



K092689
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510(k) SUMMARY

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Contact Person: James Smith, Ph.D., RAC
DeFerris, Inc.
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Date Prepared: August 27, 2009

Trade Name: Manukapli Wound Dressing

Common Name: Dressing, Wound

Classification Name: Dressing, Wound, Drug

Device Class: Unclassified

Procode: FRO

CFR Reference: N/A

Predicate Device: Derma Sciences Medihoney 100% Honey Dressings with Active Manuka Honey

Predicate 510(k) #: K081584

Device Description: Manukapli Wound Dressing consists of a sterile wound dressing designed to promote a moist wound healing environment. The device is constructed using medical grade Manukapli that is harvested and processed under controlled conditions. This Manukapli is sealed into polyethylene tubes before sterilization using gamma irradiation and is intended to be used by medical staff as part of a treatment program for patients with problematic

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wound care requirements. The device is provided sterile and is designed to be single used only. This is achieved by the tube design having a twist & shear off end cap that cannot be replaced.

Intended Use:

Manukapli Wound Dressings are sterile, single-use wound care dressings for use in moist wound management. Manukapli 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, Manukapli 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 Manukapli Wound Dressings are substantially equivalent to the predicate devices. The devices are similar in function, composition, and intended use.

Nonclinical Testing:

Standard biocompatibility tests were performed on the Manukapli Wound Dressings. The tests and assays performed are typically performed for these medical devices. All tests were performed in accordance with US FDA General Program Memorandum #G95-1 and Part-10993-1 of the International Standard Organization (ISO) Standard (Biological Evaluation of Medical Devices) by North America Science Associates, Inc. (NAMSA). The Manukapli Wound Dressings met the acceptance criteria for all tests conducted and is considered biocompatible under the conditions tested.

Conclusion of Comparison: The Manukapli Wound Dressings is 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

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Manuka Medial Limited
% DeFerris, Inc.
James Smith, PhD, RAC
29442 Pointe Royale
Laguna Niguel, California 92677

Re: K092689
Trade/Device Name: Manukapli Wound Dressings
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 30, 2010
Received: May 6, 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.

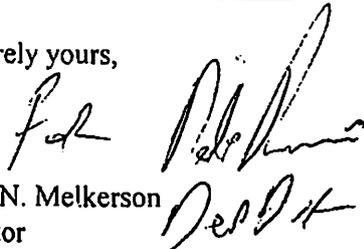
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 - James Smith, PhD, RAC

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" (21 CFR 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



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INDICATIONS FOR USE

510(k) Number (if known): K092689

Device Name: Manukapli Wound Dressings

Indications for Use:

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- 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-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krone for M&M
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

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