K053476

510(k) Summary

Sponsor Information:
AT Squared, LLC
10274 Alliance Road
Cincinnati, Ohio 45242
Phone (513) 891-9991
Fax (513) 891-9947
Contact Person: Aletha W. Tippett, M.D.
Date Prepared: November 23, 2005

JUN 26 2006

Device Name:
Proprietary Name: WoundPal
Common/Usual Name: Medicated Hydrogel Wound Dressing
Classification Name: Dressing, Wound and Burn, Hydrogel with Drug and/or Biologic (Unclassified, Product Code MGQ)

Predicate Devices:
WoundPal is substantially equivalent to the following cleared devices:

- Regenecare Wound Gel (MPM Medical, Inc., K02050540)
- Cardiotech Antibiotic Hydrogel Wound Dressing (Cardiotech Intl., K022584)
- Kendall Kerlix MD Antimicrobial Gauze Dressing (The Kendall Company LP, K990530)
- 20mL Normal Saline Topical Solution, 0.9% w/v Sodium Chloride (Steripak, K972195)

Device Description:
The proposed WoundPal is a single use wound dressing consisting of a woven cotton gauze treated with an OTC antibiotic mixture composed of Polymyxin B Sulfate USP (10,000 units/gram) and Bacitracin Zinc USP (500 units/gram) in a hydrogel with 2% w/w lidocaine hydrochloride. Normal saline 0.9% is also added to maintain a moist dressing. A trace amount of oil of wintergreen is added as a fragrance. The product is intended as a primary dressing for use in the local management of painful skin wounds. The antibiotic mixture is present to help prevent bacterial contamination of the dressing. The dressing may be held in place with a variety of secondary dressings, including an additional bandage or with the addition of an outer layer comprised of a polymeric film that may be secured by applying zinc oxide ointment USP between the film and intact skin surrounding the wound.

Intended Use:
WoundPal is intended to be used as a primary dressing in the management of partial and full-thickness wounds, including diabetic ulcers, venous stasis ulcers, pressure ulcers, surgical wounds, ischemic ulcers, traumatic wounds, superficial burns, donor sites, and abrasions and lacerations.

Technological Characteristics:
WoundPal is equivalent to the referenced predicate devices in that they are intended to be used as wound coverings and/or wound dressings. It is equivalent to the Cardiotech's Antibiotic Hydrogel Wound Dressing and Kendall Kerlix MD Antimicrobial Gauze Dressing because they all contain ingredients that help to prevent bacterial contamination of the dressing and have a broad spectrum of antimicrobial activity. WoundPal is similar to Regenecare Wound Gel because they both contain lidocaine and provide relief for painful wounds. It is similar to Steripak's Normal Saline Topical Solution because the saline present in WoundPal moistens and lubricates the wound dressing.

Although there are minor technical differences between the subject device and its predicate devices, these differences to not raise new questions of safety or efficacy. Because of the long history of safe use of the components of WoundPal independently, and in combination, the device does not raise any new safety issues and biocompatibility testing was not necessary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2006

AT Squared, LLC
c/o Aletha W. Tippett, M.D.
10274 Alliance Road
Cincinnati, Ohio 45242

Re: K053476
Trade/Device Name: WoundPal Medicated Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 16, 2006
Received: May 18, 2006

Dear Dr. Tippett:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

for

Mark Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053476

Device Name: WoundPal Medicated Wound Dressing

Indications For Use:

WoundPal is indicated for use as a primary dressing in the management of partial and full-thickness wounds, including diabetic ulcers, venous stasis ulcers, pressure ulcers, surgical wounds, ischemic ulcers, traumatic wounds, superficial burns, donor sites, and abrasions and lacerations. Absorbs wound exudates and maintains a moist environment.

Prescription Use___X____ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053476