K080949
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# 510(k) Summary
# for
# Keratec Limited
# Keratec Wound Dressings

FEB 11 2009

## 1. SUBMITTER/510(K) HOLDER

Keratec Limited.
Canterbury Agriculture and Science Centre
Gerald Street, Lincoln 7608
Canterbury
NEW ZEALAND

Contact Person: Clive Marsh
Telephone: 64 3 325 9106
Date Prepared: April 2, 2008

## 2. DEVICE NAME

Proprietary Name: Keratec Wound Dressings
Common/Usual Name: Wound Dressings
Classification Name: Wound and Burn Dressings

## 3. PREDICATE DEVICES

- Oasis Wound Matrix by Healthpoint (K061711)
- Biocore Medical Technologies Inc. MediFil Collatek Hydrogel (K022995)
- Biocore Medical Technologies Collatek Foam (K012997)
- Johnson & Johnson Collagen ORC Antimicrobial Matrix (K033523)

## 4. DEVICE DESCRIPTION

The Keratec Keragel, Kerafoam and Keraderm Wound Dressings (Keratec Wound Dressings) are designed as chronic wound treatment devices for dry to heavily exuding wounds. The Keratec Wound Dressings are sterile, single-use wound care dressings that include keratin proteins derived from sheep wool for use in moist wound management.

The primary mode of action of keratin containing dressings Keragel, Keraderm and Kerafoam is to absorb and interact with wound fluids to form a soft, hydrophilic keratin

gel that facilitates a moist wound healing environment. The secondary mode of action is to provide the cells in the wound with a friendly structural framework that allows cellular migration where no framework exists.

**Keragel** is a gel dressing that provides moisture to dry wound beds by using water, emollients, and biocompatible thickeners in a similar manner to other hydrogels.

**Kerafoam** is a keratin film coated on a polyurethane foam substrate for use in multilayered advanced wound dressings. The keratin film is in matrix form with soluble keratin proteins. The Kerafoam product forms a gel when in contact with wound exudates. The Kerafoam provides the exudate management features of other advanced moist wound dressings.

**Keraderm** is open-celled foam derived from freeze-dried keratin protein. Keraderm is re-absorbed into the developing tissue without traumatic dressing changes. Keraderm provides a bio-absorbable "scaffold" for the rapid growth of new tissue in three dimensions. Keraderm is provided in an acellular form of keratin protein.

## 5. INTENDED USE

The Keratec Keragel, Kerafoam and Keraderm Wound Dressings are indicated for dry, light and moderately exudating partial and full thickness wounds such as:

- first and second degree burns
- severe sunburns
- superficial injuries, cuts, abrasions and surgical wounds

The Keratec Wound Dressings may also be used under the guidance of a health care professional in the management of the following types of dry, light and moderately exudating partial and full thickness wounds:

- Pressure (stage I-IV) and venous stasis ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- Donor sites and grafts

The Keratec Wound Dressings are not intended to be used on third degree burns.

## 6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Both the proposed Keratec Wound Dressings and the predicate wound dressings are designed for dry, light and moderately exudating partial and full thickness wounds. These devices differ in formulation but all include a protein component that is intended to provide enhanced wound healing.

The operational principles of the proposed and predicate devices are identical. The wound dressing is applied to the wound and functions to absorb exudates and create a scaffold for tissue ingrowth. The major difference between the proposed Keratec Wound Dressings and the predicate dressings is the type of protein incorporated in the dressing. Performance testing has been conducted that confirms that the Keratec Wound Dressings are able to function as intended without causing damage to the tissues. Animal derived proteins such as collagen have been used for many years in wound dressing products without adverse effects. Additionally, safety testing has been performed to support the use of keratin in the Keratec Wound Dressing, demonstrating that the dressings do not cause adverse effects and function as intended.

The similarities in intended use, technical specifications, and functional performance between the Keratec Wound Dressings and the Biocore Medical Technologies Inc. MediFil Collatek Hydrogel (K022995), the Johnson & Johnson Collagen ORC Antimicrobial Matrix (K033523), the Medical Technologies Collatek Foam (K012997) and the Cook Biotech (Healthpoint) (K061711) Oasis Wound Matrix leads to a conclusion of substantial equivalence between the proposed and predicate devices.

## 7. PERFORMANCE TESTING

Extensive bench, biocompatibility, animal and clinical testing have been performed to support the safety and efficacy of the Keratec Wound Dressings. All of the testing showed that the dressings function as intended without adverse effects.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2009

Keratec Limited
% Medical Device Consultants, Inc.
Ms. Mary McNamara-Cullinane, RAC
Senior Regulatory Consultant
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K080949
Trade/Device Name: Keratec Wound Dressings
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 26, 2009
Received: January 28, 2009

Dear Ms. McNmara-Cullinane:

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 application (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 such 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 begin 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): K080949

Device Name: Keratec Wound Dressings

Indications for Use:

The Keratec Keragel, Kerafoam and Keraderm Wound Dressings are intended for the management of partial and full thickness wounds such as:

- first and second degree burns
- severe sunburns
- superficial injuries, cuts, abrasions and surgical wounds

The Keratec Wound Dressings may also be used under guidance of a health care professional in the management of the following types of dry, light and moderately exudating partial and full thickness wounds:

- Pressure (stage I-IV) and venous stasis ulcers
- Ulcers caused by mixed vascular etiologies
- Diabetic ulcers
- Donor sites and grafts

Keragel is intended for dry to moderately exuding wounds, Keraderm for low to highly exuding wounds and Kerafoam for moderately exuding wounds to highly exuding wounds.

The Keratec Wound Dressings are not intended to be used on third degree burns.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use___ (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)

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

**510(k) Number** K080949