

K983362

DEC 16 1998

510 (k) NU-GEL* Wound Dressing
Full Thickness Wound Submission**APPENDIX F****510(k) SUMMARY****1. DATE PREPARED**

December 1, 1998

2. SUBMITTER

Johnson & Johnson Medical
Division of Ethicon Inc.
2500 Arbrook Blvd.
P.O. Box 90130
Arlington, TX 76004-3130

3. CONTACT PERSON

Terry James Dagnon
Regulatory Affairs Project Manager
Phone: 817-262-4953
Fax: 817-262-4992

4. NAME OF THE MEDICAL DEVICE

Classification Name:	Dressing, Wound
Common/Usual Name:	Topical wound dressing
Proprietary Name:	NU-GEL* Wound Dressing

5. DEVICE CLASSIFICATION

Product Code/Classification Number:	Unclassified
Regulatory Class:	Unclassified

6. STATEMENT OF SUBSTANTIAL EQUIVALENCE

NU-GEL* Wound Dressing is substantially equivalent and identical in function to DuoDERM* CGF Control Gel Formula Border Dressing (K973688) manufactured by ConvaTec - A Division of E.R. Squibb & Sons, Inc.

7. INDICATIONS FOR USE

NU-GEL* Wound Dressing is a sterile hydrogel formulation of preserved polyvinyl pyrrolidone in water. The gel is supported by a fusible fiber fabric scrim and protected on both sides by polyethylene film. NU-GEL* Wound Dressing maintains a moist wound environment. A moist wound environment supports the wound healing process by encouraging autolytic debridement thus enabling granulation to proceed under optimum conditions. It protects against dehydration, bacterial contamination and absorbs exudate from the wound.

NU-GEL Wound Dressing is indicated for dry, light and moderately exuding partial and full thickness wounds such as:

- First and second degree burns
- Severe sunburns
- Superficial injuries, superficial lacerations, cuts, abrasions, incisions/surgical wounds, and skin tears

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NU-GEL[®] Wound Dressing should be used under health care professional direction for the following indications:

- Burns caused by radiation oncology procedures
- Pressure ulcers Stage I-IV
- Lower extremity ulcers
- Venous ulcers
- Arterial ulcers
- Ulcers of mixed etiology
- Diabetic ulcers
- Donor sites and skin grafts

Precautions:

NU-GEL[®] Wound Dressing is not indicated for use on the following:

- Third degree burns
- Lesions with active vasculitis as this type of ulcer needs more frequent observation by a healthcare professional.

NU-GEL[®] Wound Dressing may be used when visible signs of infection are present in the wound area only when proper medical treatment addresses the underlying cause.

NU-GEL[®] Wound Dressing may be used under compression therapy with healthcare profession supervision.

8. PHYSICAL DESCRIPTION

NU-GEL[®] Wound Dressing is a sterile hydrogel formulation of preserved polyvinyl pyrrolidone in water. The gel is supported by a fusible fiber fabric scrim and protected on both sides by polyethylene film. NU-GEL[®] Wound Dressing maintains a moist wound environment. A moist wound environment supports the wound healing process by encouraging autolytic debridement thus enabling granulation to proceed under optimum conditions. It protects against dehydration, bacterial contamination and absorbs exudate from the wound.

9. BIOCOMPATIBILITY

The following safety testing was conducted in accordance with ISO 10993 Part 1 Biological Evaluation of Medical Devices to support the Biocompatibility of this product.

SAFETY TESTING	
TEST	RESULTS
Cytotoxicity	Non-toxic
Primary Skin Irritation	Non-irritating
Wound Healing (Guinea Pig Excision)	No Adverse Effects
Burn Healing Study (Mice)	Reduced Inflammation-equivalent to immediately immersing the burn in ice water for 3 minutes
Porcine Partial Thickness Wound Healing	No Adverse Effects
Porcine Burn Wound Healing	No Adverse Effects
Kligman Chamber Scarification	Irritation Potential - Low



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Terry J. Dagnon
Johnson & Johnson Medical, Inc.
2500 Arbrook Blvd
P.O. Box 90130
Arlington, Texas 76004

Re: K983362
Trade Name: Nu-Gel Wound Dressing
Regulatory Class: Unclassified
Product Code: MGQ
Dated: September 23, 1998
Received: September 24, 1998

Dear Mr. Dagnon:

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.

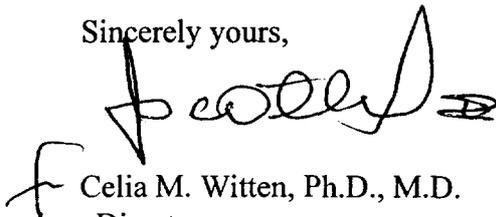
Page 2 - Mr. Terry J. Dagon

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,

A handwritten signature in black ink, appearing to read "C. Witten", with a stylized flourish at the end.

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

**510(k) NU-GEL* Wound Dressing
Full Thickness Wound Submission**

510(k) Number : K983362
Applicant: Johnson & Johnson Medical
A Division of Ethicon Inc.
2500 Arbroom Blvd.
Arlington, TX 76004-3130

Device Name: NU-GEL* Wound Dressing

Indications for Use:

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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)

[Signature]

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K983362

Prescription Use _____ Or Over-The-Counter Use X
(Per 21 CFR 801.109)