February 25, 2025

New Dimensions In Medicine Corporation
Donald E. Koopman
RA/QA Manager
P.O. Box 1408
3040 East River Road
Dayton, Ohio 45401-1408

Re: K934601
Trade/Device Name: NDM Hydrogauze™ Wound Dressing with ClearSite®
Regulation Number: 21 CFR 878.4022
Regulation Name: Hydrogel wound dressing and burn dressing
Regulatory Class: Class I
Product Code: NAE

Dear Donald E. Koopman:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 15, 1994. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code NAE.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Yu-Chieh Chiu, OHT4: Office of Surgical and Infection Control Devices, 301-796-6196, Yu-Chieh.Chiu@fda.hhs.gov.

Sincerely,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

FEB 15 1994

Donald E. Koopman, Ph.D.
.RA/QA Manager
New Dimensions In Medicine Corporation
P.O. Box 1408
3040 East River Road
Dayton, Ohio 45401-1408

Re: K934601
NDM® Hydrogauze™ Wound Dressing with Clearsite®
Regulatory Class: Unclassified
Dated: December 13, 1993
Received: December 14, 1993

Dear Dr. Donald E. Koopman:

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 to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. 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 registration, listing of devices, good manufacturing practice, and 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. 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 the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

9

2/15/94

K934601

SECTION 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION OF NDM'S MODIFIED VERSION OF ITS CLEARSITE HYDROGEL WOUND DRESSING THAT WILL BE MARKETED UNDER THE NAME HYDROGAUZE™

Pursuant to Section 12(a) of the Safe Medical Devices Act of 1990, 21 U.S.C. § 360(c)(i)(3)(A) and the regulations promulgated pursuant thereto, 21 C.F.R. §§ 807.87 and .92, the following summary of information concerning the safety and effectiveness of NDM's modified version of its ClearSite Hydrogel Wound Dressing to be marketed under the proprietary name Hydrogauze™ is hereby submitted.

A. Summary of Descriptive Information:

1. Submitter's Name, Address, Telephone Number, Regulatory Correspondent and Date Summary was Prepared:

   (a) NDM Acquisition Corporation
   3040 East River Road
   Dayton, OH 45439
   1-800-783-1767

   (b) Regulatory Correspondent of Submitter:

   Donald E. Koopman, Ph.D.
   RA/QA Manager
   NDM Corporation
   3040 East River Road
   Dayton, OH 45439
   1-800-783-1767 (Ext. 293)

   (c) Date Summary was Prepared:

   September 20, 1993

2. Name of Device:

   (a) Proprietary Name: NDM® Hydrogauze™ Wound Dressing with ClearSite®

   (b) Common, usual name: dehydrated hydrogel wound dressing.

(c) Classification Name:

(i) Current: Liquid Bandage. See 21 C.R.F. § 880.5090. (Class I)

(ii) Proposed Reclassification Name: Hydrogel Wound and Burn Dressing (Class I). See Proposed Rule 21 C.R.F. § 878.4022, 54 Federal Register 38600 (September 19, 1989).

3. Predicate Devices to which NDM is Claiming Substantial Equivalence:

NDM claims substantial equivalence for purposes of Section 510(k) to NDM's wound dressings bearing the tradenames Pharmaseal® Sterile Wound Care Dressing and ClearSite Wound Dressing, which were found substantially equivalent on July 6, 1989 under 510(k) Number K884397 with additional substantial equivalence determinations for expanded usage and modifications on October 23, 1991 under 510(k) Number K914207, April 21, 1992 under 510(k) Number K920677 and on May 12, 1993 under 510(k) Number K926202.

4. Description of the Modified Device:

(a) General Components of Device:

This sterile, single use, borderless Hydrogauze wound dressing consists of dehydrated hydrogel impregnated within the interstices of cotton gauze. One variation of this modified device will be in the form of a self-adhesive bandage, in which the dehydrated hydrogel impregnated gauze material lattice may be bonded to a pressure sensitive medical grade adhesive coated film.

(b) Operational Principles of the Modified Device:

The basic operational principles of the device are external covering and fluid absorption of wounds. The Hydrogauze wound dressing will be applied externally to secreting skin wounds as a covering to protect them against abrasion, friction, desiccation and contamination. The other basic operational principle of the device is the absorption of fluid process. The dressing does not adhere to the wound (the self-adhering version adheres to skin surrounding the wound or new skin tissue formed in wound). Removal of the wound dressing does not disrupt healing or destroy new tissue. Because of its dehydrated condition, this form of hydrogel

material is able to absorb wound exudate faster than hydrated hydrogel used in the currently marketed devices.

5. Statement of the Intended Use of the Device:

(a) Intended Usage and Patient Population.

This sterile, single use device is intended to serve as a temporary external covering for management of skin wounds secreting large amounts of exudate, such as decubitus ulcers, open surgical wounds and donor site wounds. As an external covering, the dressing is intended to protect against abrasion, friction, desiccation and contamination of the wound. With its absorptive capacity, the dressing is intended to provide rapid absorption of wound exudate for wounds secreting large amounts of exudate. The modified dressing will also be labeled as a device that creates a moist environment thereby assisting a skin wound in reaching its maximum rate of re-epithelization. The device will be labeled for use on first and second degree burns, superficial and full thickness wounds, stage I through stage IV pressure ulcers and for use in the management of dermal leg ulcers including venous stasis ulcers. The device may be used on both adult and pediatric patients. However, the device will <u>not</u> be labeled for use on third degree burns, as having any pharmacological effect on accelerating the rate of wound healing, as a long term dressing or as a treatment or cure for vascular stasis ulcers without supplemental notification to and clearance by FDA.

(b) Differences in Intended Usage From Predicate Device in Paragraph (A)(3).

There are no differences in intended usages from the predicate devices listed in Paragraph (A)(3) of this Summary.

6. Comparison of the Modified Device's Technological Characteristics to Those of the Predicate Devices in Paragraph (A)(3):

As the comparison matrix below demonstrates, the modified dressing is substantially equivalent in terms of its primary features (technological characteristics) and principles of operation to the currently-marketed NDM wound dressings.

	Currently Marketed NDM Wound Dressings	Modified NDM Hydrogauze Wound Dressing
Primary Features		
Support Scrim	Medical grade cotton or polyester gauze material	Medical grade cotton gauze
Membrane bonded to backing material	Polyurethane film	Polyurethane or vinyl film in some versions
Absorptive material that contacts wound	NDM ClearSite Hydrogel	Dehydrated NDM ClearSite Hydrogel
Flexible	Yes	Yes
Sterile	Yes	Yes
Substantially Transparent	Yes in some versions	Translucent
Able to maintain integrity after absorbing exudate	Yes	Yes
Thickness of Dressing	70-145 mils	10-60 mils
Adhesive on self-adhering version	Medical grade acrylic	Medical grade acrylic
Principles of Operation	(i) External covering of wound. (ii) The absorption process.	(i) External covering of wound. (ii) The absorption process. Because of its dehydrated condition, dehydrated hydrogel material is able to absorb wound exudate faster than hydrated hydrogel used in currently marketed device.
Bacterial barrier	Yes.	Yes, in versions with polyurethane or vinyl film; otherwise, it is recommended that a bacterial barrier be obtained by covering the dressing with a semipermeable barrier film.
Performance Standards	None applicable	None applicable

B. Assessment of Performance Data:

1. Brief Discussion of Nonclinical Tests and Their Results:

All the materials being used in the modified hydrogauze wound dressing have been tested and/or considered for biocompatability under the conditions for which the device is intended to be used. Nonclinical safety testing on the hydrogauze wound dressing demonstrated that it is: non-toxic; non-hemolytic; non-irritating to skin; non-irritating to eyes; non-mutagenic; and, non-sensitizing. The wound dressing is not a nutrient source for microorganisms. All of these tests were performed in accordance with the Good Laboratory Practices Regulations where applicable (21 C.F.R., part 58). Furthermore, the modified device has passed as a U.S.P. Class V plastic. The medical grade cotton gauze used in the device is generally recognized as safe.

2. Conclusions Drawn From Nonclinical Safety Tests:

All of the nonclinical safety testing performed on the modified device demonstrate that the dehydrated hydrogel and reduced thickness changes to the wound dressing present no new issues of safety and effectiveness when compared to the currently marketed wound dressings. Moreover, these tests demonstrate that the modified dressing can be safely used on wounds that require a rapid removal of wound exudate by absorption.