K092086
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AMERX HEALTH CARE, CORP.
a division of PROCYON

510(k) Summary

JUL 30 2009

Date Prepared: July 08, 2009

Submitter's Information:
Amerx Health Care Corporation
1300 S. Highland Ave.
Clearwater, FL 33756
www.amerigel.com

Contact Information:
Art W. Simonetti, LPN
Director of Research & Regulatory Affairs
Phone: (727) 443-0530
Fax: (727) 447-5617
Toll-Free: (800) 448-9599
Email: aws@amerxhc.com

New Device Name:

Proprietary Name:	Amerigel® Wound Dressing PLUS
Common Name:	Medicated Wound Gel
Classification Name:	Dressing, wound and burn, hydrogel w/drug and/or biologic
Product Code:	MGQ
Regulatory Class:	Unclassified

Predicate Device #1:

Trade/Device Name:	Regenecare® Wound Gel (510(k) # K020540)
Regulation Name:	Hydrogel Wound Dressing
Product Code:	MGQ
Regulatory Class:	Unclassified

Predicate Device #2:

Trade/Device Name:	AmeriGel® Wound Dressing (510(k) # K002136)
Classification Regulation Name:	Hydrogel Wound Dressing (21 CFR 878.4022)
Regulatory Class:	Class I, exempt
Product Code:	NAE

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Device Description:
AmeriGel® Wound Dressing PLUS is a hydrogel that maintains a moist environment to support wound healing. We added 4% Lidocaine HCL to the formulation in our predicate device, AmeriGel® Wound Dressing. AmeriGel® Wound Dressing has been on the market for many years. With so many painful wounds, particularly venous stasis ulcers, we wanted to offer a wound gel that would help reduce the discomfort patients feel. Since AmeriGel® Wound Dressing has been doing so well for all these years, adding the 4% Lidocaine to the Polyethylene glycol (PEG) base will finally provide relief for those patients with painful wounds. When the Lidocaine was added to our formulation of Oakin (oak extract), Meadowsweet extract, water and Zinc acetate, the physical properties remained at a pH range of 7.0 - 7.2. Lidocaine HCL is well known to be GRASE (Generally regarded as safe and effective) and AmeriGel® Wound Dressing is also well known to be safe and effective, the combination of chemicals were found compatible, safe and effective.

AmeriGel® Wound Dressing PLUS would be used to manage stage I – IV pressure ulcers, venous stasis ulcers, ulcerations caused by mixed vascular etiologies, Diabetic skin ulcers, First and second degree burns, post-surgical incisions, cuts and abrasions.

Technological Characteristics:
AmeriGel® Wound Dressing PLUS is identical in formulation to AmeriGel® Wound Dressing, except with the addition of the Lidocaine. Regenecare® Wound Gel has similar action of its formulation. The PEG base provides moisture similarly to the Aloe Vera in Regenecare®. As they are both classified as hydrogels, they also autolytically debride. Both predicate devices are packaged in plastic tubes, as will AmeriGel® Wound Dressing PLUS. Regenecare® is sterile and AmeriGel® Wound Dressing is not, nor will AmeriGel® Wound Dressing PLUS. Biocompatibility for AmeriGel® Wound Dressing was previously established by dermal irritation test on rabbits, a sensitization test on guinea pigs, and In-vitro cytotoxicity test. Of course, AmeriGel® Wound Dressing has been marketed and used on humans for almost ten years without any adverse events.

Substantial Equivalence:
The claim of substantial equivalence of AmeriGel® Wound Dressing PLUS to the predicate devices is based on the comparison of the intended use, product technical characteristics and performance. Accordingly, Amerx Health Care Corporation concluded that AmeriGel® Wound Dressing PLUS is safe and effective for its intended use, and will perform at least as well as the legally predicate devices.

1300 S. Highland Avenue • Clearwater, FL 33756-6519
Toll Free: (800) 448-9599 • (727) 443-0530 • Fax: (727) 447-5617

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2009

Amerx Health Care Corporation
% Mr. Art W. Simonetti, LPN
Director of Research & Clinical Affairs
1300 S. Highland Avenue
Clearwater, Florida 33756-6519

Re: K092086
Trade/Device Name: AmerGel® Wound Dressing PLUS
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 8, 2009
Received: July 9, 2009

Dear Mr. Simonetti:

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: K092086

Device Name: AmeriGel® Wound Dressing PLUS

Indications for Use:

Stage I – IV Pressure ulcers
Venous stasis ulcers
Ulcerations caused by mixed vascular etiologies
Diabetic skin ulcers
First and second degree burns
Post-surgical incisions
Cuts and abrasions

Prescription Use X (21 CFR 801 Subpart D)

And/Or

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NO 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

510(k) Number K092086