FEB 21 2001

K002896



# 510(k) Summary

General Information:

This 510(k) is to provide notification of substantial equivalence for the Acticoat® Calcium Alginate Dressing, which is substantially equivalent to previously marketed devices intended for wound care.

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|---|---|
| Submitted by: | Westaim Biomedical, Inc.<br>One Hampton Road, Suite 320<br>Exeter, NH 03833 |
| Contact Person: | Steven Chartier |
| Date prepared: | September 15, 2000 |
| Classification: | A final classification for wound/burn dressings has not been implemented. |
| Trade Name: | Acticoat® Calcium Alginate Dressing |
| Common Name: | Alginate Dressing |

Predicate Devices:

| | |
|---|---|
| K000051 | Acticoat® Foam Dressing |
| K983210 | Algisite M Calcium Alginate Dressing |

Indication for Use:

The Acticoat® Calcium Alginate Dressing is an effective barrier to bacterial penetration. The barrier functions of the dressing may help reduce infection in moderate to heavily exudative partial and full thickness wounds including decubitus ulcers, diabetic ulcers, venous stasis ulcers, surgical and traumatic wounds. Acticoat® dressings may be used over debrided and partial thickness wounds.

Description:

The Acticoat® Calcium Alginate Dressing is a highly absorbent non-woven calcium alginate fabric with an Acticoat® coating applied directly to its surface. It has a light grey appearance. Formatted in various sizes (5cm x 5cm, 10cm x 12.5cm, 15cm x 15cm, and a 2.5cm x 30cm rope) and packaged in Tyvek pouches.

As with other Acticoat® dressings, the Alginate dressing is an effective physical and chemical barrier to bacterial penetration which may help reduce infection in partial and full thickness wounds.

Testing:

The biocompatability of Acticoat® Calcium Alginate Dressing has been demonstrated in accordance with ISO 10993. Additional *in vitro* and *in vivo* testing has demonstrated that the performance characteristics of Acticoat® Calcium Alginate Dressing are substantially equivalent to the predicate devices.

Summary of Substantial Equivalence:

The Acticoat® Calcium Alginate Dressing consists of a non-woven calcium alginate dressing, which is substantially equivalent to the Algisite M Calcium Alginate Dressing predicate device. This dressing has been coated with nanocrystalline silver in a manner identical to that used to coat the Acticoat® Foam Dressing predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2001

Mr. Steve Chartier
Manager, Regulatory and Clinical Affairs
Westaim Biomedical, Inc.
One Hampton Road, Suite 320
Exeter, New Hampshire 03833

Re: K002896
Trade Name: Acticoat® Calicium Alginate Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: December 22, 2000
Received: December 22, 2000

Dear Mr. Chartier:

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 (Act). 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 (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 requirement, 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/dsmamain.html".

Sincerely yours,

Miriam C. Provost
for 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

# ATTACHMENT 7



510(k) Number (if known): K002896

Device Name: Acticoat Calicium Alginate Dressing

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K002896