

MAY 31 1995

ATTACHMENT 9

**510(k) SUMMARY
FOR WESTAIM TECHNOLOGIES, INC.'S
ACTICOAT™ SILVER COATED DRESSING****Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared**

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Name of Device and Name/Address of Sponsor

Acticoat™ silver coated dressing

Sponsor

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Common or Usual Name

Silver coated dressing

Classification Name

Wound and burn dressing

Predicate Devices

The Company's Acticoat™ silver coated dressing covered by this submission is substantially equivalent to other legally marketed burn and wound dressings. Specifically, Acticoat™ silver coated dressing is substantially equivalent to Vitaphore Corporation's Silver Foam Dressing (K914579).

Intended Use

Acticoat™ silver coated dressing is intended for use as an effective barrier to bacterial penetration and as a method to reduce infection of partial and full thickness wounds.

Technological Characteristics and Substantial Equivalence

A. Description of the Acticoat™ Silver Coated Dressing

Acticoat™ silver coated dressing is a 3-ply gauze wound dressing consisting of an absorbent rayon/polyester core and an upper and 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™ silver coated dressing are similar to those found in untreated gauze-based dressings in the areas of absorptivity and moisture content, abrasion resistance and adhesion, and tensile strength.

B. Substantial Equivalence of the Acticoat™ Silver Coated Dressing

The predicate device also provides the same or similar functions, characteristics, and accessories as described above for the Acticoat™ silver coated dressing. Both dressings have the same intended use and are recommended for the same indications (e.g., ulcers, first and second degree burns, trauma wounds, surgical wounds, abrasion, lacerations, and donor sites).

Like the Acticoat™ dressing, the predicate Vitaphore 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 Acticoat™ device, the predicate Vitaphore dressing is gas permeable and has a soft, pliable, cushioning texture.

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

Although there are some differences between the Acticoat™ product and its predicate Vitaphore Silver Foam Wound Dressing, these differences are minor and raise no new questions of safety or effectiveness. First, the predicate Vitaphore dressing is described as a 1-ply dressing with a silver-containing collagen-derived gel, whereas the Acticoat™ dressing is a 3-ply dressing whose upper and lower layers of mesh are coated with a silver film. Additionally, the labeling for the predicate Vitaphore dressing suggests that the dressing may, in some instances, be left unchanged for more than 24 hours, but also indicates that more frequent changes are necessary during the initial wound healing stages and that the frequency of dressing changes should be determined by a medical practitioner. On the other hand, the Acticoat™ dressing is recommended to be replaced at least once every 24 hours. The predicate Vitaphore dressing also is sterilized with an ethylene oxide ("EtO") process, while the Acticoat™ dressing is sterilized using gamma radiation. However, these few differences in technological characteristics between the Acticoat™ dressing and its predicate device are minor and do not present any new issues of safety or effectiveness.

Performance Data

The Acticoat™ silver coated dressing was subjected to the following performance testing:

- Silver dissolution
- Absorbitivity and moisture content
- Abrasion resistance and adhesion
- Tensile strength
- Biocompatibility studies (including skin irritation, sensitization and cytotoxicity)
- Silver ion exposure levels
- *In vitro* and *in vivo* studies of antimicrobial activity
- Shelf life testing

In all instances, the Acticoat™ silver coated dressing functioned as intended. These test results demonstrated that the Acticoat™ silver coated dressing is both effective for its intended use and functions in a substantially equivalent manner to the predicate device.