K973228

NOV 25 1997

Wound Management Division
Smith & Nephew, Inc.
11775 Starkey Road, P.O. Box 1970
Largo, FL 33779-1970 U.S.A.
Customer Care Center: 1 800 876-1261
Telephone: 813 392-1261 Fax: 813 399-3498
Smith+Nephew

510(K) SUMMARY

No-Sting Skin Prep

Preparation Date: August 21, 1997

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

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 No: 1017593

Classification:

Trade Name: **Smith & Nephew, Inc., No-Sting Skin Prep™**

Common Name: **Skin Preparation**

Classification Name: **(Undetermined)**

While no clear category exists for this product, the merits of the product should be discussed relative to classification.

The first portion discussed is product use as part of an Ostomy pouching process. In this situation it is our belief that **No-Sting Skin Prep™** may be considered as an accessory to an Ostomy pouch per 876.5900. This in fact represents a large use segment for this product. The product is normally applied, allowed to dry and the pouch, tube or other adhesive device is then attached over the deposited film.

The other general position is the use of **No-Sting Skin Prep™** under adhesive tapes, films, bandages, etc. The same manner of application of Skin Prep is applicable. After drying the patient, family member or health care professional will apply the adhesive device. In this case the product could be considered as a liquid bandage and be classified per 880.5090. The product becomes part of a total bandaging system since it is applied prior to the application of dressings and other bandaging products.

No-Sting Skin Prep™ is not used over open wounds, deep puncture wounds, etc.

Substantially Equivalent Products:

Product	Manufacturer
Bard Protective Barrier Film	Bard Patient Care Division Murray Hill, NJ (K821271A)
AllKare Protective Barrier Wipe	Convatec, A Bristol Myers Squibb Co. Princeton, NJ
3M No Sting Barrier Film	Manufactured for 3M Health Care, Minneapolis, MN (K920794)

Device Description:

No-Sting Skin Prep™ is a water based alcohol free liquid impregnated on to a nonwoven wipe or tufted swab applicators.

This product is sold **OTC** for use by ostomates and other individuals who wish to reduce trauma to skin upon removing adhesive devices/products. The product is applied to the skin and allowed to dry. The solvent base evaporates leaving a polymeric film on the skin. After drying, the adhesive device, dressing, Ostomy device, tape, etc., is attached.

Intended Use:

Smith & Nephew's ***"No Sting Skin Prep™"*** is intended for use as a liquid film - forming product that when applied to intact skin, forms a film for skin attachment sites for drainage tubes, external catheters, surrounding ostomy sites and adhesive dressings.

This product is sold **OTC** for use by ostomates and other individuals who wish to reduce trauma to skin upon removing adhesive devices/products. The product is applied to the skin and allowed to dry. The solvent base evaporates leaving a polymeric film on the skin. After drying, the adhesive device, dressing, Ostomy device, tape, etc., is attached.

a) ***"No Sting Skin Prep™"*** applies a coating that prepares the skin for adhesives and provides a protective interface that may reduce friction during the removal of tape. ***"No Sting Skin Prep™"*** is indicated for skin attachment sites for draining tubes, external catheters, surrounding ostomy sites and other adhesive dressings.

b) ***"No Sting Skin Prep™"*** can be used in sensitive stoma areas as a skin protectant and may reduce irritation from contact with body wastes and stoma fluid.

c) ***"No Sting Skin Prep™"*** forms a protective film on skin that serves as a skin protectant which may reduce exposure to urine and feces.

These types of products are sold **OTC** at various locations including pharmacies and home health care centers.

Technological Characteristics:

The **No-Sting Skin Prep** is technologically the same as the substantially equivalent products -

Bard Protective Barrier Film
AllKare Protective Barrier Wipe
3M No-Sting Barrier Film

in that all products incorporate a solvent carrier/polymer coating system. As the product is applied, the solvent evaporates and deposits a thin polymer coating to the skin. The technological function of the products after application are also equivalent. All products are intended to:

* deposit a thin polymeric film
* assist in protecting sensitive skin from urine, stomal secretions, etc.

Bio Compatibility

Cytotoxicity

An in vitro biocompatability test, based on the International Organization for Standardization (IS) 10993-5) guidelines, was conducted on the test article, Skin Prep Wipes - No-Sting Formula. After incubating, the cell cultures were examined macroscopically for cell decolorization around the test article and controls to determine the zone of cell lysis (if any). The cultures were then examined microscopically *100X) to verify any decolorized zones and to determine cell morphology in proximity to and beneath the test article.

The negative controls and the positive controls performed as anticipated. Under the conditions of this study, the test article showed evidence of causing cell lysis or toxicity greater than a USP grade of 2 (mild reactivity).

This is not considered significant as the product does not come into contact with open wounds. Typically beladine, alcohol and other topicals would be cytotoxic. These products are widely used in the health care sector without adverse consequences.

Contact Sensitization

A study was conducted in the guinea pig to evaluate the potential for delayed dermal contact sensitization of Skin Prep Wipes - No Sting Formula.

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

Animal Primary Irritation

The test article, Skin Prep Wipes - No Sting Formula, was evaluated for primary skin irritation in accordance with the guidelines of the Federal Hazardous Substances Act (FHSA) Regulations, 16 CFR 1500.

Under the conditions of this study, no irritation was observed on the skin of the rabbits. The primary irritation index was calculated to be 0.00. The test article would not be considered a primary irritant to the skin since the empirical score was less than 5.00.

Preservation

The product is sold non-sterile. When innoculated and evaluated per USP 23, the product is adequately preserved.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1997

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

Re: K973228
No-Sting Skin Prep™
Regulatory Class: I
Product Code: KMF
Dated: August 21, 1997
Received: August 27, 1997

Dear Mr. Irvin:

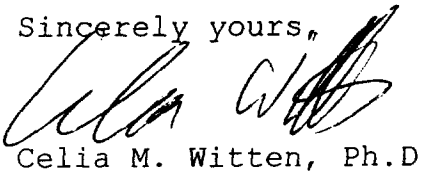
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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,



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

K973328

510(k) Number 973228:

Device Name: *"No Sting Skin Prep™"*

Indications for Use:

Smith & Nephew's ***"No Sting Skin Prep™"*** is intended for use as a liquid film - forming product that when applied to intact skin, forms a film for skin attachment sites for drainage tubes, external catheters, surrounding ostomy sites and adhesive dressings.

a) ***"No Sting Skin Prep™"*** applies a coating that prepares the skin for adhesives and provides a protective interface that may reduce friction during the removal of tape. ***"No Sting Skin Prep™"*** is indicated for skin attachment sites for draining tubes, external catheters, surrounding ostomy sites and other adhesive dressings.

b) ***"No Sting Skin Prep™"*** can be used in sensitive stoma areas as a skin protectant and may reduce irritation from contact with body wastes and stoma fluid.

c) ***"No Sting Skin Prep™"*** forms a protective film on skin that serves as a skin protectant which may reduce exposure to urine and feces.

(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 K973328

Prescription Use _____ OR Over-the Counter Use X

(Per 21CFR 801.109)

(Optional Format 1-2-96)