wounds.

(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 K983833

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter
Use _____

(Optional Format 1-2-96)