

DEC 10 1998

K983210

*510(k) Summary*

*Algisite M - Calcium Alginate Dressing*

Preparation Date: September 8, 1998

Submitter: Jim G. Irvin  
Address: Smith & Nephew Inc.  
Wound Management Division  
11775 Starkey Road  
Largo, FL 33773-4727  
Phone: (813) 392-1261  
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Registration Official / Contact Person:

Jim Irvin, Vice President  
Quality Assurance and Regulatory Affairs  
Smith & Nephew, Inc.  
Wound Management Division

Manufacturer Identification/Establishment Registration Number

Smith & Nephew Inc.  
Wound Management Division  
11775 Starkey Road  
Largo, FL 33773-4727  
Phone (813) 392-1261  
Fax (813) 399-3468

Establishment Registration Number: 1017593

Classification:

Trade Name: **Algisite M - Calcium Alginate Dressing**  
Common Name: **Calcium Alginate Dressing**  
Classification Name: **Class I Wound and Burns Dressing**

Substantially Equivalent Products:

<b>Product</b>	<b>Distributor/Manufacturer</b>
<b>ALGOSTERIL ® Alginate Dressing</b>	<b>For Johnson &amp; Johnson Medical Inc. by Les Laboratoires Brothier S.A. Nanterre, France</b>
<b>KALTOSTAT ® Wound Dressing</b>	<b>Calgon Vestal Laboratories St. Louis, MS (K940407)</b>
<b>Sorbsan ™ Topical Wound Dressing</b>	<b>For Dow B. Hickman, Inc. By Steriseal Limited Worcestershire, England (K914575)</b>

Device Description

**Algisite M - Calcium Alginate Dressing**

Technological Characteristics:

The **Algisite M - Calcium Alginate Dressing** is technologically the same as the substantially equivalent products:

*ALGOSTERIL ® Alginate Dressing*  
*KALTOSTAT ® Wound Dressing*  
*Sorbsan ™ Topical Wound Dressing*

## Bio Compatibility

### Cytotoxicity

An agar - overlay cytotoxicity test, utilizing a culture of mouse L929 cells, was conducted on the test article, Algisite M, in order to determine the potential for in vitro cytotoxicity. After incubating at 37°C for 24 hours, the cell cultures were inspected for evidence of cytolysis.

The sample of Algisite M and the negative control were non-toxic and the positive control toxic to L929 cells under the conditions of the test.

### British Standard 5736 Part 8 Assessment of Skin Irritation

The test article, Algisite M, was evaluated according to British Standard 5736 "Evaluation of medical devices for biological hazards: Part 8 Method of test for skin irritation of solid medical devices". The test is designed to assess the irritation potential of the test material by its direct contact with rabbit skin for five consecutive days.

Under conditions of this study, Algisite M, is considered non-irritant following 5-day repeated application to rabbit skin.

### Magnusson & Kligman Maximization Study in the Guinea Pig

This study was performed according to Safeparm Standards Protocol Number GM 09/83/85D and was designed to assess the contact sensitization potential of Algisite M.

The test material produced a 0% (0/20) sensitization rate and was classified as a non-sensitizer to guinea pig skin.

### Acute Systemic Toxicity of Saline Extracts of Calcium Alginate in The Mouse

The test article, Algisite M, was evaluated according to British Standard 5736 "Evaluation of medical devices for biological hazards: Part 3 Method of test for systemic toxicity; assessment of acute toxicity of extracts from medical devices". The results of the study will provide information on the acute toxic effects attributable to leachable inherent or extraneous substances of value in predicting the suitability of the test article for its intended use.

A saline extract of calcium alginate passed the prescribed acute systemic toxicity test in the mouse.

### Haemolysis

The test article, Algisite M, was evaluated using the U.S. National Formulary XIV method.

The haemolysis value of Algisite M was found to be 4.45% by the above Blood compatibility haemolysis test. As the haemolysis value is less than 5% the sample is considered to be non-haemolytic.

### Sterilization

**Algisite M - Calcium Alginate Dressing** is gamma irradiated to achieve a sterility assurance level of at  $10^{-6}$  or better in a validated process according to EN 552 “Sterilization of medical devices - validation and routine control of sterilization by irradiation”, and ISO 11137 “Sterilization of health care products - Requirements for validation and routine control - Radiation sterilization.”



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Jim Irvin  
Vice President, Quality Assurance and Regulatory Affairs  
Smith and Nephew, Incorporated  
Wound Management Division  
11775 Starkey Road  
Largo, Florida 33773-4727

Re: K983210  
Trade Name: Algisite M – Calcium Alginate Dressing  
Regulatory Class: Unclassified  
Product Code: KMF  
Dated: September 8, 1998  
Received: September 14, 1998

Dear Mr. Irvin:

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).

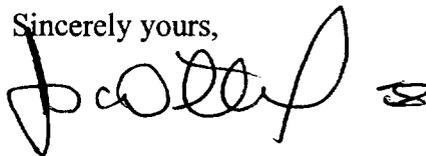
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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,



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

K983210

ATTACHMENT NO. 3 (Revised Indications)

510(k) Number (if known):

Device Name: Algisite M - Calcium Alginate dressing

Indications for Use:

For OTC applications, Algisite M may be used for the management of minor conditions such as:

- \* Lacerations
- \* Abrasions
- \* Skin Tears
- \* Minor Burns

Under the care of a healthcare professional, Algisite M may be used for the management of full and partial thickness wounds including:

- Leg Ulcers
- Pressure Ulcers
- Diabetic Foot Ulcers
- Surgical Wounds

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*[Handwritten Signature]*

(Division) Sign-Off

Division of General Restorative Devices

510(k) Number

K983210

Prescription Use \_\_\_\_\_

OR

Over-The-Counter Use \_\_\_\_\_

X

(Per 21 CFR 801.109)