K083334
page 1 of 3

# southwest technologies inc.

"Treating the world well" ®

510(k) Summary

JUL 30 2009

## ELASTO-GEL MANUKA HONEY WOUND DRESSING


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

**Contact Person:** Edward J. Stout, CEO
Southwest Technologies, Inc.
1746 Levee Rd
N. Kansas City, MO 64116

Telephone: (816) 221-2442
Fax: (816) 221-3995
email: swtech@birch.net


**2. Device Name and Classification**

Proprietary Name: Elasto-Gel Manuka Honey Wound Dressing
Common Name: Wound Dressing
Classification Name: Dressing (Product code KMF? 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)
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)

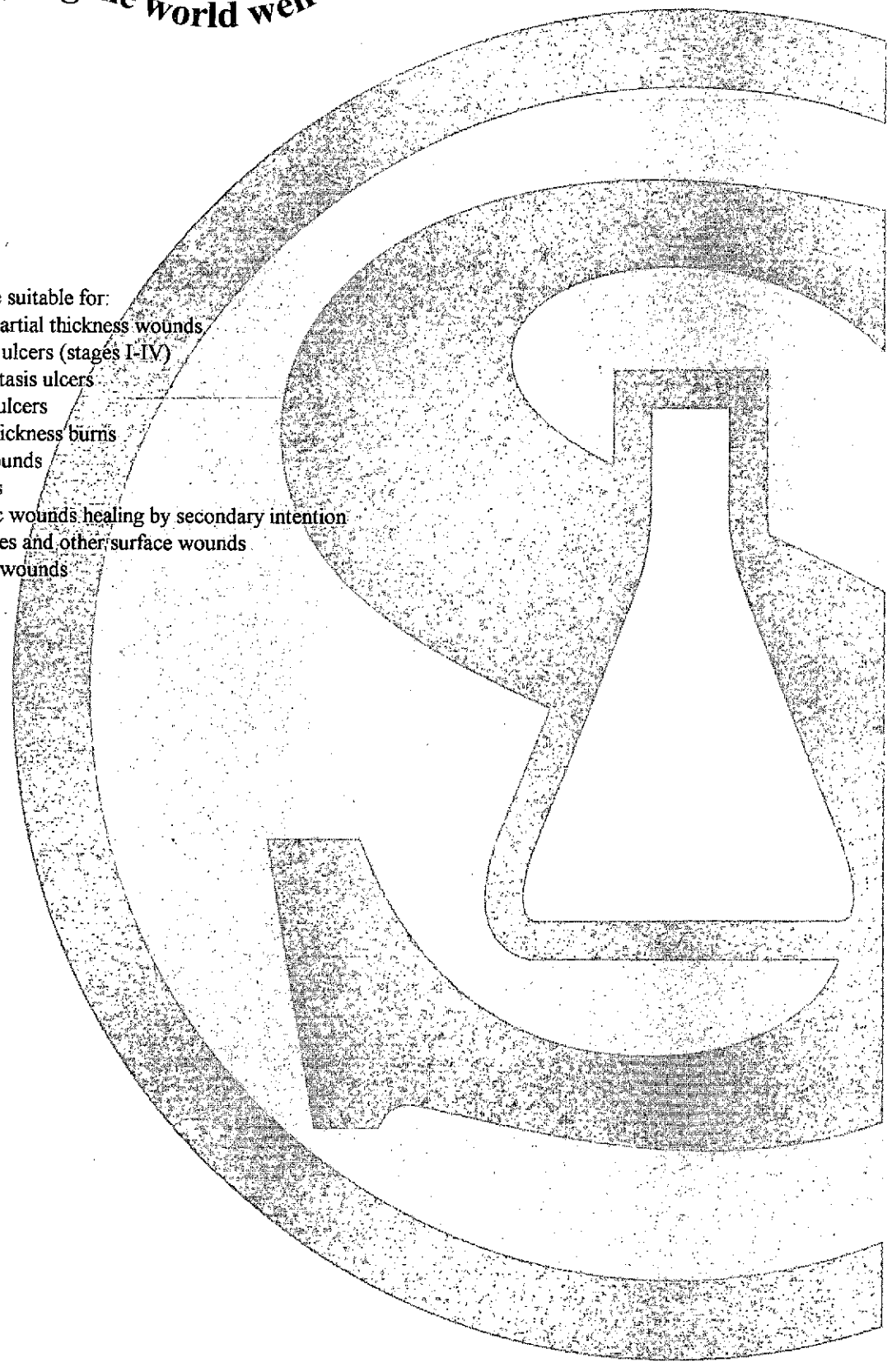
**4. Device Description**

Elasto-Gel Manuka dressings are supplied as a gel(amorphous) or gel sheet. Elasto-Gel Manuka Honey sheet dressing is a sterile primary single use dressing comprised of an insoluble polyacrylamide polymer matrix in the form of a continuous sheet with plasticizer of glycerine, honey, and water. 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 Elasto-Gel Manuka Honey amorphous gel dressing, is formulated to produce a high viscosity fluid mixture suitable for filling wound cavities. 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 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 absorb excess wound exudate.

# southwest technologies inc.

"Treating the world well"®



**5. Intended Use**

These products are suitable for:

- full and partial thickness wounds
- pressure ulcers (stages I-IV)
- venous stasis ulcers
- diabetic ulcers
- partial thickness burns
- acute wounds
- abrasions
- traumatic wounds healing by secondary intention
- donor sites and other surface wounds
- surgical wounds





1746 Levee Road, North Kansas City, MO. 64116 ph:(800) 247-9951 ph:(816) 221-2442 fax:(816) 221-3995 www.elastogel.com

# southwest technologies inc.

"Treating the world well"®

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

| Device Name | Elasto-Gel™ Manuka Honey Wound Dressing | Medihoney Primary Dressing | API-MED™ ACTIVEMANUKA HONEY ABSORBENT DRESSING | Elasto-Gel™ Occlusive wound Dressing | |
|---|---|---|---|---|---|
| Manufacturer | Southwest Techologies Inc | Derma Sciences | Derma Sciences | Southwest Technologies, Inc | |
| Indications For use | Prolonged use in Full and partial thickness chronic and acute wounds. | Used to manage with minimal to moderate amounts of exudate. | Used in the Management Of chronic and acute wounds. | Used in the Management of partial and full thickness and partial chronic and Acute wounds. | |
| Material | Polyacrylamide+glycerine+Water + Manuka Honey or PolyAcrylate + Water + Manuka honey +glycerine | Manuka Honey + Alginate | Manuka Honey+ Alginate | Polyacrylamide+ glycerine + Water | |
| Honey Source | New Zealand | ? | | NA | |
| Properties of Sheet Absorbent Soft Sheet | Yes | Yes | Yes | Yes | |
| Disolves or "melts" in wound fluid | No | Yes | Yes | No | |
| Bio-Compatibility | Yes | Yes | Yes | Yes | |
| Sterile | Yes | Yes | Yes | Yes | |

## 7. Performance Testing

The biocompatibility testing and case studies demonstrates that these dressings are safe for their intended use. Cytotoxicity, sensitization, acute systemic injection, intracutaneous, and irritation testing was performed.



Elasto-Gel™ TocAid™ Comfort Aid® Finger Bobs™ Crutch-Mate™ GoldDust™ Stimulen

1746 Levee Road, North Kansas City, MO. 64116 ph:(800) 247-9951 ph:(816) 221-2442 fax:(816) 221-3995 www.elastogel.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2009

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

Re: K083334
Trade/Device Name: Elasto-Gel Manuka Honey Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 22, 2009
Received: June 23, 2009

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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): K083334

Device Name: Elasto-Gel Manuka Honey Wound Dressing

Indications For Use:

Elasto-gel Manuka Honey wound Dressings are indicated for use in management of wounds. Full and partial thickness wounds, pressure ulcers, (stages 1 –IV) venous stasis ulcers, diabetic ulcers, abrasions, surface wounds, traumatic wounds (healing by secondary intention), donor site wounds, and surgical wounds

Prescription Use X AND/OR Over-the-Counter ___
(Part 21CFR 801 Subpart D) (21 CFR 801 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 MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083334