K981713

JUL 31 1998

# *510(k) Summary*

# *CicaNet* Wound Contact Layer Dressing*

Preparation Date: May 15, 1998


Submitter: Jim G. Irvin
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Wound Management Division
11775 Starkey Road
Largo, FL 33773-4727
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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
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Establishment Registration Number: 1017593

Classification:

Trade Name: **CicaNet***

Common Name: **Wound Dressing**

Classification Name: **(Unclassified)**

Substantially Equivalent Products:

| Product | Manufacturer |
|---|---|
| 3M Tegapore™ Wound Contact Material | 3M Health Care<br>St. Paul, MN |
| DERMANET™ Wound Contact Layer | DeRoyal Wound Care<br>Powell, TN |
| Conformant 2™ Transparent, Non-Adherent, Wound Veil | EXU-DRY Wound Care Products, Inc.<br>Bronx, NY |
| TELFA CLEAR™ Nonadherent Wound Dressing | Kendall Healthcare Products<br>Mansfield, MA |
| N-TERFACE® Interpositional Surfacing Material | Winfield Laboratories<br>Dallas, TX (K973538) |

Device Description

**CicaNet* Wound Contact Layer Dressing** is an air permeable, transparent, bi-axially stretched net constructed of high density polyethylene. This product is used in moist wound management of partial and full thickness wounds.

Wound contact layer dressings are indicated to provide covering for the wound bed.

**Indications for Use**

For OTC applications, **CicaNet* Wound Contact Layer Dressing** may be used for the management of minor wounds including

- Abrasions
- Skin tears
- Minor burns and scalds

Under the care of a healthcare professional, **CicaNet* Wound Contact Layer Dressing** may be used in the management of partial and full thickness wounds including:

- Leg ulcers
- Pressure ulcers
- Second degree burns
- Surgical wounds
- Diabetic foot ulcers

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Technological Characteristics:

The **CicaNet* Wound Contact Layer Dressing** is technologically the same as the substantially equivalent products:

*3M Tegapore ™ Wound Contact Material*
*DERMANET ™ Wound Contact Layer*
*Conformant 2 ™ Transparent, Non-Adherent, Wound Veil*
*TELFA CLEAR ™ Nonadherent Wound Dressing*
*N-TERFACE® Interpositional Surfaceing Material*

in that all products are an air permeable, transparent, non-adherent wound contact layer.

Bio Compatibility

Cytotoxicity

A study was conducted using mouse fibroblast cells as the substrate in order to determine the cytotoxicity of **CicaNet* Wound Contact Layer Dressing.**

**Conclusion:** Under the conditions of the study, the test article was found to be non-toxic.

Contact Sensitization

A study was conducted in the guinea pig to evaluate the potential for delayed dermal contact sensitization of **CicaNet* Wound Contact Layer Dressing.**

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

Animal Primary Irritation

**CicaNet* Wound Contact Layer Dressing** was evaluated for primary skin irritation in accordance with the guidelines of the Federal Hazardous Substances Act (FHSA) Regulations, 16 CFR 1500.

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

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

**CicaNet* Wound Contact Layer Dressing** was evaluated to determine whether the presence of any leachable chemicals would cause in vitro red blood cell hemolysis.

**Conclusion**: The mean hemolytic index for **CicaNet* Wound Contact Layer Dressing** extract was 0%. **CicaNet* Wound Contact Layer Dressing** is nonhemolytic.

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USP Systemic Toxicity Study in the Mouse (Extracts)

**CicaNet* Wound Contact Layer Dressing** was evaluated for systemic toxicity in accordance with the guidelines of the current USP.

Conclusion: There was no mortality or evidence of systemic toxicity from **CicaNet* Wound Contact Layer Dressing**

Sterilization

The method of sterilization will be Ethylene Oxide. An SAL of $10^{-6}$ will be achieved. Ethylene Oxide residuals will conform to FDA guidelines as originally published (Federal Register, Friday, June 23, 1978, Part V, "Proposed Maximum Residue Limits and Maximum Levels of Exposure").

Packaging

The product is packaged in a cold seal, peel apart, white, Kraft, ETO sterilizable Detectable Prior Opening (DPO) system, paper pouch. The individual dressings are protected by a parchment inner-wrap.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 1998

Mr. Jim G. Irvin
Vice President, Quality Assurance & Regulatory Affairs
Wound Management Division
Smith & Nephew, Inc.
11775 Starkey Road
Largo, Florida 33773

Re: K981713
Trade Name: Cicanet Wound Contact Layer Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: May 15, 1998
Received: May 15, 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

K981713

510 (k) Number (if known)

Device Name: **CicaNet* Wound Contact Layer Dressing**

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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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981713

Prescription Use _____ OR Over-The-Counter Use ✓

(Per 21CFR 801.109)

(Optional Format 1-2-96)