K973036

NOV 12 1997

510(k) Summary of Safety and Effectiveness

Manufacturer: 3M Medical Products Division
3M Center
St. Paul, Minnesota 55133

Regulatory Affairs Contact: Karen C. Holmen
Regulatory Affairs Specialist
3M Medical Products Group
3M Center 275-3E-08
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Date Summary Prepared: 7/25/97

Product Trade Name: 3M Tegaderm™ Transparent Dressing (original frame style and easy application frame style)
3M Tegaderm™ Transparenet Dressing (First Aid Delivery)
3M Tegaderm™ HP Transparent Dressing
3M Tegaderm™ Transparent I.V. Dressing

Common Name: Wound dressing, IV Secural dressing

Classification: Intravascular catheter securement device, wound dressings, and/or protective eye covering, Class I.

Predicate Devices: 3M Tegaderm Transparent Dressings mentioned above, Op-Site^{R} Transparent Permeable Membrane, OpSite^{R} I.V. 3000 Bioclusive™ Transparent Dressing, Transeal™ Transparent Dressing, Conmed Veni-Gard® Dressing, Pro-Clude® Transparent Wound Dressing, Polyskin® M.R. Moisture Responsive Transparent Dressing

Description: 3M Tegaderm™ Transparent Dressing consists of a thin, polyurethane film backing with a hypoallergenic, acrylate, pressure sensitive adhesive. The dressing is transparent and possess good oxygen and moisture vapor permeability and yet is impermeable to liquids and bacteria.

Intended Use: 3M Tegaderm™ Transparent Dressings can be used over a variety of IV catheters and other devices, for wound management and as a protective eye covering. Tegaderm HP dressing provides stronger adhesion, particularly in problem areas. The later was designed to stay on even longer and help reduce unscheduled dressing changes in challenging situations, e.g. diaphoretic patients, conditions of high humidity, febrile patients, any high moisture-prone areas for venous catheterization, such as the jugular area, and difficult-to-dress wound areas (sacral).

Substantial Equivalence: This 510(k) proposed to delete a warning on current labeling for 3M Tegaderm™ Transparent Dressings, specifically, the warning regarding its use over arterial catheter sites. Neither literature, clinical studies, CDC guidelines for the Prevention of Intravascular Device-Related Infections, nor FDA Device Labeling Guidance re the use of Precautions, Warnings or Contraindications support such a warning. Furthermore, 3M Tegaderm Transparent Dressings are substantially equivalent to other standard transparent dressings on the market, none of which contraindicate or warn against use over arterial catheter sites at this time, as evidenced by labeling presented in this submission.

Note: The term "substantial equivalence" is used only in the context of 21 CRF Part 807, Subpart E (Premarket Notification Procedures).

Summary of Testing: No product data submitted; this submission is seeking deletion of a contraindication/warning from current labeling and relied on known literature, lack of conclusive clinical studies, CDC Guidelines for Prevention of Intravascular Device-Related Infections, and FDA guidance as support for the proposed deletion. All data supplied in previous 510(k)s are not changed and are applicable to this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 12 1997

Ms. Karen C. Holmen
Regulatory Affairs Specialist
3M Health Care
3M Center 275-3E-08 PO Box 3275
St. Paul, Minnesota 55133-3275

Re: K973036
3M™ Tegaderm™ Transparent Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: August 7, 1997
Received: August 14, 1997

Dear Ms. Holmen:

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,

for 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) Number (if Known): K973036

Device Name: 3M™ Tegaderm™ Transparent Dressings

Indications for Use:

3M Tegaderm Transparent Dressings can be used to cover and protect catheter sites and wounds, to create a moist enviroment for wound healing, as a secondary dressing, as a protective cover over at risk skin, to secure devices to the skin and as a protective eye covering. It can also be used to create a moist wound environment to facilitate autolytic debridement. Common applications include: IV catheters, other intravascular catheters and percutaneous devices, clean closed surgical incisions, skin graft donor sites, Stage I or II pressure ulcers, superficial wounds such as abrasions, skin tears, and blister, first and second degree burns, chafed skin or skin continuously exposed to moisture, secondary dressing over gauze, alginates or hydrogels, protective eye covering during surgery or for patients with corneal abrasions.

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

Concurrence of CHRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973036

Prescription Use: __V__ OR Over-the-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)