



MANUKAMED

K102659
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510(k) SUMMARY

Submitted by:

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Date Prepared: September 10, 2010
Trade Name: MANUKAhd wound dressings
Common Name: Adhesive Wound Dressing
Classification Name: Dressing, Wound, Drug
Device Class: Unclassified
Procode: FRO
Predicate Device 1: Derma Sciences MediHoney Primary Dressings with Active Manuka (*Leptospermum*) Honey in a hydrocolloid sheet.
Predicate 510(k) #: K081584
Predicate Device 2: Manuka Medical, Ltd. Manukapli Wound Dressing
Predicate 510(k) #: K092689
Device Description: MANUKAhd wound dressings are highly absorbent, sterile, single-use wound care dressings for use in moist wound management. The primary device is a super absorbent polymer (SAP) fibre material impregnated with medical

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Nottinghamshire NG18 5BR, United Kingdom



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Manuka honey and coated with carboxymethyl cellulose (CMC). The device incorporates 100% active *Leptospermum* medical grade Manuka honey that is harvested and processed under controlled conditions. One version of the product (MANUKAhd Border) has the honey-impregnated pad retained in a central position on an adhesive backing. Another version of the device (MANUKAhd Rope) is identical to the primary device, but spiral cut to provide the care provider flexibility in packing a wound bed.

Intended Use:

MANUKAhd wound dressings are highly absorbent, sterile, single-use wound care dressings, with or without adhesive borders, for use in moist wound management. Under the supervision of a healthcare professional, MANUKAhd wound dressings may be used for:

- Leg Ulcers
- Pressure Ulcers
- 1st and 2nd Degree Burns (Superficial and Partial Thickness)
- Diabetic Foot Ulcers
- Surgical Wounds
- Traumatic Wounds

Technology Comparison:

The MANUKAhd wound dressings are substantially equivalent to the predicate devices. The devices are similar in function, composition, and intended use. All devices utilize Manuka honey incorporated into an absorbent matrix (SAP fiber for MANUKAhd products, and hydrocolloid gel for MediHoney products). MANUKAhd dressings have a hydrocolloid surface coating that combines with exudate to assist in dressing removal. Product configurations are also similar, including optional adhesive backings and a variety of sizes to accommodate a variety of wounds types. All products are provided as single-use devices in individually-sterilized packaging.

Nonclinical Testing:

Standard biocompatibility tests were performed on the MANUKAhd wound dressings; including cytotoxicity, intracutaneous reactivity, systemic toxicity, sensitization, and wound healing studies. The tests executed are typically performed for these medical devices. All tests were performed in accordance with US FDA General Program Memorandum #G95-1 Part-10993-1 of the International Standard Organization (ISO) Standard (Biological

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Evaluation of Medical Devices) by North American Science Associates, Inc. (NAMSA). The MANUKAhd wound dressing met the acceptance criteria for all tests conducted and is considered biocompatible under the conditions tested.

Conclusion of Comparison: The MANUKAhd wound dressings are substantially equivalent to the currently-marketed predicate devices.

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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

Manuka Medical, Ltd.
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James Smith, Ph.D.
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Laguna Niguel, California 92677

DEC - 8 2010

Re: K102659
Trade/Device Name: MANUKAhd Wound Dressings
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 07, 2010
Received: November 12, 2010

Dear Dr. Smith:

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

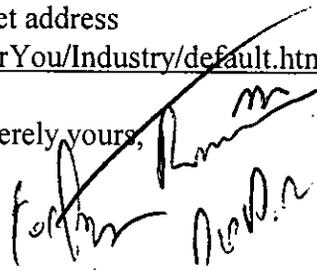
Page 2 – James Smith, Ph.D.

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

INDICATIONS FOR USE

DEC - 8 2010

510(k) Number (if known): K102659

Device Name: MANUKAhd wound dressings

Indications for Use:

MANUKAhd wound dressings are highly absorbent, sterile, single-use wound care dressings, with or without adhesive borders, for use in moist wound management.

MANUKAhd wound dressings may be used Over-The-Counter for:

- Minor Abrasions
- Lacerations
- Minor Cuts
- Minor Scalds and Burns

Under the supervision of a healthcare professional, MANUKAhd wound dressings may be used for:

- Leg Ulcers
- Pressure Ulcers
- 1st and 2nd Degree Burns (superficial and Partial Thickness)
- Diabetic Foot Ulcers
- Surgical Wounds
- Traumatic Wounds

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MXXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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