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

FEB 2 2 2011

1. SPONSOR

Kam Garcha
Derma Sciences, Inc.
104 Shorting Road
Toronto, Ontario M1S 3S4
Canada
Telephone: 416-299-4003

Date Prepared: June 23, 2010

2. DEVICE NAME

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

3. PREDICATE DEVICES

- Derma Sciences OTC Medihoney Dressings with Active Manuka Honey (K081584)
- Derma Sciences Medihoney Dressing with Active Manuka Honey (K080315)
- Medihoney Primary Wound Dressings with Active Manuka Honey (K072956)
- API-MED Active Manuka Honey Wound Dressings (K053095)

4. DEVICE DESCRIPTION

Derma Sciences Medihoney Gel Dressings with Active Manuka Honey are sterile, wound care dressings for use in moist wound management. The Derma Sciences Medihoney Gel Dressing with Active Manuka Honey is offered in 10, 20, and 25 oz tubes sizes. The dressings are comprised of honey an emulsifier and a surfactant.

The proposed Medihoney Gel 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.

5. INTENDED USE

The Derma Sciences Medihoney Gel Dressings with Active Manuka Honey provide a moist environment conducive to wound healing and are indicated for light to moderately exuding wounds.

For over the counter use, Medihoney™ Gel Dressings with Active Manuka Honey may be used for:

- minor abrasions
- lacerations
- minor cuts
- minor scalds and burns

Under the supervision of a healthcare professional, The Derma Sciences Medihoney Gel Dressings provide a moist environment conducive to wound healing and are indicated for light to moderate exuding wounds. The Medihoney Gel Wound Dressings are intended for the management of the following:

- 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 technological characteristics of the Derma Sciences Medihoney Gel Dressings with Active Manuka Honey and the parent Medihoney Wound Dressings with Active Manuka Honey are substantially equivalent in that they are all honey based dressings suitable for use on pressure sores, leg ulcers, post-operative wounds, superficial wounds and abrasions. In addition, both the proposed and predicate devices are intended for both OTC and prescription use.

The modifications made to the Medihoney Wound Dressings with Active Manuka Honey Dressings to produce the Derma Sciences Medihoney Gel Dressings with Active Manuka Honey are limited to a slight change in formulation. The proposed Medihoney Gel Wound Dressings with Active Manuka Honey are comprised of 80%

Active Manuka Honey, 15% Myristyl Myristate and 5% Plantacare 810 compared to the parent Medihoney Primary Dressings which are comprised of 100% honey, 80% Active Manuka Honey and 20% sodium alginate powder or 95% w/w Active Manuka Honey and 5% w/w Calcium Alginate. The addition of the Myristyl Myristate and Plantacare 810 increases the viscosity of the gel which helps to improve adherence to the wound bed. This slight change in formulation provides the user with a wider variety of honey dressings and does not represent a significant change in technological

The intended use of the Derma Sciences Medihoney Gel Dressings with Active Manuka Honey and the predicate devices are identical in that they are all intended to provide a moist environment conducive to wound healing. The Derma Sciences Medihoney Gel Dressings with Active Manuka Honey are identical to the parent Medihoney Dressing in indications in that they are both indicated for management of light to moderately exuding wounds including partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure and diabetic).

7. PERFORMANCE TESTING

Biocompatibility testing performed to support the formulation change for the modified dressings demonstrates that the Medihoney Gel Dressings with Active Manuka Honey are safe for their intended use. The biocompatibility testing included cytotoxicity, implantation, sensitization, and irritation testing (repeat patch insult testing).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Derma Sciences, Inc.
% Medical Device Consultants, Inc.
Mr. Ronald S. Warren
49 Plain Street
North Attleboro, Massachusetts 02760

FEB 22 2011

Re: K101793
Trade/Device Name: Derma Sciences Medihoney Gel Dressings with Active Manuka Honey
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 17, 2011
Received: January 19, 2011

Dear Mr. Warren:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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.

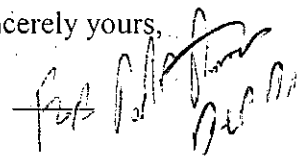
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101793

Device Name: Derma Sciences Medihoney Gel Dressings with Active Manuka Honey

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ___X___ (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)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101793