JUN - 7 2000

EXHIBIT D

K992221

510K Summary of Safety and Efficacy
ACTICOAT® Primary Antimicrobial Dressing

May 17, 2000

1. **Submitter**

Westaim Biomedical, Inc
One Hampton Rd. Suite 302
Exeter, NH 03833

Steve Chartier
Manager, Regulatory and Clinical Affairs
(603) 775-7300

2. **Device Name**

Proprietary Name:	ACTICOAT® Primary Antimicrobial Dressing
Common Name:	Dressing
Classification Name:	Dressing
Regulatory Class:	Unclassified

3. **Intended Use**

The Acticoat® Primary Antimicrobial Dressing is an effective barrier to bacterial and fungal[1] penetration. The barrier function of the dressing may help reduce infections in partial and full thickness wounds including decubitis ulcers, venous stasis ulcers, Neuropathic ulcers, first- and second-degree burns, donor sites and surgical wounds. It may be used over grafted and partial thickness wounds.

4. **Device Description**

Acticoat® primary antimicrobial dressings consists of single-coated, non-adherent, high-density polyethylene mesh (HDPE). The sustained release of silver actively protects the wound site from bacterial and fungal[1] contamination.

The dressing will be sold in a variety of sizes the size used will depend on the size of the wound. The smallest dressing size will be 2" x 2" while the largest will be a 4" x 48" roll.

How Supplied

2" x 2"	(5cm x 5 cm)
4" x 4"	(10 cm x 10 cm)
4" x 8"	(10 cm x 20 cm)
8" x 16"	(20 cm x 40 cm)
16" x 16"	(40 cm x 40 cm)
4" x 48"	(10 cm x 120 cm)

[1] based on *in vitro* testing. Data on file.

5. Predicate Device Comparison

Acticoat® Primary Antimicrobial Dressing is the identical skin contact layer that is used in the Acticoat® Composite dressing (K983883). The absorbent outer layer has been omitted. This configuration allows the user to choose an appropriate secondary dressing.

This product is also similar to N'Terface dressing distributed by Winfield Laboratories. (K820298 and K973538). Both products are manufactured from HDPE and intended for use as a primary dressing to minimize damage to the wound bed during dressing changes. The only difference between these two products is that the Acticoat® dressing has an antimicrobial coating.

The table below compares the features and characteristics of the ACTICOAT® Primary antimicrobial dressing to the predicate products.

Comparison of the ACTICOAT® Contact Layer Dressing to Predicate Products

	Acticoat Antimicrobial Contact Layer Dressing	**Acticoat® Composite Dressing (K983883)**	**Winfield Labs N'Terface (K820198 & K973538)**
INTENDED USE			
Wound Dressing	Yes	Yes	Yes
DESIGN			
HDPE Skin Contact Layer	Yes	Yes	Yes
Absorbable	No	Yes	No
Antimicrobial silver coating	YES	Yes	NO
MATERIALS			
	HDPE	HDPE & Polyurethane backing Absorbent material	HDPE

6. Biocompatibility

The biocompatibility of Acticoat® Primary Antimicrobial Dressing has been demonstrated through appropriate *in vivo* and *in vitro* tests as well as previous tests on individual components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2000

Mr. Steve Chartier
Manager, Regulatory and Clinical Affairs
Westaim Biomedical, Inc.
One Hampton Road, Suite 302
Exeter, New Hampshire 03833

Re: K992221
Trade Name: ACTICOAT® Primary Antimicrobial Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: April 13, 2000
Received: April 14, 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,

Donna R Lochner

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

Device Name: **ACTICOAT® Primary Antimicrobial Dressing**

K 992221

The Acticoat® silver coated contact layer dressing is an effective barrier to bacterial and fungal penetration.[1] The barrier function of the dressing may help reduce infections in partial and full thickness wounds including decubitus ulcers, venous stasis ulcers, Neuropathic ulcers, diabetic ulcers, first- and second-degree burns, donor sites and surgical wounds. It may be used over debrided and grafted partial thickness wounds.

It has not been evaluated in third degree burns.

[1] based on in vitro testing. Data on file.

(Please do not write below this line - Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer.

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K992221

Prescription Use ✓ OR Over-the-Counter Use ____

(Per 21 CFR §801.109)

(Optional Format 1-2-96)