DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 7 - 2004

Mr. Joseph S. Tokarz
Director, Regulatory Affairs
Hollister Incorporated
2000 Hollister Drive
Libertyville, Illinois 60048

Re: K040779
Trade/Device Name: Restore Wound Cleanser
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: I
Product Code: KMF
Dated: March 24, 2004
Received: March 26, 2004

Dear Mr. Tokarz:

This letter corrects our substantially equivalent letter of May 17, 2004 regarding the identification of the Restore Wound Cleanser as a prescription device. The device will be marketed as an over-the-counter (OTC) product.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate 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) that do not require approval of a premarket approval (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 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 Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N. Milkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040779

Device Name: Restore Wound Cleanser

Indications For Use:
The restore Wound Cleanser is intended for the removal of foreign material such as dirt and debris from dermal wounds.

Prescription Use _____ AND/OR Over-The-Counter Use ____X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A Milkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040779

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MAY 17 2004

Hollister Incorporated
Restore Wound Cleanser
Pre-market notification –510(k)

510(k) Summary

1. Sponsor's name, Address and Contact Person

Sponsor	Contact Person
Hollister Incorporated 2000 Hollister Drive Libertyville IL. 60048	Joseph S. Tokarz Director, Regulatory Affairs Hollister Incorporated 2000 Hollister Drive Libertyville, IL 60048 Ph: (847) 680-2849 Fax: (847) 918-3860

Date Summary Prepared – March 23, 2004

2. Name of Device:
Restore Wound Cleanser

3. Name of Predicate Device(s)
- Carrington Carra Klenz Wound Cleanser K022670
- Allclenz Wound Cleanser K965120
- Derma Sciences Dermagran Wound Cleanser with Zinc K945802

4. Description of Device
The Restore Wound Cleanser is a buffered isotonic water based surfactant solution that is a clear colorless slightly viscous liquid that is intended to remove foreign material such as dirt and debris from dermal wounds. The device can be used on low, medium or high exudating dermal wounds. The product is available in an 8oz. spray bottle. The Restore Wound Cleanser is applied to the dermal wound area using a trigger spray closure that helps facilitate the removal of foreign material such as dirt and debris.

5. Statement of Intended Use
The Restore Wound Cleanser is intended for the removal of foreign material such as dirt and debris from dermal wounds.

6. Statement of Technological Characteristics and Substantial Equivalence
The Restore wound cleanser is substantially equivalent to the predicate devices identified in item 3 above in its intended use. All of the wound cleansers are intended for use on dermal wounds and abrasions. The R and the predicate devices are all indicated for high, medium, and low exudating dermal wounds.estore Wound Cleanser

Issues of biomaterial safety or biocompatibility have been addressed based upon biomaterial history or in separate in-vitro or in-vivo laboratory evaluations using licensed commercial reference laboratories. This assessment has been conducted based on the principles

and guidelines established by various governmental regulatory agencies and standard setting organizations.

Among these are the following:

- -- ISO 10993, International Standard Organization (ISO) Standard
- -- General Program Memorandum #G95-1, U.S. FDA Office of Device Evaluation
- -- United Stated Pharmacopoeia (USP)
- -- Federal Hazardous Substances Act Regulations (FHSA), 16CFR Part 1500
- -- FDA Good Laboratory Practice (GLP) Regulations, 21CFR Part 58

The biocompatibility tests that have been performed demonstrate that the Restore Wound Cleanser is considered appropriate for its intended use.

7. Conclusion

Based on the information presented above it is concluded that the proposed Restore Wound Cleanser is safe and effective for its intended use and is substantially equivalent to the identified predicate devices.