K981150

JUN 22 1998

# *510(k) Summary*

# *SoloSite® Gel Conformable Dressing*


Preparation Date: March 27, 1998

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

Packaging Company Identification /Establishment Registration Number

Tecnol Medical Products, Inc.
6316 Airport Freeway
Fort Worth, TX 76117
Phone (817) 831-4700
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Establishment Registration Number: 1643958


Classification:

Trade Name: **Smith & Nephew, Inc., Solo Site® Conformable Wound Dressing**

Common Name: **Conformable Wound Dressing**

Classification Name: **Unclassified**

Substantially Equivalent Products:

| Product | Manufacturer |
|---|---|
| **Biolex™ Impregnated Wound Dressing** | **Bard Patient Care Division Murray Hill, NJ (K935096)** |
| **CarraGauze® Carrasyn® Hydrogel wound Dressing Saturated Pad** | **Carrington Laboratories, Inc. Irving, TX (K962218)** |
| **MPM GelPad™ Hydrogel Saturate Dressing** | **Marketing Professionals in Medicine, Inc. Arlington, TX (K933495)** |
| **Restore ™ Hydrogel Impregnated Sponge** | **By Renaissance Pharmaceutical for Hollister Inc. Libertyville IL** |

Device Description

**SoloSite® Gel Conformable Dressing** is a non woven (70/30 rayon polyester blend) dressing impregnated with SoloSite® wound gel contained in a heat sealable, peal apart metalized/polyethylene pouch.

The product is applied in such a manner to completely cover the wound surface with the dressing and secured in place with an appropriate secondary dressing.

Gel conformable dressings are indicated to provide covering of the wound bed as well as creating a moist wound healing environment.

**SoloSite® Gel Conformable Dressing** is used to create a moist wound environment for the treatment of minor conditions such as:

* Minor burns
* Superficial lacerations, cuts and abrasions (partial thickness wounds) and skin tears

Under the direction of a healthcare professional, **SoloSite® Gel Conformable Dressing** is used to create a moist wound environment for the management of:

* Venous ulcers (leg ulcers)
* Surgical incisions
* Diabetic foot ulcers
* Pressure ulcers (including stage IV).

Additionally, **SoloSite® Gel Conformable Dressing,** creates a moist wound environment which assists in autolytic debridement of wounds covered with necrotic tissue.

Technological Characteristics:

The **SoloSite® Gel Conformable Dressing** is technologically the same as the substantially equivalent products:

*Biolex™ Impregnated Wound Dressing*
*CarraGauze™ Carrasyn™ Hydrogel wound Dressing Saturated Pad*
*MPM GelPad™ Hydrogel Saturate Dressing*
*Restore™*

in that all products are hydrogel impregnated dressings indicated to provide covering of the wound bed as well as creating a moist wound healing environment.

## Bio Compatibility

### Cytotoxicity

An in vitro biocompatibility test, based on the International Organization for Standardization (ISO 10993-5) guidelines, was conducted on the test article, **SoloSite® Gel Conformable Dressing**, in order to determine the potential for in vitro cytotoxicity.

**Conclusion:** Under the conditions of this study, the test article showed no evidence of causing cell lysis or toxicity grater then a USP grade of 2 (mild reactivity). The test article was mildly cytotoxic an passed this ISO study.

### Animal Primary Irritation

The test article, **SoloSite® Gel Conformable Dressing**, was evaluated for primary skin irritation in accordance with the guidelines of the Federal Hazardous Substances Act (FHSA) Regulations, 16 CFR 1500.

Under conditions of this study, barely perceptible irritation was observed on the skin of the rabbits. The primary irritation index was calculated to be 0.88.

**Conclusion:** The test article would not be considered a primary irritant to the skin since the empirical score was less than 5.00.

### Delayed Contact Sensitization Study in the Guinea Pig (Repeated Patch Method)

A study was conducted in the guinea pig to evaluate the potential for delayed dermal contact sensitization of **SoloSite® Gel Conformable Dressing**. The study was conducted based on the requirements of the International Organization for Standardization Part 10: Tests for Irritation and Sensitization.

**Conclusion:** Under the conditions of this study, the test article showed no evidence of causing delayed dermal contact sensitization in the guinea pig.

### Acute Systemic Toxicity Study in The Mouse

The test article, **SoloSite® Gel Conformable Dressing**, was evaluated for systemic toxicity based on the requirements of the International Organization for Standardization: Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity.

**Conclusion**: Under the conditions of this test there was no mortality or evidence of significant systemic toxicity.

Genotoxicity: *Salmonella typhimurium* - Reverse Mutation Study

A Salmonella typhimurium reverse mutation standard plate incorporation study was conducted to determine whether **SoloSite® Gel Conformable Dressing**, would cause mutagenic changes in histidine-dependent Salmonella typhimurium strains in the presence and absence of S9 metabolic activation

**Conclusion**: Under the conditions of this assay, SoloSite CWD was not considered to be mutagenic to Salmonella typhimurium tester strains

Hemolysis Study - *In Vitro* Procedure (Extract Method)

The test article, **SoloSite® Gel Conformable Dressing**, was evaluated to determine whether the presence of any leachable chemicals from the test article would cause in vitro red blood cell hemolysis.

**Conclusion**: Under the conditions of this study, the mean hemolytic index for the test article extract was 0%. The test article extract was nonhemolytic.

Preservation

**SoloSite® Gel Conformable Dressing** is a preserved product and does not undergo sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 1998

Mr. Jim G. Irvin
Vice President
Quality Assurance & Regulatory Affairs
Smith & Nephew, Incorporated
11775 Starkey Road
P.O. Box 1970
Largo, Florida 33779-1970

Re: K981150
Trade Name: SoloSite® Conformable Wound Dressing
Regulatory Class: Unclassified
Product Code: MGQ
Dated: March 27, 1998
Received: March 31, 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,

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

K981150

510(k) Number (if known):

Device Name: **SoloSite® Gel Conformable Dressing**

Indications for Use:

**SoloSite® Gel Conformable Dressing** is used to create a moist wound environment for the treatment of minor conditions such as:

* Minor burns
* Superficial lacerations, cuts and abrasions (partial thickness wounds) and skin tears

Under the direction of a healthcare professional, **SoloSite® Gel Conformable Dressing** is used to create a moist wound environment for the management of:

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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 _____ OR Over-The-Counter Use ✓

(Per 21CFR 801.109)

(Optional Format 1-2-96)

**(Division Sign-Off)**
**Division of General Restorative Devices**
**510(k) Number** K981150