

**510(k) Summary**  
**for**  
**Derma Sciences Medihoney Primary Dressings**  
**with Active Manuka Honey**

**1. SPONSOR**

Derma Sciences  
214 Carnegie Center  
Suite 100  
Princeton, NJ 08540

NOV 07 2007

Contact Person: Barry Wolfenson  
Derma Sciences  
214 Carnegie Center, Suite 100  
Princeton, NJ 08540  
Telephone: 609.514.4744 x1103

Date Prepared: October 18, 2007

**2. DEVICE NAME**

Proprietary Name: Derma Sciences Medihoney Primary Dressings with  
Active Manuka Honey  
Common/Usual Name: Wound Dressing  
Classification Name: Dressing

**3. PREDICATE DEVICES**

API-MED Active Manuka Honey Wound Dressings (K053095)

**4. DEVICE DESCRIPTION**

Derma Sciences Medihoney Primary Dressings with Active Manuka Honey are sterile, single-use wound care dressings for use in moist wound management. The Derma Sciences Medihoney Primary Dressings with Active Manuka Honey are offered in several sizes including 2" x 2", 3/4 x 12", 4" x 4" and 4" x 5". The dressings are comprised of honey and sodium alginate.

The proposed Medihoney Primary Dressing with Active Manuka Honey contains Active Manuka Honey. As wound exudate is absorbed, the alginate forms a gel,

which assists in maintaining a moist environment that aids supports the autolytic debridement for optimal wound healing, and allows intact removal.

## 5. INTENDED USE

The Derma Sciences Honey Primary Wound Dressing provides a moist environment conducive to wound healing and is indicated for light to moderately wounds such as:

- diabetic foot ulcers
- leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology)
- pressure ulcers / sores (partial and full thickness)
- 1st and 2nd degree partial thickness burns
- donor sites, and traumatic and surgical wounds.

## 6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Derma Sciences Honey Primary Wound Dressing into the market is essentially identical to the parent API-MED Active Manuka Honey Wound Dressings subject of K0453095. The differences between the Derma Sciences Medihoney Primary Dressings with Active Manuka Honey and the predicate device are limited to a slight formulation change, the addition of an optional adhesive backing and a slight indication change.

The technological characteristics of the Derma Sciences Medihoney Primary Dressings with Active Manuka Honey and the parent API-MED Active Manuka Honey Wound Dressings are substantially equivalent in that they are all dressings suitable for use on pressure sores, leg ulcers, post-operative wounds, superficial wounds and abrasions.

The modifications made to the API-MED Active Manuka Honey Dressings to produce the Derma Sciences Medihoney Primary Dressings with Active Manuka Honey are limited to a slight change in formulation. The proposed Honey Primary Wound Dressings are comprised of 80% w/w of Active Manuka Honey and 20% hydrocolloidal gelling agents and the parent API-MED Active Manuka Honey Dressings are comprised of 95% Active Manuka Honey and 5% calcium alginate. This slight change in formulation simply provides the user with a wider variety of honey dressings and does not represent a significant change in technological characteristics of the Medihoney Primary Dressings with Active Manuka Honey. The only differences between the Derma Sciences Medihoney Primary Dressings with

Active Manuka Honey and the predicate devices include slightly different dressing composition which are minor and do not affect the safety and effectiveness of the device.

## 7. PERFORMANCE TESTING

Biocompatibility testing performed to support the formulation change for the modified dressings demonstrates that the Medihoney Primary Dressings with Active Manuka Honey are safe for their intended use. Cytotoxicity, sensitization, and irritation testing was performed successfully using the Derma Sciences Wound Dressings.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 07 2007

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

Re: K072956

Trade/Device Name: Derma Sciences Medihoney Primary Dressing with Active Manuka  
Honey

Regulatory Class: Unclassified

Product Code: FRO

Dated: October 18, 2007

Received: October 19 2007

Dear Ms. McNamara-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.

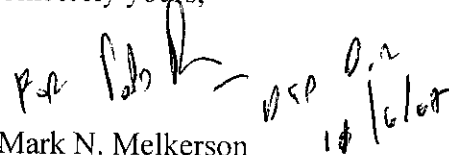
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

Handwritten signature of Mark N. Melkerson in black ink. The signature is stylized and includes the date "10/16/08" written vertically to the right of the signature.

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): K072956

Device Name: Derma Sciences Medihoney Primary Dressing with Active Manuka Honey

### Indications for Use:

The Derma Sciences Medihoney Primary Dressing with Active Manuka Honey provides a moist environment conducive to wound healing and is indicated for light to moderately exuding wounds such as:

- diabetic foot ulcers
- leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology)
- pressure ulcers / sores (partial and full thickness)
- 1st and 2nd degree partial thickness burns
- donor sites, and traumatic and surgical wounds.


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** K072956