FEB 20 1998

Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048-3781

K980209

Hollister Incorporated
Thin Film Wound Dressings

Safety and Effectiveness Summary

1. Submitter's name, Address and Contact Person

Submitter
Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

Contact Person
Joseph S. Tokarz
Manager, Regulatory Affairs
Phone (847)680-2849
Fax (847)918-3860

Date Summary Prepared - January 5, 1998

2. Name of Device:

SimpliCare Thin Film Wound Dressing

3. Name of Predicate Device(s)

Innovative Technologies Transparent Thin Film Wound Dressing
Innovative Technologies Intelligent Thin Film Wound Dressing

4. Description of Device

The Hollister Incorporated Thin Film Wound Dressings are transparent polyurethane films that are backed with a pressure sensitive acrylic adhesive. An unique closed cell foam application grid allows for easy handling of the film dressing during application to the wound sites. The Hollister Thin Film Wound Dressings are designed to have a high moisture vapor transmission rate and are intended to provide a moist wound healing environment to facilitate the normal wound healing process. The Hollister Thin Film Wound Dressings provide a barrier to bacteria and external contaminates such as feces and urine.

The dressings are also intended to be used on IV sites or as secondary fixation devices for products such as alginates, gels, and foams used for venous stasis and diabetic ulcers.

The Hollister Thin Film Wound Dressings are presented sterile and are available in a variety of sizes to accommodate various sizes of wounds.

5. Statement of Intended Use

The Hollister Thin Film Wound Dressings are intended to provide a moist wound healing environment to facilitate the normal wound healing process. The Hollister Thin Film

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Thin Film Wound Dressings

Wound Dressings provide a barrier to bacteria and external contaminates such as urine and feces. The Hollister Thin Film Wound Dressings are also intended to be used on IV sites or as secondary fixation devices for products such as alginates, gels and foam dressings used for venous stasis and diabetic ulcers.

1. Indications for Use

OTC:
- minor burns
- superficial cuts, lacerations and abrasions
- minor irritations of the skin

Under the care of a health care professional:
- non-exuding to minimally exuding wounds
- pressure sores
- lacerations/abrasions
- partial and full thickness wounds
- surgical incisions
- second degree burns
- donor sites
- IV sites
- secondary fixation device

2. Contraindications for Use
- Third degree burns

6. Statement of Technological Characteristics of the Device

A. The Hollister Transparent Film Dressings are comprised of two parts: A transparent film dressing with removable backing paper and a foam application grid. The Transparent Film Dressings are permeable to moisture vapor and oxygen. The films transmit water, but retain other exudate components creating the ideal environment for wound healing.

Characteristic	Hollister Proposed 1	Hollister Proposed 2	I.T. Transparent Film	I. T. Intelligent Filr
Intended Use	intended to provide a moist wound healing environment to facilitate the normal wound healing process	same	same	same

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Thin Film Wound Dressings

Characteristic	Hollister Proposed 1	Hollister Proposed 2	I.T. Transparent Film	I. T. Intelligent Film
Indications for Use	OTC: • minor burns • superficial cuts, lacerations and abrasions • minor irritations of the skin **Under the care of a health care professional:** • non-exuding to minimally exuding wounds • pressure sores • lacerations/ abrasions • partial and full thickness wounds • surgical incisions • second degree burns • donor sites • IV sites • secondary fixation device	OTC: • minor burns • superficial cuts, lacerations and abrasions • minor irritations of the skin **Under the care of a health care professional:** • non-exuding to minimally exuding wounds • pressure sores • lacerations/ abrasions • partial and full thickness wounds • surgical incisions • second degree burns • donor sites • IV sites • secondary fixation device	• Partial thickness wounds • Pressure sores • Abrasions • Superficial burns • Lacerations • Donor sites • IV sites • Fixation device • Post-operative surgical wounds	• Partial thickness wounds • Pressure sores • Abrasions • Superficial burns • Lacerations • Donor sites • IV sites • Fixation device • Post-operative surgical wounds
Contraindications for Use	Third degree burns	Third degree burns	Third degree burns	Third degree burns
Transparent	Yes	Yes	Yes	Yes
Film Composition	Polyurethane film/ pressure sensitive acrylic adhesive laminate	Polyurethane film/ pressure sensitive acrylic adhesive laminate	Polyurethane film/ pressure sensitive acrylic adhesive laminate	Polyurethane film/ pressure sensitive acrylic adhesive laminate
Application Grid	Closed cell Polyethylene/Ethylene Vinyl Acetate Copolymer Foam/ Acrylic Adhesive Laminate	Closed cell Polyethylene/Ethylene Vinyl Acetate Copolymer Foam/ Acrylic Adhesive Laminate	NA	NA
MVTR $g/m^2/24$ h	<2500	3000-6000	<2500	3000-15000
Sterilization method	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation

B. Material Biocompatibility: The biocompatibility of the Hollister Thin Film Wound Dressings was assessed based on principles and guidelines established by various governmental and standard setting organizations, such as: EN 30993, European Commission (EC) Standard; General Program Memorandum #G95-1, U.S. FDA Office of Device Evaluation; United Stated Pharmacopeia (USP). Material biocompatibility issues have been addressed based upon biomaterial history or in separate in vitro or in vivo laboratory evaluations using licensed commercial reference laboratories. These evaluations have been contracted either by Hollister or the suppliers of the materials. Based upon the results of this assessment, the materials used to fabricate the Hollister Thin Film Wound Dressings are considered biocompatible and appropriate for their intended use.

C. Based upon information presented above, the Hollister Thin Film Wound Dressings are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 20 1998

Mr. Joseph S. Tokarz
Manager, Regulatory Affairs
Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048-3781

Re: K980209

Trade Name: SimpliCare Thin Film Wound Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: January 19, 1998
Received: January 21, 1998

Dear Mr. Tokarz:

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).

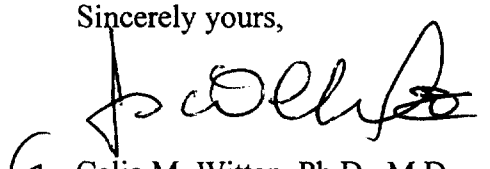
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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

Hollister Incorporated
Thin Film Wound Dressings

b. Statement of Indications for Use

510(k) Number (if Known): K980209
Device Name: Hollister Thin Film Wound Dressings

Indications For Use:

The Hollister Thin Film Wound Dressings are intended to provide a moist wound healing environment to facilitate the normal wound healing process. The Hollister Thin Film Wound Dressings provide a barrier to bacteria and external contaminates such as urine and feces. The Hollister Thin Film Wound Dressings are also intended to be used on IV sites or as secondary fixation devices for products such as alginates, gels and foam dressings used for venous stasis and diabetic ulcers.

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   OTC:
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   Under the care of a health care professional:
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   - post-operative surgical wounds
   - second degree burns
   - donor sites
   - IV sites
   - secondary fixation device

2. Contraindications for Use
   - Third degree burns

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR AND Over-the-Counter-Use ✓

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980209