

K982577

OCT 21 1998

510(k) SUMMARY**Neurogena MD™ Cream with Glycerin
(79 MGQ)**

1. SUBMITTER'S NAME
2. CONTACT PERSON AT NEUROGENA
3. DATE THAT 510(k) SUMMARY WAS PREPARED
4. NAME OF THE MEDICAL DEVICE (Classification / Common / Proprietary)
5. LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED
6. DESCRIPTION OF THE DEVICE
7. INTENDED USE OF THE DEVICE
8. TECHNOLOGICAL COMPARISON BETWEEN SUBJECT AND PREDICATE DEVICES
9. SUMMARY OF SAFETY STUDIES AND CONCLUSIONS FROM SAFETY STUDIES

1. SUBMITTER'S NAME
NEUROGENA CORPORATION 5760 West 96th Street Los Angeles, CA 90045
Telephone: (310) 642-1150 Fax: (310) 337-2156

2. CONTACT PERSON AT NEUROGENA CORPORATION
Dr. Yohini Appa Director Claims, Safety/Regulatory Affairs
Telephone: (310) 337-5585 Fax: (310) 216-5399

3. DATE THAT 510(k) SUMMARY WAS PREPARED

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510(k) SUMMARY
Neutrogena MD™ Cream with Glycerin

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4. NAME OF THE MEDICAL DEVICE	
Classification name	<i>Dressing, wound and burn, hydrogel (Surgery 79 MGQ)</i>
Common / usual name	<i>Hydrogel dressing</i>
Proprietary name	<i>Neutrogena MD™ Cream with Glycerin</i>

5. LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED
<ul style="list-style-type: none"> • SoloSite Dermal Wound Gel (Smith & Nephew, K932263) • Spand-Gel Wound Gel (K864124, Medi-Tech International)

6. DESCRIPTION OF THE DEVICE
Neutrogena MD™ Cream with Glycerin is a hydrogel wound dressing composed primarily of water and glycerin.

7. INTENDED USE OF THE DEVICE
<p>Neutrogena MD™ Cream with Glycerin is intended for use in the management of minor burns and abrasions associated with resurfacing procedures, such as dermabrasion, chemical resurfacing, or laser resurfacing, in order to provide a moist wound healing environment that is supportive of healing.</p> <p>For external use only. Not intended for use on 3rd degree burns.</p>

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8. TECHNOLOGICAL COMPARISON BETWEEN SUBJECT AND PREDICATE DEVICES

Neutrogena MD™ Cream with Glycerin, Solosite (K932263) and Spand-Gel (K864124) are all formulated to help maintain a moist wound healing microenvironment.

Neutrogena MD™ Cream with Glycerin, Solosite (K932263) and Spand-Gel (K864124) are all hydrogels composed primarily of glycerin and water.

While other hydrogel products (e.g., Vigilon [Bard] and Cutinova Gel-Film [Beiersdorf]) include an occlusive backing, Neutrogena MD™ Cream with Glycerin, Solosite (K932263) and Spand-Gel (K864124) are all packaged in plastic tube dispensers.

Neutrogena MD™ Cream with Glycerin, Solosite (K932263) and Spand-Gel (K864124) all contain similar preservative systems (methylparaben/propylparaben).

Spand-Gel contains a small amount of absorbent polycarbonate beads that gives it an absorbent property.

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9. SUMMARY OF SAFETY STUDIES AND CONCLUSIONS FROM SAFETY STUDIES

Neutrogena MD™ Cream with Glycerin has been evaluated through *in vitro* tests and animal safety studies. This data is consistent in indicating that this product is safe for use as a topical wound management product. The categories of preclinical safety tests and the safety test conclusions are as follows:

- Cytotoxicity - USP Agar Diffusion
 - ▷ product *met the requirements of the USP*
- Primary Skin Irritation In Rabbits
 - ▷ product is *not classified as a primary irritant or as a corrosive*
- Delayed Contact Hypersensitivity in Guinea Pigs
 - ▷ product *is not a sensitizer*

Neutrogena MD™ Cream with Glycerin has also been evaluated in the following clinical studies:

- Appa, Y. and L. Hemingway. May 10, 1994. *Dry skin healing. A controlled double-blind clinical evaluation of cream and liquid moisturizers.* Research and Development Department Report. Neutrogena Corporation, Los Angeles, CA.
- Goldman, M. 1998. Preliminary results from:
The Effect of an Integrative Wound Management Regimen for Skin Following Facial Resurfacing Procedures (GS9710.01/A1)
 - ▷ product is "...suitable for use in resurfacing procedures".



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Yohini Appa, Ph.D.
Neutrogena Corporation
5760 West 96th Street
Los Angeles, California 90045

Re: K982577
Trade Name: Neutrogena MD™ Cream with Glycerin
Regulatory Class: Unclassified
Product Code: MGQ
Dated: July 24, 1998
Received: July 24, 1998

Dear Dr. Appa:

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).

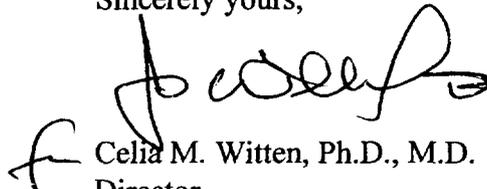
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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,

A handwritten signature in black ink, appearing to read 'C. Witten', is written over the typed name.

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K982577

Device Name: Neutrogena MD™ Cream with Glycerin

Indications For Use:

Neutrogena MD™ Cream with Glycerin is intended for use in the management of minor burns and abrasions associated with resurfacing procedures, such as dermabrasion, chemical resurfacing, or laser resurfacing, in order to provide a moist wound environment that is supportive of healing.

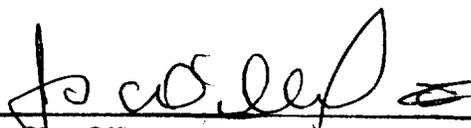
For external use only. Not intended for use on 3rd degree burns.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRII, Office of Device Evaluation (ODE)

Prescription Use ✓
(per 21 CFR 801.109)

OR Over-The-Counter Use _____



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982577