K982892

OCT 26 [redacted] 510(k) Summary of Safety and Effectiveness

Manufacturer:	**3M Medical Products** **3M Center** **St. Paul, Minnesota 55144-1000**
Regulatory Affairs Contact:	**Anna E. McRight** **Regulatory Affairs Specialist** **3M Medical Products Resource Division** **3M Center, Building 275-3E-08** **St. Paul, Minnesota 55144-1000**
Telephone:	**(651) 733-7948**
Date Summary Prepared:	**August 13, 1998**
Product Trade Name:	**3M Tegasorb™ THIN Hydrocolloid Dressing**
Common Name:	**Wound Dressing**
Classification:	**Wound Dressing**
Predicate Devices:	**3M Tegasorb™ Ulcer Dressing (see also, K924280, May 12, 1993, for competitive comparable products).**
Description:	**[3M Tegasorb™ and] 3M Tegasorb™ Thin Hydrocolloid Dressings are sterile wound dressings which consist of a hypoallergenic hydrocolloid adhesive with an outer clear adhesive cover film. The film is moisture vapor permeable and water and bacteria impermeable. The products are not designed, sold or intended for use except as indicated. Over the wound site, [3M Tegasorb and] 3M Tegasorb THIN Hydrocolloid dressings interact with wound fluid to create a soft, semi-transparent absorbent mass. The dressings maintain a moist wound environment, which has been shown to enhance wound healing.** (continued)

K982897

Intended Use:	**3M Tegasorb™ THIN Hydrocolloid Dressing is intended for use as a dressing for partial thickness dermal ulcers, leg ulcers, superficial wounds, abrasions, first- and second-degree burns, and donor sites. It may also be used as a protective dressing on at-risk, undamaged skin or on skin beginning to show signs of damage from friction or shear.**
Substantial Equivalence:	**This premarket notification was submitted for package insert changes only. The comparative products remain identical to those submitted in the premarket notification, K924280, cleared for marketing by FDA on May 12, 1993.**
Summary of Testing:	**See K924280 which provided biocompatibility test results to support 3M Tegasorb™ THIN Hydrocolloid Dressing as acceptable for its intended use.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 1998

Anna E. McRight.
3M Medical Products Division
Building 275 - 3E- 08
St. Paul, Minnesota 55144

Re: K982892
Trade Name: 3M Tegasorb™ Thin Hydrocolloid Dressing
K982893
Trade Name: 3M Tegasorb™ Hydrocolloid Dressing
Regulatory Class: Unclassifed
Product Code: KMF
Dated: August 13 and 14, 1998
Received: August 17, 1998

Dear Ms. McRight:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined the devices are 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 devices subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. These devices may not be labeled for use on third degree burns.

2. These devices may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.

3. These devices may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.

4. These devices 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 devices and would require a premarket notification submission (21 CFR 807.81).

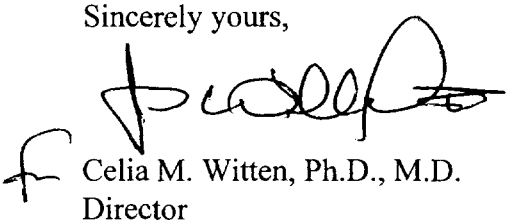
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your devices are 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 devices 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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

K982892

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510(k) Number (if known): ~~**K924280, May 12, 1993**~~

Device name: 3M Tegasorb™ THIN Hydrocolloid Dressing, Product Number series 90021-90025.

Indications for Use:

The following conditions are considered appropriate for OTC use by the lay person:

- **Superficial wounds such as cuts, lacerations, or abrasions**
- **First-degree burns**
- **Skin needing protection from friction or sheer**

The following conditions are considered appropriate for OTC use under the supervision of a health care professional:

- **Partial thickness dermal ulcers**
- **Leg ulcers**
- **Second-degree burns**
- **Donor sites**

[PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED]

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over the Counter Use** ✓

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982892