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southwest technologies inc.

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NOV - 3 2010

510(k) Summary

ELASTO-GEL OTC MANUKA HONEY WOUND DRESSING

1. **Sponsor:** Southwest Technologies, Inc.
1746 Levee Road
N. Kansas City, MO 64116

Contact Person: Edward I. Stout, CEO
Southwest Technologies, Inc.
1746 Levee Rd
N. Kansas City, MO 64116
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2. Device Name and Classification

Proprietary Name: OTC Elasto-Gel Manuka Honey Wound Dressing (K102478)
Common Name: Wound Dressing
Classification Name: Dressing Product code FRO
Classification: To my knowledge, FDA has not classified this device.

3. Substantial Equivalence Claim- Predicate Devices

Legally marketed devices:
Elasto-Gel Occlusive Dressing by Southwest Technologies (K872165)
Elasto-gel Manuka Honey Wound Dressings (K083334)
Derma Sciences API_MED™ Active Manuka Honey Absorbent Dressing by Derma Sciences Canada, Inc (K053095) Product Code FRO
Derma Sciences Medihoney Primary Dressings with Active Manuka Honey by Derma Sciences (K072956)

4. Device Description

OTC Elasto-Gel Manuka dressings are supplied as a gel (amorphous) a thickened viscosity honey or a gel sheet. OTC Elasto-Gel Manuka Honey sheet dressing is the same composition and identical to the Parent Product .The dressings will be supplied in many sizes, for example: 2x3, 4x4, 6x8, and possibly other additional sizes and shapes.

The amorphous gel is a mixture of a super absorbent crosslinked sodium polyacrylic acid, glycerine, honey and water. The crosslinked polyacrylamide polymer is insoluble in the wound fluid but has a relatively high capacity for absorption of the wound fluid, while releasing the glycerine, honey, and water into the wound fluid to establish a chemical equilibrium. The OTC Elasto-Gel Manuka Honey Amorphous gel dressing, is formulated to produce a high viscosity fluid mixture suitable for surface wounds cuts, scrapes and abrasions. The gel sheet is a moderately adhesive soft gel sheet that will protect the wound from shear, friction and pressure, suitable as a protective padding and cushioning device as well as functioning as a dressing. The OTC Elasto-Gel with Manuka Honey are limited to a slight change in indications and over the counter use.

The products will not dry out or become stuck to the wound. In most cases soon after application to the wound the pain level will be diminished .The products will help provide a moist healing environment and will aid in the healing process.

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5. **Intended Use (for OTC)**
Minor Cuts & Abrasions, Scrapes
Surface Wounds, Minor Scalds and Burns

6. **Technological Characteristics and Substantial Equivalence Comparison to Predicate Devices**

Device Name	Elasto-Gel™ Manuka Honey Wound Dressing	OTC API-MED Medihoney Primary & 100 % Honey Dressing with Active Manuka Honey	API-MED™ ACTIVEMANUKA HONEY ABSORBENT DRESSING	Elasto-Gel™ Occlusive wound Dressing	Derma Sciences OTC Medihoney Dressings with Active Manuka Honey
Manufacturer	Southwest Techologies Inc	Derma Sciences	Derma Sciences	Southwest Technologies, Inc	Derma Sciences
Indications For use	Prolonged use in Full and partial thick-ness chronic and acute wounds.	Used to manage with minimal to moderate amounts of exudate.	Used in the Of chronic and acute wounds.	Used in the Management of partial and full thickness and partial chronic and Acute wounds.	Used for Minor abrasions Lacerations Minor cuts Minor scalds and burns
Material	Polyacrylamide+glyce rine+Water + Manuka Honey or PolyAcrylate + Water + Manuka honey +glycerine	Manuka Honey + Alginate	Manuka Honey+ Alginate	Polyacrylamide+ glycerine + Water	Manuka Honey + Alginate
Honey Source	New Zealand	?		NA	
Properties of Sheet Absorbent Soft Sheet	Yes	No	Yes	Yes	Yes
Dissolves or "melts" In wound fluid	No	Yes	Yes	No	No
Bio-Compatibility	Yes	Yes	Yes	Yes	Yes
Sterile	Yes	Yes	Yes	Yes	Yes

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

Southwest Technologies, Inc.
% Mr. Edward I. Stout, CEO
1746 Levee Road
North Kansas City, Missouri 64116

NOV - 3 2010

Re: K102478
Trade/Device Name: OTC Elasto-Gel Manuka Honey Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 25, 2010
Received: October 13, 2010

Dear Mr. Stout:

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

NOV - 3 2010

510(K)Number (If Known) K102478

Device Name : OTC Elasto-Gel Manuka Honey Wound Dressing

Indications for Use: The OTC Manuka Honey Wound Dressing is indicated for minor cuts, minor abrasions, minor scalds and minor burns.

Prescription Use___ (Part 21CFR 801Subpart D)	**AND/OR**	**Over the Counter__X__** (Part 21CFR 801Subpart D)

David Krause for MXM

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

510(k) Number K102478