3/1/99

K984370

510(k) SUMMARY

Applicant:	Mölnlycke Health Care 500 Baldwin Tower Eddystone, PA 19022
Proprietary Name:	Hypergel® - 20% Hypertonic Saline Gel
Contact Person:	Miguel A. Negron, Manager, Regulatory Affairs & Quality Tel. 610-499-3383
Substantially Equivalent Device:	Hypergel® - 20% Hypertonic Protective Wound Gel

Hypergel® 20% Hypertonic Saline Gel is a sterile sodium chloride solution in amorphus gel form. Hypergel is composed of water, sodium chloride, sodium hydroxide, xanthan gum, and potassium phosphate. Hypergel provides a moist wound environment. Moist wound environment is known to support autolytic debridement. Hypergel is recommended for the softening and removal of dry necrosis in wounds such as pressure ulcers, venous and arterial leg ulcers, diabetic ulcers, and open surgical wounds.

Hypergel® 20% Hypertonic Saline Gel represents a new formulation of Mölnlycke Health Care currently marketed Hypergel Protective Wound Gel product. This new formulation provides a higher viscosity.

Hypergel® 20% Hypertonic Saline Gel is provided in 5 gm and 15 gm volumes in aluminum tubes. The tube nozzle is sealed with an aluminum foil which can be opened by employing a puncturing device integral to the inner surface of the cap. The nozzles are fitted with a poly retaining ring/collar which prevents the aluminum foil from being inadvertently punctured during manufacturing and handling.

The biocompatibility of Hypergel have been determined when tested in accordance with the ISO 10993 Part I, "Biological Evaluation of Medical Devices" with FDA modified matrix (Guidance effective July 1, 1995).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 1999

Mr. Miguel A. Negron
Manager, Regulatory Affairs and Quality
Mölynlycke Health Care
500 Baldwin Tower
Eddystone, Pennsylvania 19022

Re: K984370
Trade Name: Hypergel® - 20% Hypertonic Saline Gel
Regulatory Class: Unclassifed
Product Code: MGQ
Dated: December 4, 1998
Received: December 7, 1998

Dear Mr. Negron:

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).

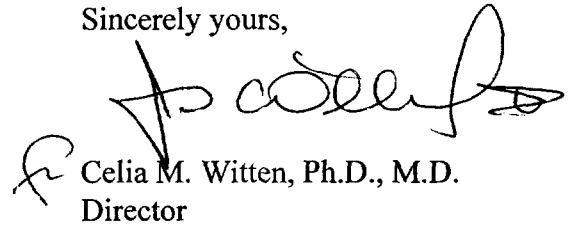
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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

K984370

Section 8: Indications for Use Statement

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: K984370

Mölnlycke Health Care

Device Name: Hypergel® - 20% Hypertonic Saline Gel

Indications for Use:

Hypergel provides a moist wound environment. Moist wound environment is known to support autolytic debridement. Hypergel is recommended for the softening and removal of dry necrosis in wounds such as pressure ulcers, venous and arterial leg ulcers, diabetic ulcers, and open surgical wounds.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

Or Over-The-Counter Use _____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984370