K970660

AUG 1 2 1997

510(k) PUBLIC SUMMARY

Submitter:

Derma Sciences, Inc.
121 West Grace Street
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Contact Person: Mary Clark, RN, PA-C
Director of Scientific Affairs

Date Summary Prepared: February 4, 1997

Name of the Device: Dermagran Wound Management System

Identification of Predicate Devices: Dermagran Wound Cleanser with Zinc: K945802 and K954743

Dermagran-B Hydrophilic Wound Ointment: K944491, K954739 and K963603

Description of the Device:

Dermagran Wound Management System (System) contains two components, Dermagran Wound Cleanser with Zinc and Dermagran-B Hydrophilic Ointment. The System, when applied to the wound provides a wound cleanser and primary cover and/or filler for wound deficiencies. The System absorbs exudate and creates a moist, mildly acidic wound environment. The moist environment created by the System is conducive to wound healing and autolytic debridement.

The System is useful in the management of various skin injuries which result in lacerations, abrasions, post-surgical wounds, skin ulcerations (pressure, diabetic, venous stasis), surgical incisions, and partial thickness burns.

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Intended Use:

Dermagran® Wound Management System (Systerm), when applied to the wound provides a wound cleanser and primary cover and/or filler for wound deficiencies. The System absorbs exudate and creates a moist, mildly acidic wound environment. The moist environment created by the System is conducive to wound healing and autolytic debridement.

The System is useful in the management of various skin injuries which result in lacerations, abrasions, post-surgical wounds, skin ulcerations (pressure, diabetic, venous stasis), surgical incisions, and partial thickness burns.

Comparison of device characteristics to predicate:

Derma Sciences, Inc. presently markets the predicate devices, Dermagran Wound Cleanser with zinc and Dermagran-B Hydrophilic Wound Ointment as separate products. The Dermagran Wound Cleanser with zinc is intended to cleanse wound prior to being covered with a dressing and the Dermagran-B Hydrophilic Wound Ointment is used as an occlusive, hydrophilic dressing to cover dermal wounds. Both products are indicated for various wounds such as; dermal ulcers, surgical wounds, abrasions, etc The Systerm, when applied to the wound provides a wound cleanser and primary cover and/or filler for wound deficiencies. The System absorbs exudate and creates a moist, mildly acidic wound environment The moist environment created by the System is conducive to wound healing and autolytic debridement These are the same characteristics provided by the predicates.

There is no difference in the design or formulation of the components from that which is described in K945802, K944491, K954739, K954743, K963603.

Labeling of the Dermagran Wound Management System contains the same indications as the predicates

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Testing for the Dermagran Wound Management System:

The components of the Dermagran Wound Management System were tested to determine the acute and sub-chronic toxicity in rabbits. The results from these studies indicated that the components did not produce any toxicity to the rabbits. Delayed contact hypersensitivity was determined in the guinea pig model. Results from this test did not indicate any signs of delayed hypersensitivity from components of the Dermagran Wound Management System.

Human volunteers were tested for dermal sensitivity to the components of the Dermagran Wound Management System. Results from this test did not indicate any significant signs of sensitivity from the components.

Finally, several clinical studies were preformed which demonstrated that the components when used as a system provide the same benefit as the predicate devices.

Conclusion:

Based on the indications for use, the materials used in the device, the performance characteristics it is concluded that the Dermagran Wound Management System is substantially equivalent to Dermagran Wound Cleanser with Zinc and Dermagran-B Hydrophilic Wound Ointment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Derma Sciences, Inc.
c/o Kenneth Palmer, Ph.D.
Senior Technical Advisor
Quintiles-Medical Technology Consultants
15825 Shady Grove Road, Suite 90
Rockville, Maryland 20850

AUG 12 1997

Re: K970660
Dermagran® Wound Management System
Regulatory Class: Unclassified
Product Code: KMF
Dated: June 25, 1997
Received: June 27, 1997

Dear Dr. Palmer:

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).

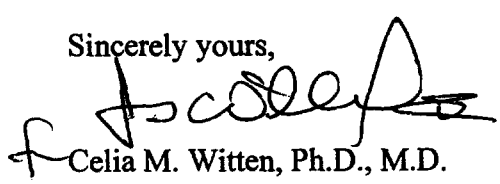
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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

INDICATIONS FOR USE

510(k) Number
K970660

Device Name
Dermagran® Wound Management System

Indications for Use

Dermagran® Wound Management System (Systerm), when applied to the wound provides a wound cleanser and primary cover and/or filler for wound deficiencies. The System absorbs exudate and creates a moist, mildly acidic wound environment. The moist environment created by the System is conducive to wound healing and autolytic debridement.

The System is useful in the management of various skin injuries which result in lacerations, abrasions, post-surgical wounds, skin ulcerations (pressure, diabetic, venous stasis), surgical incisions, and partial thickness burns.

Concurrence of CDRH, Office of Device Evaluation (ODE)

☒ Prescription Use (per 21 CFR 801.109)

☐ Over-the Counter Use

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970660