K081246

Tissue Technologies Holdings, LLC
800 East Leigh St., Suite 51
Richmond, VA 23219

Section 5. 510(k) Summary
TT-102 Wound Dressing
April 30, 2008

AUG 13 2009

Submitter's Name and Address:

Tissue Technologies Holdings, LLC
800 East Leigh Street, Suite 51
Richmond, VA 23219

Contact Person:

Dr. Yousef Mohajer
VP of Technical Development
Telephone & Fax: (804) 225-7447

Name of Medical Device:

Trade name: TT-102 Wound Dressing
Common name: Silver Wound Dressing
Classification name: Dressing, Wound, Drug

Substantial Equivalence:

TT-102 Wound Dressing is substantially equivalent to:

TT-101 Wound Care Dressing (K 061060)
Manufactured by an FDA registered contract manufacturer

AQUACEL® Ag with Hydrofiber (K063271)
Manufactured by ConvaTec, A division of E. R. Squibb and Sons, LLC

Device Classification:

Unclassified, Product Code- FRO

Device Description:

TT-102 Wound Care Dressing is a highly absorbent, sterile, single-use primary dressing comprised of phosphorylated cellulose with ionically bound silver. The dressing prevents microbial colonization in the dressing.

Indications for Use:

The TT-102 Wound Dressing is indicated for the management of:

- Diabetic ulcers
- Venous ulcers
- Pressure ulcers
- Ulcers caused by mixed vascular etiologies
- Full thickness and partial thickness wounds
- Traumatic wound healing by secondary intention

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- Dehisced surgical wounds
- Abrasions
- Donor sites and other bleeding wounds

Contraindication:

This dressing is not indicated for burns. The dressing should not be used by persons allergic to silver.

Technical Characteristics:

The TT-102 dressing is a cellulose derivative and, like its predicate device AQUACEL® Ag, has a high capacity to absorb and retain wound exudate. Whereas AQUACEL® Ag is composed of carboxymethyl cellulose with ionic silver, TT-102 is made by adding ionic silver into phosphorylated cellulose. In both products, silver is highly bound to the matrix of the dressing allowing it to prevent colonization by microbes.

Safety:

Biocompatibility studies have demonstrated TT-102 Antimicrobial Wound Dressing to be non-toxic, non-irritating, non-sensitizing and non-cytotoxic.

Performance Testing:

The antimicrobial activity of the immobilized silver dressing was determined according to ASTM E2149-01 against the following organisms:

Staphylococcus aureus ATCC 6538

Staphylococcus aureus, methicillin resistant (MRSA) ATCC 33591

Escherichia coli ATCC 8739

Pseudomonas aeruginosa ATCC 9027

Enterococcus faecalis, vancomycin-resistant enterococci (VRE) ATCC 51575

Candida albicans ATCC 10231

Performance Summary:

TT-102 was found to be an effective antimicrobial dressing for various microbes including *Staphylococcus aureus, Staphylococcus aureus* (MRSA), *Enterococcus faecalis* VRE, and other pathogens.

Clinical Evaluation:

No clinical evaluation has been done on this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Tissue Technologies Holdings, LLC
% I. Kelman Cohen, MD
President and CEO
1400 Aqua Vista Lane
Richmond, Virginia 23231

AUG 13 2009

Re: K081246
Trade/Device Name: TT-102 Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 11, 2009
Received: August 11, 2009

Dear Dr. Cohen:

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

Form Approved: OMB No. 0910-0120; Expiration Date: xx/xx/xx

Indications for Use

510(k) Number (if known): K081246

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 MKM

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

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