

OCT 14 1999

K991214



Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048-3781

Hollister Incorporated
SimpliCare Transparent Wound Dressing
October 4, 1999

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
Ph (847)680-2849
Fax (847)918-3860

Date Summary Prepared – July 8, 1999

2. Name of Device:

Hollister SimpliCare Transparent Wound Dressing

3. Name of Predicate Device(s)

Bioclusive Transparent Dressing, K923235
EpiVIEW Thin Film Dressing, K961319

4. Description of Device

The Hollister SimpliCare Transparent Wound Dressing is a polyurethane film that is backed with a pressure sensitive acrylic adhesive. A unique closed cell foam application grid allows for easy handling of the film dressing during application to the wound sites. The Hollister Transparent Wound Dressing is designed to have a high moisture vapor transmission rate and is intended to provide a moist wound healing environment to facilitate the normal wound healing process. The Hollister Transparent Wound Dressing provides a barrier to viral¹ and bacterial contaminants and other external contaminants such as feces and urine while the dressing remains intact without leakage.

The dressing is also intended to be used on IV sites or as secondary fixation device for products such as alginates, gels, and foam dressings.

The Hollister Transparent Wound Dressing is presented sterile and is available in a variety of sizes to accommodate various sizes of wounds.

5a. Statement of Intended Use (Prescription)

The SimpliCare Transparent Wound Dressing is intended to provide a moist wound healing environment to facilitate the normal wound healing process. The SimpliCare Transparent Wound Dressing provides a barrier to viral and bacterial contaminants and other external contaminants such as urine and feces. The SimpliCare Wound Dressing is also intended to be used on IV sites or as secondary fixation device for products such as alginates, gels and

¹ ASTM F1671-97 "Standard Test Method for Resistance of Materials used in Protective clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System."

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foam dressings.

The SimpliCare Transparent Wound Dressing is indicated for use on wounds including:

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

This wound dressing may also be used for non-exudating to minimally exudating partial and full thickness wounds such as:

- pressure ulcers
- lacerations/abrasions
- surgical incisions
- second degree burns
- donor sites

In addition, the SimpliCare Transparent Wound Dressing can be used on IV sites and as a secondary fixation device

Contraindications for Use

- third degree burns

5b. Statement of Intended Use (OTC)

The SimpliCare Transparent Wound Dressing is intended to provide a moist wound healing environment to facilitate the normal wound healing process. The SimpliCare Transparent Wound Dressing provides a barrier to bacterial contaminants and other external contaminants such as urine and feces. The SimpliCare Wound Dressing is also intended to be used on IV sites or as secondary fixation device for products such as alginates, gels and foam dressings.

The SimpliCare Transparent Wound Dressing is indicated for use on wounds including:

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

This wound dressing may also be used under the care of a health care professional for non-exudating to minimally exudating partial and full thickness wounds such as:

- pressure ulcers
- lacerations/abrasions
- surgical incisions



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- second degree burns
- donor sites

In addition, the SimpliCare Transparent Wound Dressing can be used on IV sites and as a secondary fixation device.

Contraindications for Use

- third degree burns

6. Statement of Technological Characteristics of the Device

- A. The Hollister Transparent Wound Dressing is comprised of two parts: A transparent film dressing with removable backing paper and a foam application grid. The Transparent Wound Dressing is permeable to moisture vapor and oxygen. The film transmits water, but retains other exudate components creating the ideal environment for wound healing.
- B. **Material Biocompatibility:** The biocompatibility of the Hollister Transparent Wound Dressing 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 States 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 Transparent Wound Dressings are considered biocompatible and appropriate for their intended use.
- C. Based upon information presented above, the Hollister SimpliCare Transparent Wound Dressings are substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 1999

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

Re: K991214
Trade Name: SimpliCare Transparent Wound Dressing
Regulatory Class: Unclassified
Product Code: MGP
Dated: July 8, 1999
Received: July 20, 1999

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 enclosures) 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 (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

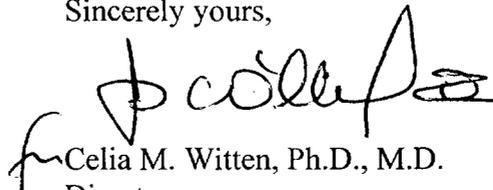
A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (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.

Page 2 – Mr. Joseph S. Tokarz

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 "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.

Director

Division of General and

Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosures

Hollister Incorporated
SimpliCare Transparent Wound Dressing

c.

Statements of Indications for Use

510(k) Number (if known): K991214
Device Name: SimpliCare Transparent Wound Dressing

Indications For Use:

The SimpliCare Transparent Wound Dressing is intended to provide a moist wound healing environment to facilitate the normal wound healing process. The SimpliCare Transparent Wound Dressing provides a barrier to viral and bacterial contaminants and other external contaminants such as urine and feces. The SimpliCare Wound Dressing is also intended to be used on IV sites or as secondary fixation device for products such as alginates, gels and foam dressings.

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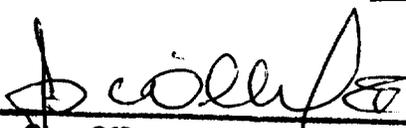
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter-Use


 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K991214