DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 25, 2015

Derma Sciences Incorporated
Ms. Nancy Angus
Associate Director of Regulatory Affairs
214 Carnegie Center, Suite 300
Princeton, New Jersey 08540

Re: K133279
Trade/Device Name: Calcium Alginate Dressing with Active Leptospermum Honey; Adhesive/Non-Adhesive Honeycolloid Dressing with Active Leptospermum Honey; Dressing with Active Leptospermum Honey; Gel Dressing with Active Leptospermum Honey; Adhesive/Non-Adhesive Hydrogel Colloidal Sheet with Leptospermum Honey
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 22, 2015
Received: May 26, 2015

Dear Ms. Angus:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133279

Device Name
Calcium Alginate Dressing with Active Leptospermum Honey; Adhesive/Non-Adhesive Honeycolloid Dressing with Active Leptospermum Honey; Dressing with Active Leptospermum Honey; Gel Dressing with Active Leptospermum Honey; Adhesive/Non-Adhesive Hydrogel Colloidal Sheet with Leptospermum Honey

Indications for Use *(Describe)*
Medihoney Calcium Alginate Dressing with Active Leptospermum Honey are indicated for the management of moderate to heavily exuding wounds by providing a moist environment, which is conducive to wound healing, and supports and aids autolytic debridement. These 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
• traumatic and surgical wounds

Medihoney Adhesive and Non-Adhesive Honeycolloid Dressings with Active Leptospermum Honey are indicated for the management of light to moderately exuding wounds by providing a moist environment, which is conducive to wound healing, and supports and aids autolytic debridement. These 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
• traumatic and surgical wounds

Medihoney Dressings with Active Leptospermum Honey are indicated for the management of light to moderately exuding wounds by providing a moist environment, which is conducive to wound healing, and supports and aids autolytic debridement. These 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
• traumatic and surgical wounds

Medihoney Gel Dressing with Active Leptospermum Honey are indicated for the management of light to moderately exuding wounds by providing a moist environment, which is conducive to wound healing, and supports and aids autolytic debridement. These 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
• traumatic and surgical wounds

The Medihoney Adhesive and Non-Adhesive Hydrogel Colloidal Sheet with Leptospermum Honey are indicated for the management of non-draining to lightly exuding wounds by providing a moist environment, which is conducive to wound

healing, and supports and aids autolytic debridement. These 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
- traumatic and surgical wounds

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
For the
Derma Sciences, Inc.
Medihoney Dressings

Date Prepared: June 23, 2015

1. SUBMITTER/510(K) HOLDER/CONTACT PERSON

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2. DEVICE NAME

Proprietary Name: Medihoney Wound Dressings including the following

- Calcium Alginate Dressing with Active Leptospermum Honey
- Adhesive/Non-Adhesive Honeycolloid Dressing with Active Leptospermum Honey
- Dressing with Active Leptospermum Honey
- Gel Dressing with Active Leptospermum Honey
- Adhesive/Non-Adhesive Hydrogel Colloidal Sheet with Leptospermum Honey

Common/Usual Name: Wound Dressing
Classification Name: Wound Dressing

3. PREDICATE DEVICES

Derma Sciences believes the primary Medihoney Dressing predicate is the following based on general to specific use.

K080315 Derma Sciences Medihoney Dressings with Active Manuka Honey *(Dressing with Active Leptospermum Honey)*

Reference predicates are as follows:

Autolytic Debridement:
K024054 XYLOS XCell Antimicrobial Dressing
K072068 BAGTech's BioAquaCare

4. DEVICE DESCRIPTION

The primary component of the Medihoney Family of Dressings is Active Manuka Honey. The composition, formulation and materials of the Medihoney Dressings are described below. The Medihoney Family of Dressings **are provided sterile** to the user and are NOT required to be sterilized.

Calcium Alginate Dressing with Active Leptospermum Honey: comprised of 95% Active Manuka Honey and 5% Calcium Alginate. As wound exudate is absorbed, the alginate forms a gel, which assists in maintaining a moist environment that aids and supports the autolytic debridement. Sizes: ¾”x 12”/2”x2”/4”x5”

Adhesive/Non-Adhesive Honeycolloid Dressing with Active Leptospermum Honey: comprised of 80% Active Manuka Honey and 20% Sodium Alginate Powder (hydrocolloid sheet) As wound exudate is absorbed, the alginate forms a gel, which assists in maintaining a moist environment that aids and supports the autolytic debridement. Sizes: 2”x2,”/4”x5” (non-adhesive)/2”x2”/4.5”x4.5” (adhesive)

Dressing with Active Leptospermum Honey: comprised of 100% Active Manuka Honey and are sterile wound dressings for use in moist wound management. The Medihoney Dressing comprised of 100% Active Manuka Honey helps to maintain a moist environment. The Medihoney Dressing with Active Manuka Honey is offered in several sizes including 0.5, 1, and 1.5 oz. tube sizes.

Gel Dressing with Active Leptospermum Honey: comprised of 80% Active Manuka Honey, 15% Myristyl Myristate and 5% Plantacare 810. As wound exudate is absorbed, the

dressing forms a gel, which assists in maintaining a moist environment that aids and supports autolytic debridement. The Medihoney Gel Dressings are offered in 0.5 and 1.5 oz sizes

Adhesive/Non-Adhesive Hydrogel Colloidal Sheet with Leptospermum Honey: comprised of 63% Leptospermum Honey and hydrogel both with and without an adhesive border. As wound exudate is absorbed, the dressing forms a gel, which assists in maintaining a moist environment that aids and supports autolytic debridement. The Medihoney Hydrogel Sheet Dressings are offered in 1.8”x1.8”/2.4”x2.4”/4.3”x4.3”/8”x8”/8”x12” (adhesive) 2.8”x2.8”/4.5”x4.5” (non-adhesive)

There are NO new instructions or operational differences for the Medihoney Dressings with new indications. The instructions for use are identical to the original dressings cleared in K053095, K072956, K080315, K101793, K110546.

5. INTENDED USE

The mechanism of action, intended environment and functionality are all identical to the original Medihoney dressings. The new indications are consistent with standard wound care practices and intended uses and is in line with the predicate device indications for use.

Medihoney Calcium Alginate Dressing with Active Leptospermum Honey are indicated for the management of moderate to heavily exuding wounds by providing a moist environment, which is conducive to wound healing, and supports and aids autolytic debridement. These 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
- traumatic and surgical wounds

Medihoney Adhesive and Non-Adhesive Honeycolloid Dressings with Active Leptospermum Honey are indicated for the management of light to moderately exuding wounds by providing a moist environment, which is conducive to wound healing, and supports and aids autolytic debridement. These 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
- traumatic and surgical wounds

Medihoney Dressings with Active Leptospermum Honey are indicated for the management of light to moderately exuding wounds by providing a moist environment, which is conducive to wound healing, and supports and aids autolytic debridement. These 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
- traumatic and surgical wounds

Medihoney Gel Dressing with Active Leptospermum Honey are indicated for the management of light to moderately exuding wounds by providing a moist environment, which is conducive to wound healing, and supports and aids autolytic debridement. These 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
- traumatic and surgical wounds

The Medihoney Adhesive and Non-Adhesive Hydrogel Colloidal Sheet with Leptospermum Honey are indicated for the management of non-draining to lightly exuding wounds by providing a moist environment, which is conducive to wound healing, and supports and aids autolytic debridement. These 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
- traumatic and surgical wounds

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The indication for use is slightly different than the original 510(k)'s for all of the Medihoney Family of dressings, but are similar to those described in the predicates. Section 20 includes a large amount of clinical data from literature to support the new indications. In addition, the proposed indication is included in previously cleared predicate devices. Utilizing the FDA guidance document, the addition of autolytic debridement to the indications represents a general to specific indication. By specifying autolytic debridement, the labeling will simply be more specific in that the proposed indication was covered previously in the general indications.

NO changes have been made to the design or technological characteristics of the Medihoney Family of Dressings since they are identical in configuration and function to those previously cleared. The technological characteristics of the Medihoney Family of Dressings are identical to

the predicates since they are all comprised of sterile honey based substrates, intended to function as coverings for various wound types. As stated above, the only change that is the subject of this bundled 510(k) submission, is the additional indication of aiding autolytic debridement.

The proposed Medihoney Family of Dressings and the predicate device are identical in that they are all composed of a dressing that contains a component in the formulation that contributes to a moist wound environment. The proposed and predicate device are identical in the functional and technological characteristics since they are the same device.

The operational characteristics of the proposed Medihoney Family of Dressings are identical to the predicate devices in that they are all intended to be used as primary or secondary coverings for the management of a variety of wounds. They provide a moist wound environment conducive to wound healing and autolytic debridement.

The technological characteristics of the proposed Medihoney Family of Wound Dressings and the predicate devices are identical in that they are dressings that include a moist gel like component and are suitable for the management of a variety of wounds.

NO changes have been to the design or technological characteristics of the Medihoney Family of Dressings since they are identical in configuration and function to those previously cleared. The technological characteristics of the Medihoney Family of Dressings are identical to the predicates since they are all comprised of sterile honey based substrates, intended to function as coverings for various wound types. As stated above, the only change that is the subject of this bundled 510(k) submission is the additional indication consisting of autolytic debridement.

Section 21 includes clinical data from literature to support the autolytic debridement indication. In addition, all of the proposed indications are included in previously cleared predicate devices described above.

The proposed Medihoney Family of Dressings and the predicate devices are identical in that they are all composed of a dressing that contains a component in the formulation that contributes to a moist wound environment. The proposed and predicate devices are identical in functional and technological characteristics since they are the same device.

The technological characteristics of the proposed Medihoney Family of Wound Dressings and the predicate devices are identical in that they are dressings that include a moist gel like component and are suitable for the management of a variety of wounds.

The general to specific indications rationale described above demonstrates that autolytic debridement represents a more specific indication which falls under the general wound care

indications previously cleared in the Derma Sciences Medihoney 510k submissions. The labeling for Medihoney Family of Wound Dressings is essentially identical to the labeling cleared for the predicate devices. Derma Sciences believes that the above rationale, the clinical data from literature included in Section 21 and the comparison table demonstrate substantial equivalence of the proposed Medihoney Family of Wound Dressings to the predicate devices.

The labeling for Medihoney Family of Wound Dressings is essentially identical to the labeling cleared for the predicate devices. Derma Sciences believes that the above rationale, the clinical data from literature included in Section 21, and the comparison table demonstrate substantial equivalence of the proposed Medihoney Family of Wound Dressings to the predicate devices.

In conclusion, the Derma Sciences Medihoney Family of dressings is substantially equivalent to the predicate devices with respect to material composition, device characteristics and intended use. There have been no configuration or material changes since the FDA cleared the original 510k submissions. Therefore, the technological characteristics support the substantial equivalence to the original Medihoney dressings and to the predicate devices listed above that have similar indications for use.

7. PERFORMANCE TESTING

The Medihoney Family of Dressings have been subjected to extensive testing to assess the biocompatibility and the performance of the device as described in each of their respective 510(k) submissions.

The case studies described support the proposed indications for use for the Medihoney Dressings. The clinical data from published literature represents hundreds of cases that demonstrate safe and effective use of the Medihoney Dressings. Derma Sciences believes this clinical data plus the predicate device indications for use support the substantial equivalence of the Medihoney Dressings to the predicate devices. The Medihoney Family of Dressings was shown to be safe and effective as a wound dressing as shown in the published clinical studies that utilized the proposed indications.

The extensive safety and effectiveness evidence demonstrated in both the non-clinical and published clinical testing support the safe use for the proposed indication. The conclusions drawn from the non-clinical and published clinical tests demonstrate that the Medihoney Family of Dressings are safe, effective, and perform as well as the predicate devices as evidenced by the clinical studies in literature. The clinical data presented in this submission supports the use of the Medihoney Family of Dressings for the autolytic debridement indication.