



K092086
Page 1072

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

K002086
Page 2 of 2

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.



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.

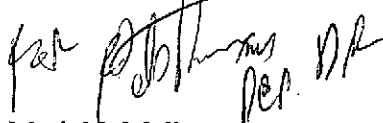
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 - Mr. Art W. Simonetti, LPN

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" (21 CFR 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,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a stylized flourish at the end.

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

510(k) Number K092086



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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

AUG 25 2009

Re: K092086/A001
Trade/Device Name: AmerGel® Wound Dressing PLUS
Dated: August 4, 2009
Received: August 13, 2009

Dear Mr. Simonetti:

We have received the information in your letter dated August 4, 2009, regarding the 510(k) notification K092086 previously submitted for the device referenced above. Based solely on the change or modification that you have described, it appears that you have significantly changed or modified the design, components, method of manufacture, device labeling, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). Please note that we did not review any data submitted with this add to file. You will need to submit a new 510(k) to the address below and receive Food and Drug Administration clearance prior to marketing your device with these changes. Please refer to our guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device" at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm>. Your letter referenced above will be added to the original 510(k) file with a copy of this letter. If you have any questions please contact Sam Arepalli, Ph.D., at (301) 796 6434 or the Division of Small Manufacturers, International and Consumer Assistance at (800) 638-2041 or (301) 796-7100.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Sincerely yours,

For Pte D [Signature]
Mark N. Melkerson
Director

Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Premarket Notification [510(k)] Review Traditional/Abbreviated

K092086/A001

Date: August 21, 2009
To: The Record
From: Sam Arepalli, Ph.D.
Branch: Plastic and Reconstructive Surgery Branch
Division: Division of General, Restorative, and Neurological Devices
Office: Office of Device Evaluation
510(k) Holder: Amerx Health Care Corp.
1300 S. Highland Ave.
Clearwater, Florida 33756
Devices Name: AmeriGel Wound Dressing Plus
Contact: Art W. Simonetti
Ph: 727 443 0530; Fax: 727 447 5617

*Agree with 8/25/09
Recommend A1202
Pth? D. R. N.A.*

Background and Review:

The subject device contains 4% lidocaine. The subject device was cleared under K092086 as prescription device for the indications for use of: For the management of Stage I-IV pressure ulcers, venous stasis ulcers, ulcerations caused by mixed vascular etiologies, diabetic skin ulcers, 1st and 2nd degree burns, post-surgical incisions, cuts and abrasions (refer to SE letter dated July 30, 2009).

The sponsor submitted this amendment asking the Agency whether the same device could be cleared for OTC under the procode MGQ.

The sponsor was contacted on August 18, 2009 and Mr. Semonetti was given feedback. He was specifically informed that the subject device as it contains lidocaine, a drug will be

assigned FRO procode.

The additional information submitted needs a new 510(k) [Boilerplate letter K30] should be sent to the sponsor.

SKA Repullo
Reviewer

8/24/09
Date

David Krone
Branch Chief

to comment Aug. 24, 2009
Date

PRSB

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 8-14-09

SAM

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s):

K092086/A1

To: Division Director:

SU/DSORD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

☒ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN])

☐ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

☐ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

☐ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

☐ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by:



Date:

8/21/09



K092086/A1

August 4, 2009

Department of Health & Human Services
Food and Drug Administration
CDRH/ODE

Document Mail Center (HFZ-401)

9200 Corporate Blvd
Rockville, MD 20850

FDA CDRH DMC

AUG 13 2009

Received

RE: K092086

Trade/Device Name: AmeriGel® Wound Dressing PLUS

Regulatory Class: Unclassified

Product Code: FRO

Dated July 8, 2009

Received: July 9, 2009

To whom it may concern:

I have received your letter of clearance dated July 30, 2009 for AmeriGel® Wound Dressing PLUS. I believe there was miscommunication on my part, as I was seeking a classification of MGQ because the product is a hydrogel. If we do not have the MGQ classification, then we lose our ability to have providers bill DMERC as A6248.

I have attached the 510k Premarket Notification from Regenecare® Wound Gel which was our predicate device. The only difference is that they have 2% Lidocaine and we were contemplating 4% Lidocaine.

We would like a MGQ Product Code so our product falls under a medicated hydrogel wound dressing. If we have to drop the Lidocaine to 2%, then we will certainly do that. Our predicate device has one version that is prescription and one that is OTC. We desire the OTC determination, just as they have.

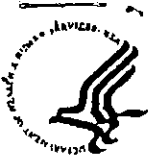
If the above cannot be obtained, would you please explain why, so I can have a better understanding of your decision to give us a Product Code of FRO.

Awaiting a response,

Art W. Simonetti, LPN

Director of Research & Regulatory Affairs

CS



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:

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510(k) Premarket Notification



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Device Classification Name

Dressing, Wound And Burn, Hydrogel
W/Drug And/Or Biologic

510(K) Number

K992074

Device Name

MPM REGENECARE WOUND GEL

Applicant

MPM MEDICAL, INC.
 6401 Meadows West Dr.
 Fort Worth, TX 76132

Contact

Richard A Hamer

Classification Product Code

MGQ

Date Received

06/18/1999

Decision Date

12/23/1999

Decision

Substantially Equivalent (SE)

Classification Advisory Committee

General & Plastic Surgery

Review Advisory Committee

General & Plastic Surgery

Statement/Summary/Purged Status

Summary Only

Summary

Summary

Type

Traditional

Reviewed By Third Party

No

Expedited Review

No

K020540

NOV 1 2002

510(k) SUMMARY

I. ADMINISTRATIVE

Submitter: MPM Medical, Inc.
2301 Crown Court
Irving, Texas 75038
(982) 893-4060

Contact Person: Paul R. Miller

Date of Preparation: February 18, 2002

II. DEVICE NAME

Proprietary Name: Regenecare™ Wound Gel
Common Name: Medicated Wound Gel
Classification Name: Medicated Hydrogel Wound and Burn Dressing

III. PREDICATE DEVICE

MPM Regenecare™ Wound Gel; K992074 (MPM Medical, Inc.)

IV. DEVICE DESCRIPTION

Regenecare™ Wound Gel is a viscous hydrogel wound dressing containing 2% w/w lidocaine as a topical anesthetic intended for use in the local management of painful skin wounds. The product is supplied sterile in plastic tubes.

V. INTENDED USE

Local management of skin wounds, including pressure ulcers, venous stasis ulcers, first and second degree burns, and superficial wounds and scrapes.

The biocompatibility of the predicate device has been established by a primary dermal irritation test in rabbits, a sensitization test in guinea pigs, and an *in vitro* cytotoxicity test. Since the safety of topical lidocaine (up to 4%) has been well established through a long history of over-the-counter use, the addition of 2% lidocaine to the original formulation does not raise any new biocompatibility issues.

VI. COMPARISON TO PREDICATE DEVICE

Regenecare™ Wound Gel is similar in composition, and identical in function and intended use, to MPM Regenecare™ Wound Gel (MPM Medical) and other legally marketed hydrogel wound dressing products.

Accordingly, MPM Medical concluded that Regenecare™ Wound Gel is safe and effective for its intended use, and performs at least as well as legally marketed predicate devices, such as the MPM Regenecare™ Wound Gel.

DEC 23 1999

K992074

510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: MPM Medical, Inc.
P.O. Box 151335
Arlington, Texas 76015

Contact Person: Paul Miller

Date of Preparation: October 18, 1999

II. DEVICE NAME

Proprietary Name: MPM Regenecare™ Wound Gel
Common Name: Wound Dressing
Classification Name: Hydrogel wound and burn dressing

III. PREDICATE DEVICE

MPM Hydrogel™ Dressing (MPM Medical, Inc.; K952276)

IV. DEVICE DESCRIPTION

MPM Regenecare™ Wound Gel is a viscous hydrogel wound dressing intended for use in the local management of skin wounds. The product is supplied sterile in 3 oz. plastic tubes.

Biocompatibility of the device has been established by a primary dermal irritation test in rabbits, a sensitization test in guinea pigs, and an *in vitro* cytotoxicity test.

V. INTENDED USE

Local management of skin wounds, including pressure ulcers, venous stasis ulcers, first and second degree burns, and superficial wounds and scrapes.

SRA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 8/24/09

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K092086 / AL

To: Division Director: SY / DSON D

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

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☒ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

Already provided the response. Ref to K092086/AL

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☐ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

☐ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: SRA Hettalli 9/1/09

Date: _____

DMC 9/1/09 I concur 9/1/2009



K092086 / A2

August 12, 2009

Department of Health & Human Services
Food and Drug Administration
Division of Surgical, Orthopedic and Restorative Devices
CDRH/ODE
ATTN: Mark N. Melkerson, Director
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, MD 20850

FDA CDRH DMC

AUG 24 2009

Received

RE: K092086

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

Dear Mr. Melkerson,

I have received your letter of clearance dated July 30, 2009 for AmeriGel® Wound Dressing PLUS. I believe there was a miscommunication on my part, as I was seeking a Product Code of MGQ "Dressing, wound and burn, hydrogel w/ drug and/or biologic" for AmeriGel® and OTC use. Without the MGQ code we lose our ability to have providers bill DMERC as A6248 as reimbursement when they dispense the product.

I have attached the product description from Regenecare® HA Wound Gel, our predicate device. On page 2, you will see where I highlighted that it is a "non-prescription" product.

Also, the other difference is Regenecare® contains 2% Lidocaine and AmeriGel® would contain 4%. Since you underlined the "4% Lidocaine" in our 510k, I assume that was an issue. If we have to drop the Lidocaine to 2%, then we will certainly do that to be considered MGQ and OTC as Regenecare® HA.

If the above cannot be obtained, would you please explain why, so I can have a better understanding of your decision to give us a Product Code of FRO.

Thank you,

Art W. Simonetti, LPN
Director of Research & Regulatory Affairs

K-13

1300 S. Highland Avenue • Clearwater, FL 33756-6519

Toll Free: (800) 448-9599 • (727) 443-0530 • Fax: (727) 447-5617

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV or call 301-796-8118



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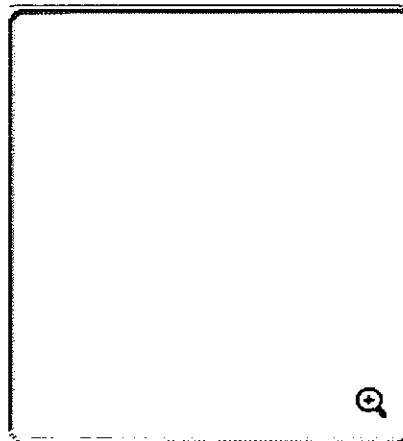
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Regenecare HA

[HomeProduct Details](#)

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Regenecare® HA Wound Care Gel

with 2% Lidocaine

An amorphous hydrogel dressing proven to reduce pain intensity without side effects Proven to reduce both pain and itching in cross-over study

Regenecare HA Wound Gels have been shown to be effective in the management of:

Dermatological Problems

- Radiation reactions
- Abrasions and skin tears
- Burns and cuts

- Psoriasis
- Shingles
- Dry and moist desquamation

Wound Problems

- Diabetic and vascular ulcers
- Partial and full thickness wounds
- Pain associated with debridement

Why they work:

- 2% Lidocaine HC I reduces pain, inflammation, breaks "itch and scratch" cycle
- Medium molecular weight polysaccharides in Aloe Vera reduce inflammation, moisturize plus stimulate micro-circulation and immune factors to help heal wounds quickly
- Marine collagen acts as humectant, natural barrier.
- RegenecareHA contains hyaluronic acid which donates moisture to the cells, connects fibrin to build skin matrix effectively

Directions:

- Cleanse the irritated area to remove extraneous material.
- Apply to dry, painful skin or tissue three times a day or as needed to assist in pain relief and provide a moist environment for healing.

Non Prescription

Contains Hyaluronic Acid, an active anti-inflammatory with powerful moisturizing properties

Case Studies - Regenecare HA

1

A Cross-Over Clinical Study of Forty Seven Patients with Painful Deep Wounds Showed Regenecare® Hydrogel Application was Highly Significant in Alleviating Dressing Related Pain.

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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

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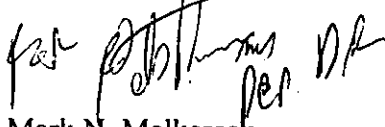
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 - Mr. Art W. Simonetti, LPN

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. Melkersen

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

510(k) Number K092086



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

July 13, 2009

AMERX HEALTH CARE CORP.
1300 S. HIGHLAND AVE.
CLEARWATER, FLORIDA 33756
UNITED STATES
ATTN: ART W. SIMONETTI, LPN

510k Number: K092086

Received: 7/9/2009

Product: AMERIGEL WOUND DRESSING PLUS 1

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/mdufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions. Compliance with Section 510(k) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007"

(http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/electsub.html. In addition, the 510(k) Program Video is now available for viewing on line at www.fda.gov/cdrh/video/510k.wmv.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Screening Checklist for Traditional/Abbreviated Premarket Notification [510(k)] Submissions

based on

**Guidance for Industry and FDA Staff
Format for Traditional and Abbreviated 510(k)s**

<http://www.fda.gov/cdrh/ode/guidance/1567.html>

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html	✓		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Cover Sheet www.fda.gov/opacom/morechoices/fdaforms/FDA-3514.pdf	✓		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		
Indications for Use Statement	Device Advice "Content of a 510(k)" Section D www.fda.gov/cdrh/devadvice/314312.html#link_6	✓		
510(k) Summary or 510(k) Statement	Device Advice "Content of a 510(k)" Section E www.fda.gov/cdrh/devadvice/314312.html#link_7	✓		
Truthful and Accuracy Statement	Device Advice "Content of a 510(k)" Section G www.fda.gov/cdrh/devadvice/314312.html#link_9	✓		
Class III Summary and Certification	Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html			✓
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html			✓
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations www.fda.gov/cdrh/ode/guidance/1131.html FDA Standards program www.fda.gov/cdrh/stdsprog.html Declaration of conformity www.fda.gov/cdrh/devadvice/3145.html#link_9 Required Elements for Declaration of Conformity to Recognized Standard www.fda.gov/cdrh/ode/regrecstand.html			✓
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	✓		

Title	Related Information	Present	Inadequate	N/A
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3), www.fda.gov/cdrh/k863.html			
Proposed Labeling	Device Advice "Content of a 510(k)" Section H www.fda.gov/cdrh/devadvice/314312.html#link_10			
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) www.fda.gov/cdrh/ode/guidance/361.html For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices www.fda.gov/cdrh/ode/guidance/1216.html			
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" www.fda.gov/cdrh/g951.html			
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices www.fda.gov/cdrh/ode/software.html			✓
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program www.fda.gov/cdrh/emc See also IEC 60601-1- 2 Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests (Second Edition, 2001)			✓
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			✓
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			✓
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 Certification/Disclosure Forms: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf			✓
Kit Certification	Device Advice http://www.fda.gov/cdrh/devadvice/314c.html			✓

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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on your check.		
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html				
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) AMERX HEALTH CARE CORPORATION 1300 S Highland Ave Clearwater FL 33756 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 593201771	2. CONTACT NAME Arthur Simonetti 2.1 E-MAIL ADDRESS aws@amerxhc.com 2.2 TELEPHONE NUMBER (include Area code) 727-4430530 211 2.3 FACSIMILE (FAX) NUMBER (Include Area code)			
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) Select an application type: <table border="0"> <tr> <td> ☒ Premarket notification(510(k)); except for third party ☐ 513(g) Request for Information ☐ Biologics License Application (BLA) ☐ Premarket Approval Application (PMA) ☐ Modular PMA ☐ Product Development Protocol (PDP) ☐ Premarket Report (PMR) ☐ Annual Fee for Periodic Reporting (APR) ☐ 30-Day Notice </td> <td> 3.1 Select a center ☒ CDRH ☐ CBER 3.2 Select one of the types below ☒ Original Application Supplement Types: ☐ Efficacy (BLA) ☐ Panel Track (PMA, PMR, PDP) ☐ Real-Time (PMA, PMR, PDP) ☐ 180-day (PMA, PMR, PDP) </td> </tr> </table>			☒ Premarket notification(510(k)); except for third party ☐ 513(g) Request for Information ☐ Biologics License Application (BLA) ☐ Premarket Approval Application (PMA) ☐ Modular PMA ☐ Product Development Protocol (PDP) ☐ Premarket Report (PMR) ☐ Annual Fee for Periodic Reporting (APR) ☐ 30-Day Notice	3.1 Select a center ☒ CDRH ☐ CBER 3.2 Select one of the types below ☒ Original Application Supplement Types: ☐ Efficacy (BLA) ☐ Panel Track (PMA, PMR, PDP) ☐ Real-Time (PMA, PMR, PDP) ☐ 180-day (PMA, PMR, PDP)
☒ Premarket notification(510(k)); except for third party ☐ 513(g) Request for Information ☐ Biologics License Application (BLA) ☐ Premarket Approval Application (PMA) ☐ Modular PMA ☐ Product Development Protocol (PDP) ☐ Premarket Report (PMR) ☐ Annual Fee for Periodic Reporting (APR) ☐ 30-Day Notice	3.1 Select a center ☒ CDRH ☐ CBER 3.2 Select one of the types below ☒ Original Application Supplement Types: ☐ Efficacy (BLA) ☐ Panel Track (PMA, PMR, PDP) ☐ Real-Time (PMA, PMR, PDP) ☐ 180-day (PMA, PMR, PDP)			
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) ☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA ☒ NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:				
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? ☒ YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <i>WE ARE DISTRIBUTOR/LABELER</i> ☐ NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information) <i>ERROR</i>				
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <table border="0"> <tr> <td> ☐ This application is the first PMA submitted by a qualified small business, including any affiliates ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only </td> <td> ☐ The sole purpose of the application is to support conditions of use for a pediatric population ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially </td> </tr> </table>			☐ This application is the first PMA submitted by a qualified small business, including any affiliates ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	☐ The sole purpose of the application is to support conditions of use for a pediatric population ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
☐ This application is the first PMA submitted by a qualified small business, including any affiliates ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	☐ The sole purpose of the application is to support conditions of use for a pediatric population ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) ☐ YES ☒ NO				
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b) (4)				

24-Jun-2009

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 7/08/2009	User Fee Payment ID Number (b) (4)	FDA Submission Document Number (if known)
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SECTION A		TYPE OF SUBMISSION		
PMA ☐ Original Submission ☐ Premarket Report ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment ☐ Licensing Agreement	PMA & HDE Supplement ☐ Regular (180 day) ☐ Special ☐ Panel Track (PMA Only) ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA & HDE Supplement ☐ Other	PDP ☐ Original PDP ☐ Notice of Completion ☐ Amendment to PDP	510(k) ☒ Original Submission: ☒ Traditional ☐ Special ☐ Abbreviated (Complete section I, Page 5) ☐ Additional Information ☐ Third Party	Meeting ☐ Pre-510(K) Meeting ☐ Pre-IDE Meeting ☐ Pre-PMA Meeting ☐ Pre-PDP Meeting ☐ Day 100 Meeting ☐ Agreement Meeting ☐ Determination Meeting ☐ Other (specify):
IDE ☐ Original Submission ☐ Amendment ☐ Supplement	Humanitarian Device Exemption (HDE) ☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment	Class II Exemption Petition ☐ Original Submission ☐ Additional Information	Evaluation of Automatic Class III Designation (De Novo) ☐ Original Submission ☐ Additional Information	Other Submission ☐ 513(g) ☐ Other (describe submission):

Have you used or cited Standards in your submission? ☐ Yes ☐ No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name Amrx Health Care Corporation		Establishment Registration Number (if known)	
Division Name (if applicable)		Phone Number (including area code) (727) 443-0530	
Street Address 1300 S. Highland Ave.		FAX Number (including area code) (727) 447-5617	
City Clearwater	State / Province FL	ZIP/Postal Code 33756	Country USA
Contact Name Art W. Simonetti, LPN			
Contact Title Director of Research & Regulatory Affairs		Contact E-mail Address aws@amrxhc.com	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name None			
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1

REASON FOR APPLICATION - PMA, PDP, OR HDE

Records processed under FOIA Request #2017-631; Released by CDRH on 07-17-2017.

☐ New Device ☐ Withdrawal ☐ Additional or Expanded Indications ☐ Request for Extension ☐ Post-approval Study Protocol ☐ Request for Applicant Hold ☐ Request for Removal of Applicant Hold ☐ Request to Remove or Add Manufacturing Site	☐ Change in design, component, or specification: ☐ Software / Hardware ☐ Color Additive ☐ Material ☐ Specifications ☐ Other (specify below)	☐ Location change: ☐ Manufacturer ☐ Sterilizer ☐ Packager
☐ Process change: ☐ Manufacturing ☐ Packaging ☐ Sterilization ☐ Other (specify below)	☐ Labeling change: ☐ Indications ☐ Instructions ☐ Performance Characteristics ☐ Shelf Life ☐ Trade Name ☐ Other (specify below)	☐ Report Submission: ☐ Annual or Periodic ☐ Post-approval Study ☐ Adverse Reaction ☐ Device Defect ☐ Amendment
☐ Response to FDA correspondence:		☐ Change in Ownership ☐ Change in Correspondent ☐ Change of Applicant Address

☐ Other Reason (specify):

SECTION D2

REASON FOR APPLICATION - IDE

☐ New Device ☐ New Indication ☐ Addition of Institution ☐ Expansion / Extension of Study ☐ IRB Certification ☐ Termination of Study ☐ Withdrawal of Application ☐ Unanticipated Adverse Effect ☐ Notification of Emergency Use ☐ Compassionate Use Request ☐ Treatment IDE ☐ Continued Access	☐ Change in: ☐ Correspondent / Applicant ☐ Design / Device ☐ Informed Consent ☐ Manufacturer ☐ Manufacturing Process ☐ Protocol - Feasibility ☐ Protocol - Other ☐ Sponsor	☐ Response to FDA Letter Concerning: ☐ Conditional Approval ☐ Deemed Approved ☐ Deficient Final Report ☐ Deficient Progress Report ☐ Deficient Investigator Report ☐ Disapproval ☐ Request Extension of Time to Respond to FDA ☐ Request Meeting ☐ Request Hearing
☐ Report submission: ☐ Current Investigator ☐ Annual Progress Report ☐ Site Waiver Report ☐ Final		

☐ Other Reason (specify):

SECTION D3

REASON FOR SUBMISSION - 510(k)

☒ New Device	☐ Additional or Expanded Indications	☐ Change in Technology
--	---	---

☐ Other Reason (specify):

SECTION E

ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	MGQ	2	NAE	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- ☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1 K020540	1 Regenecare Wound Gel	1 MPM Medical, Inc.
2 K002136	2 AmeriGel Wound Dressing	2 Kova Laboratories, Inc.
3	3	3
4	4	4
5	5	5
6	6	6

SECTION F

PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Common Name: Medicated Wound Gel Classification Name: Medicated Hydrogel Wound and Burn Dressing

Trade or Proprietary or Model Name for This Device	Model Number
AmeriGel Wound Dressing PLUS 1/2 oz. (15g tube)	1 A2025
2 AmeriGel Wound Dressing PLUS 1 oz. (30g tube)	2 A2026
3 AmeriGel Wound Dressing PLUS 3 oz. (90g tube)	3 A2027
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing☐ Animal Trials☐ Human Trials

SECTION G

PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code MGQ	C.F.R. Section (if applicable)	Device Class
Classification Panel Dressing, wound and burn, hydrogel w/drug and/or biologic		☐ Class I ☐ Class II ☐ Class III ☒ Unclassified

Indications (from labeling)

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.

Note: Submission of this information does not effect the need to submit a 2891 and 2891a Device Establishment Registration form.		FDA Document Number (if known) 17-631; Released by CDRH on 07-17-2017.	
SECTION II MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number		☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☒ Repackager / Relabeler
Company / Institution Name Amerx Health Care Corporation (Labeler ID # 61470)		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) (727) 443-0530	
Street Address 1300 S. Highland Ave.		FAX Number (including area code) (727) 447-5617	
City Clearwater	State / Province FL	ZIP Code 33756	Country USA
Contact Name Art W. Simonetti, LPN	Contact Title Director of Research & Regulatory Affairs		Contact E-mail Address aws@amerxhc.com

(b)(4) Confidential and Proprietary Information

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number		☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name None		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address

SECTION I:

UTILIZATION OF STANDARDS

Records processed under FOIA Request #2017-631; Released by CDRH on 07-17-2017.

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, Maryland 20857

In agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.



Traditional 510(k) Notification

Date Prepared: July 8, 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:

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

Predicate Device:

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

Basis for Submission:

The purpose of this submission is to bring a new device to market. There are many patients who suffer with painful wounds, especially venous stasis ulcerations in particular. This new formulation will help address that issue and provide comfort to the patient while their wound heals.

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)? ^A	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)? ^A	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?	X	
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

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 _____
(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)



510(k) Summary

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

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.

TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as Director of Research & Regulatory Affairs for Amerx Health Care Corporation, I believe to the best of my knowledge, that all data and information submitted in the Premarket Notification are truthful and accurate and that no material fact has been omitted.


Signature

Art W. Simonetti, LPN
Typed Name

July 08, 2009
Date

Premarket Notification 510(k) Number

This Section does not apply

This Section does not apply

This Section does not apply



Executive Summary

There are numerous wound care dressings on the market, but more importantly there are many patients with painful wounds. Amerx Health Care Corporation felt that there should be a safe and effective wound gel that would offer relief to those who have to tolerate the discomfort. Our original hydrogel wound filler, AmeriGel® Wound Dressing has been healing wounds for many years. It contains Oakin® (Oak extract/tannins), Meadowsweet extract, water, and Zinc acetate in a Polyethylene Glycol (PEG) base. AmeriGel® Wound Dressing has been very effective in the management of Stage I – IV pressure ulcers, venous stasis ulcers, diabetic skin ulcers, first and second degree burns and post-surgical wound dehiscence. Having a proven track record in managing these wounds, it was decided to add 4% Lidocaine HCL to the formula to minimize the pain from various ulcers, such as venous stasis ulcer. We aware that one of our other predicate devices, Regencare™ Wound Gel (510(k) K020540), was cleared by the FDA containing 2% Lidocaine in November 2002.

Device Description:

AmeriGel® Wound Dressing PLUS is a hydrogel wound dressing containing Oakin and 4% w/w Lidocaine as a topical anesthetic intended for use in the local management of various painful wounds. The product will be supplied non-sterile in plastic tubes.

Intended Use:

Local management of 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.

The biocompatibility of the predicate device (AmeriGel® Wound Dressing) has been established by a primary dermal irritation test in rabbits, a sensitization test in guinea pigs, and In-vitro cytotoxicity test from our original 510(k) K002136 submission. Since the safety of topical Lidocaine (up to 4%) has been well established through a long history of over-the-counter use, the addition of 4% Lidocaine to the original formulation does not raise any new biocompatibility issues.

Comparison to Predicate Device:

Company	Amerx Health Care	MPM Medical, Inc.	Amerx Health Care
Proprietary Name	AmeriGel® Wound Dressing PLUS	Regenecare® HA	AmeriGel® Wound Dressing
510(k) Number	Not assigned	K020540	K002136
Intended Use	Stage I-IV pressure ulcers, diabetic skin ulcers, venous stasis ulcers, post-surgical incisions, ulcerations caused by mixed vascular etiologies, cuts and abrasions	Stage I-IV pressure ulcers, diabetic skin ulcers, venous stasis ulcers, post-surgical incisions.	Stage I-IV pressure ulcers, diabetic skin ulcers, venous stasis ulcers, post-surgical incisions, cuts and abrasions
Material Characteristics	PEG based hydrogel with Oakin, Zinc acetate and 4% Lidocaine HCL	Aloe Vera based hydrogel, Collagen, 2% Lidocaine, and Hyaluronic acid	PEG based hydrogel with Oakin, Zinc acetate
Forms	Clear viscous hydrogel	Clear viscous hydrogel	Clear viscous hydrogel
How Supplied	Not sterile	Sterile	Not sterile
Sterilization Method	None	Gamma Irradiation	None
Packaging	Tube	Tube	Tube

All three devices have the same intended use, are all clear viscous hydrogels, and have similar packaging. AmeriGel® Wound Dressing PLUS contains almost identical ingredients as the original AmeriGel® Wound Dressing and are both packaged non-sterile. The only difference in ingredients is the addition of 4% Lidocaine HCL to AmeriGel® Wound Dressing PLUS. The Lidocaine HCL helps reduce pain and inflammation. Lidocaine HCL is found in the predicate device, Regenecare® HA.

Summary of Technological Characteristics:

AmeriGel® Wound Dressing PLUS is identical to its predicate device AmeriGel® Wound Dressing, with the exception of the 4% Lidocaine. PEG offers similar properties as Hyaluronic acid and Aloe Vera in providing moisture and a barrier to the wound. AmeriGel® Wound Dressing PLUS should perform identically to its predicate with the added advantage of addressing the discomfort during a dressing change.

Summary of Substantial Equivalence:

The claim of Substantial Equivalence of AmeriGel® Wound Dressing PLUS to its two predicate devices is based on the comparison of the intended use, product technical characteristics and the FDA monograph for Lidocaine HCL is a Panel 1 and GRASE.

Device Description

AmeriGel® Wound Dressing PLUS is a medicated hydrogel that contains (alphabetical):

1. Lidocaine HCL 4%
2. Meadowsweet extract
3. Oakin (Oak extract/Tannins)
4. Polyethylene glycol 400 and Polyethylene glycol 3350
5. Water
6. Zinc acetate

AmeriGel® Wound Dressing PLUS encourages healing by maintaining a moist wound environment, proliferating proteins to the wound bed and promoting granulation tissue development. It will be available in a ½ oz, 1 oz, and 3 oz. tubes.



Substantial Equivalence Discussion

Date Prepared: July 7, 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:

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

Predicate Device:

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

New Device Description:

AmeriGel® Wound Dressing PLUS is a hydrogel wound dressing containing Oakin and 4% w/w Lidocaine as a topical anesthetic intended for use in the local management of various painful wounds. The product will be supplied non-sterile in plastic tubes.

Intended Use:

Local management of 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.

Comparison to Predicate Devices:

Company	Amerx Health Care	MPM Medical, Inc.	Amerx Health Care
Proprietary Name	AmeriGel® Wound Dressing PLUS	Regenecare® HA	AmeriGel® Wound Dressing
510(k) Number	Not assigned	K020540	K002136
Intended Use	Stage I-IV pressure ulcers, diabetic skin ulcers, venous stasis ulcers, post-surgical incisions, ulcerations caused by mixed vascular etiologies, cuts and abrasions.	Stage I-IV pressure ulcers, diabetic skin ulcers, venous stasis ulcers, post-surgical incisions.	Stage I-IV pressure ulcers, diabetic skin ulcers, venous stasis ulcers, post-surgical incisions, cuts and abrasions
Material Characteristics	PEG based hydrogel with Oakin, Zinc acetate	Aloe Vera based hydrogel, Collagen, 2% Lidocaine, and Hyaluronic acid	PEG based hydrogel with Oakin and 4% Lidocaine
Forms	Clear viscous hydrogel	Clear viscous hydrogel	Clear viscous hydrogel
How Supplied	Not sterile	Sterile	Not sterile
Sterilization Method	None	Gamma Irradiation	None
Packaging	Tube	Tube	Tube

All three devices have the same intended use, are all clear viscous hydrogels, and have similar packaging. AmeriGel® Wound Dressing PLUS contains almost identical ingredients as the original AmeriGel® Wound Dressing and are both packaged non-sterile. The only difference in ingredients is the addition of 4% Lidocaine HCL to

Technological Characteristics:

AmeriGel® Wound Dressing PLUS is identical to its predicate device AmeriGel® Wound Dressing, with the exception of the 4% Lidocaine. PEG offers similar properties as Hyaluronic acid and Aloe Vera in providing moisture and a barrier to the wound. AmeriGel® Wound Dressing PLUS should perform identically to its predicate with the added advantage of addressing the discomfort during a dressing change.

Summary of Substantial Equivalence:

The claim of Substantial Equivalence of AmeriGel® Wound Dressing PLUS to its two predicate devices is based on the comparison of the intended use, product technical characteristics and the FDA monograph for Lidocaine is a Panel 1 and GRASE.

Accordingly, Amerx Health Care Corporation concluded that AmeriGel® Wound Dressing PLUS is safe and effective for its intended use, and performs at least as well as the legally marketed predicate devices, such as AmeriGel® Wound Dressing and Regenecare® HA.

Proposed Labeling

AmeriGel® Wound Dressing PLUS

A soothing hydrogel wound dressing that promotes a moist wound environment that is ideal for the healing process.

Indications:

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.

Directions:

Cleanse the wound and blot it dry. Apply a thin layer of AmeriGel® to the wound surface and the skin immediately surrounding the wound once daily. Cover the wound with a moistened gauze dressing.

Ingredients: (Alphabetical)

Lidocaine HCL w/w 4%, Meadowsweet extract, Oakin (Oak extract), Polyethylene glycol 400, Polyethylene glycol 3350, Water, and Zinc acetate.

Warning:

Do not use the product if you are allergic to any ingredients. If condition worsens or does not improve within 7 days, consult a physician. Do not use on children under 2 years of age without consulting a physician.

Manufactured for Amerx Health Care Corp., Clearwater, FL 33756
1-800-448-9599 www.amerigel.com

Lot#:

Exp. Date:

Cat #:

NDC:

UPC:

Net Wt:

Sterilization and Shelf Life

AmeriGel® Wound Dressing PLUS manufacturing processes will be identical as the original filing of AmeriGel® Wound Dressing. The product is stable and all ingredients are compatible. The product will have a shelf life of 2 years, as our original predicate device, AmeriGel® Wound Dressing.

Biocompatibility

AmeriGel® Wound Dressing PLUS will be manufactured in the identical manner as its predicate device AmeriGel® Wound Dressing. The product is stable and all ingredients are compatible. As our original predicate device AmeriGel® Wound Dressing has been on the market for many years and there have been no adverse events filed, however many testimonials to its efficacy.

This Section does not apply

This Section does not apply

This Section does not apply

This Section does not apply

This Section does not apply



AUG 17 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Art W. Simonetti
Director of Clinical Affairs
Amerx Health Care Corporation
1150 Cleveland Street
Suite 410
Clearwater, Florida 33755

Re: 510(k) Number: K002136
Device: Amerigel Ointment
Dated: July 10, 2000
Received: July 14, 2000
Classification Regulation Name: Hydrogel Wound Dressing (21 CFR 878.4022)
Regulatory Class: Class I, exempt
Product Code: NAE

Dear Mr. Simonetti:

We have reviewed your premarket notification submission and have found this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). Therefore, you may immediately begin marketing this device as described in your premarket notification.

The Final Rule exempting your device type was published in the Federal Register on October 5, 1999, Vol. 64, No. 192, pages 53927-53929, and was effective November 4, 1999. Therefore, manufacturers of devices falling within the above classification regulation and corresponding product code are now exempt from the premarket notification requirements of the Act if they meet the classification criteria. Your device's product code, classification regulation name and regulatory class are shown above. When listing your device with the Food and Drug Administration, please use this product code. We suggest that you review this above referenced regulation since it may grant other exemptions from certain general controls of the Act.

In the future, new but substantially equivalent devices which fall within the above classification regulation name and meet the classification criteria may be marketed without sending a premarket notification submission to the Food and Drug Administration. We suggest, however, that you review the section(s) entitled "Limitations on Exemptions" in the above referenced Federal Register notice to determine whether or not your new device(s) meets the exemption criteria. This Federal Register notice may be accessed on the World Wide Web at [www.fda.gov/ohrms/dockets/98fr/110398.txt] or obtained by facsimile from the Division of Small Manufacturers Assistance's Facts On Demand at (800) 899-0381 or (301) 827-0111.

Page 2 - Mr. Art W. Simonetti

If you have any questions regarding this letter, please contact the Premarket Notification Staff at (301) 594-1190 or the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Dan R. Bochner

CM Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K020540

NOV 1 2002

510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: MPM Medical, Inc.
2301 Crown Court
Irving, Texas 75038
(982) 893-4060

Contact Person: Paul R. Miller

Date of Preparation: February 18, 2002

II. DEVICE NAME

Proprietary Name: Regenecare™ Wound Gel
Common Name: Medicated Wound Gel
Classification Name: Medicated Hydrogel Wound and Burn Dressing

III. PREDICATE DEVICE

MPM Regenecare™ Wound Gel; K992074 (MPM Medical, Inc.)

IV. DEVICE DESCRIPTION

Regenecare™ Wound Gel is a viscous hydrogel wound dressing containing 2% w/w lidocaine as a topical anesthetic intended for use in the local management of painful skin wounds. The product is supplied sterile in plastic tubes.

V. INTENDED USE

Local management of skin wounds, including pressure ulcers, venous stasis ulcers, first and second degree burns, and superficial wounds and scrapes.

The biocompatibility of the predicate device has been established by a primary dermal irritation test in rabbits, a sensitization test in guinea pigs, and an *in vitro* cytotoxicity test. Since the safety of topical lidocaine (up to 4%) has been well established through a long history of over-the-counter use, the addition of 2% lidocaine to the original formulation does not raise any new biocompatibility issues.

VI. COMPARISON TO PREDICATE DEVICE

Regenecare™ Wound Gel is similar in composition, and identical in function and intended use, to MPM Regenecare™ Wound Gel (MPM Medical) and other legally marketed hydrogel wound dressing products.

Accordingly, MPM Medical concluded that Regenecare™ Wound Gel is safe and effective for its intended use, and performs at least as well as legally marketed predicate devices, such as the MPM Regenecare™ Wound Gel.

Premarket Notification: Regenecare™ Wound Gel

010



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2002

MPM Medical, Inc.
Paul R. Miller
President
2301 Crown Court
Irving, Texas 75038

Re: K020540

Trade/Device Name: Regenecare™ Wound Gel
Regulation Name: Hydrogel Wound Dressing
Regulatory Class: Unclassified
Product Code: MGQ
Dated: July 30, 2002
Received: August 5, 2002

Dear Mr. Miller:

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.

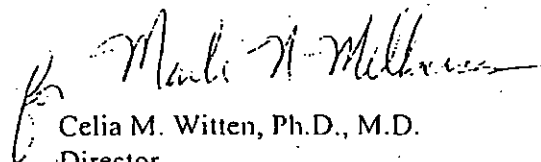
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Mr. Paul R. Miller

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director

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

Enclosure

510(k) Number (if known): K020540

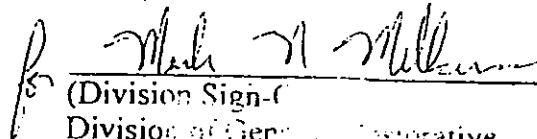
Device Name: Regenecare™ Wound Gel

Indications for Use:

Local management of skin wounds, including pressure ulcers, venous stasis ulcers, first and second degree burns, and superficial wounds and scrapes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-
Division of General, Reproductive
and Neurological Devices

510(k) Number K020540

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)

Premarket Notification: Regenecare™ Wound Gel

Amerx Health Care does not have a new packaging design for the outer box of AmeriGel® Wound Dressing PLUS. However, it will contain the proposed labeling as stated in Section 13. It will have a different look than our predicate AmeriGel® Wound Dressing to eliminate confusion and potential errors.

Enclosed are the packaging pictures of both identified hydrogel predicate devices.



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AMERIGEL™
WOUND DRESSING

**MAXIMUM
 STRENGTH**

**Approved For
 Open Deep Wounds**

**Diabetic Ulcers • Stasis Ulcers
 Pressure Ulcers Stages I-IV
 Surgical Wounds • Friction Tears
 Cuts & Scrapes • Itch & Rash Relief
 1st & 2nd Degree Burns**



The **ONLY** Wound Care Product with
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Net Wt. 1 oz (28.3g)

NDC-61470-1014-1



CAT# A2001

For product information visit
www.amerigel.com or call (800) 448-9599

AMERX HEALTH CARE CORP.
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 Clearwater, FL 33755
 Manufactured for:

Approved For
Open Deep Wounds
Diabetic Ulcers • Stasis Ulcers
Pressure Ulcers Stages I-IV
Surgical Wounds • Friction Tears
Cuts & Scrapes • Itch & Rash Relief
1st & 2nd Degree Burns

Promotes a moist wound environment that is
 ideal for the healing process.
Indications: Management of Stage I-IV pressure
 ulcers, stasis ulcers, diabetic skin ulcers, post-
 surgical incisions, 1st and 2nd degree burns, cuts,
 abrasions and skin irritations.
Directions: Cleanse the wound and blot it dry.
 Apply a thin layer of Amerigel to the wound
 surface and to the skin immediately surrounding
 the wound once or twice daily. Cover the wound
 with a moistened gauze bandage.
Ingredients: Meadowsweet Extract, Oak Extract
 (OakainSM), Polyethylene Glycol 400, Polyethylene
 Glycol 3350, Water, Zinc Acetate.
Warning: If condition worsens or does not
 improve within 7 days, consult a physician. Avoid
 contact with the eyes. Do not use on children
 under 2 years of age without consulting a physician.

HYDROGEL
WOUND DRESSING

AMERIGEL™
PREMIUM
WOUND
DRESSING

NDC 61470-1014-1

AMERIGELTM

WOUND DRESSING

Promotes a moist wound environment that is ideal for the healing process.

Indications: Management of Stage I/II pressure ulcers, surgical incisions, skin ulcers, post-surgical incisions, 1st and 2nd degree burns, cuts, abrasions and skin irritations.

Directions: Cleanse the wound and blot it dry. Apply a thin layer of Amerigel to the wound surface and to the skin immediately surrounding the wound once or twice daily. Cover the wound with a moistened gauze bandage.

Ingredients: Meadowsweet Extract, Oak Extract (OakinTM), Polyethylene Glycol 400, Polyethylene Glycol 3350, Water, Zinc Acetate.

Manufactured for:
AMERIGELTM
WOUND DRESSING
A Division of Procyon Corp.
Clearwater, FL 33756

For product information visit:
www.amerigel.com or
call (800) 448-9599

Warning: If condition worsens or does not improve within 7 days, consult a physician. Avoid contact with the eyes. Do not use on children under 2 years of age without consulting a physician.

PREMIUM WOUND DRESSING
Net Wt. 1 oz (28.3g)



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WOUND CARE
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[PAIN MANAGEMENT](#) Regenecare HA

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JUN 26 2009 16:26:51

SSL Certificates

MPM
MEDICAL, INC.

Regenecare HA

☒ E-mail this product to a Friend

REGENECARE HA 3oz WOUND GEL (TUBE)



ITEM NUMBER: MPM00107

Description:

- Regenecare HA Wound Gel.
- Size: 3oz.
- Indicated for: The temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites or minor skin irritation. RegenecareHA® has also been shown to effectively treat skin problems associated with epidermal growth factor receptors such as puritis and rash. In addition, Foot and Hand Syndrome (PPE), responds favorably to application of RegenecareHA® 3 to 4 times per day. In addition, Regenecare can be applied to leg ulcers.
- Contains: 2% Lidocaine a topical anesthetic, Collagen (Humectant), Pure aloe vera extract (Moisturizer), and Hyaluronic acid.
- **SOLD BY THE TUBE.**

Price: \$16.50

Quantity: 1

[Add to Cart](#)

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K092086

July 8, 2009

Food and Drug Administration
CDRH / ODE
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, MD 20850

Received
JUL - 9 2009
FDA CDRH DMC

To whom it may concern:

The purpose for this 510(k) submission is to add Lidocaine 4%, established by the FDA monograph to be safe and effective, into our device (hydrogel) that was cleared by the FDA as safe and effective.

Simply put, we are adding an already known safe and effective ingredient to an already safe and effective cleared device. If there is a "Fast Track" or a way to expedite this submission, it would certainly be most appreciated.

Thank you,

Art W. Simonetti, LPN
Director of Research & Clinical Affairs
Board Member, Foot and Ankle Institute, Miami, FL
Peer-Review Board Member for the Foot & Ankle Online Journal

K5

SC
unclassified



COVER SHEET MEMORANDUM

From: Reviewer Name

Subject: 510(k) Number

To: The Record

Please list CTS decision code

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	X	
510(k) Summary /510(k) Statement	Attach Summary	X	
Truthful and Accurate Statement.	Must be present for a Final Decision	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			X
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both <u>prescription</u> & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		X	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)		X	X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age ≤ 21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days - < 2 years old)			X
Child (2 years - < 12 years old)			X
Adolescent (12 years - < 18 years old)			X
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		X

Regulation Number unclassified Class* drussing Product Code FRO
 (*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: David Krane PRSB July 30, 2009
 (Branch Chief) (Branch Code) (Date)

Final Review: _____
 (Division Director) (Date)

[Handwritten signature]



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

K092086

Date: July 14, 2009
To: The Record
From: Sam Arepalli, Ph.D.
Branch: Plastic and Reconstructive Surgery Branch
Division: Division of General, Restorative, and Neurological Devices
Office: Office of Device Evaluation
510(k) Holder: Amerx Health Care Corp.
1300 S. Highland Ave.
Clearwater, Florida 33756
Devices Name: AmeriGel Wound Dressing Plus
Contact: Art W. Simonetti
Ph: 727 443 0530; Fax: 727 447 5617

*OK
Art W. Simonetti
7/15/09*

I. Purpose of Submission

The 510(k) holder would like to introduce the following device into interstate commerce.
Devices name: AmeriGel Wound Dressing Plus

II. Document History

The sponsor is seeking clearance of the devices namely, AmeriGel Wound Dressing Plus. The subject device is identical to the one cleared under K002136 (AmeriGel) except that the subject device contains 4% lidocaine. The indications for use of the subject device are identical to those of the previously cleared device under K002136. The device biocompatibility is not required as 4% of lidocaine addition will not change the biocompatibility profile (lidocaine is approved by CDER upto 4% and is a monographed product). The sterilization, shelf-life will be the same that of the predicate device (K002136). No other performance data are required in SE decision-making process.

III. Recommendation: SE

Regulation Number: Unclassified
Regulation Name: Dressing
Regulatory Class: Unclassified
Product Code: FRO

IV. Administrative Requirements**Table 1**

	YES	NO	N/A	MISC
Indications for Use page (Prescription)	X			
Truthful and Accuracy Statement	X			
510(k) Summary	X			
Standards Form		X		

V. Device Description - Subject Devices:

The subject device is hydrogel containing 4% lidocaine. The subject device is identical to the one cleared under K002136 (AmeriGel) except that the subject device contains 4% lidocaine. The other components of the dressing are: Water:, Meadowsweet extract, PEG 400, PEG 3350, and Zinc acetate.

Predicate Device - Device Description:

Identical to subject device except the predicate device (AmeriGel cleared under K002136) does not contain lidocaine.

VI. Predicate Device Comparison**Indications for Use Subject Device:**

Indicated for the management of Stage I-IV pressure ulcers, venous stasis ulcers, ulcerations caused by mixed vascular etiologies, diabetic skin ulcers, 1st and 2nd degree burns, post-surgical incisions, cuts and abrasions

Indications for Use Predicate Device:

Same as the subject device as listed above

VII. Labeling

Product labels are provided in
The box label is not provided.

The package insert (Instructions for Use) contains: Device description, indications for use statement, warnings, lot #, catalogue #, directions for use, and manufacturer's name and address.

VIII. Sterilization/Shelf Life/Reuse/Pyrogenicity/Shelf-life

Same as the predicate device (K002136 & K970133)

Shelf-life:

Same as the predicate device (K002136 & K970133) – 2 years

Packaging:

Same as the predicate device (K002136 & K970133)

IX. Biocompatibility

The subject device is identical to predicate device (K002136) except the subject dressing contains

4% lidocaine. Addition of lidocaine will not change the biocompatibility properties of the device and lidocaine is approved by CDER (monograph) up to 4%.

X. Software:
NOT APPLICABLE

XI. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety
NOT APPLICABLE

XII. Performance Testing – Bench:
None provided. None required.

Performance Testing – Animal Wound Healing Study:
None provided. None required.

XIII. Performance Testing- In Vitro Data (Microbiological):
None provided. None required.

XIV. Performance Testing – Clinical
None provided. None required.

XV. Substantial Equivalence Discussion

Table 3

	YES	NO	
1. Same Indication Statement?	x		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	x		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?	x		If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?			If NO = <u>Request Data</u>
9. Data Demonstrate Equivalence?			Final Decision:

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect of safety or effectiveness issue:
3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XVI. Deficiencies (Original Submission)

None

XVII. Contact History

SR [Signature] 7/22/09
Reviewer Date

David Krane Ironen July 28, 2009
Branch Chief Date

510 (k) M E M O R A N D U M
K002136

Date: August 11, 2000
From: Sam Arepalli, Ph.D.
To: File
Subject: K002136
Device: Amerigel Ointment
Wound Dressing (Common name)
Hydrogel (Classification name)

Classification: Class I, exempt

Product Code: NAE

Sponsor: Amerx Health Care Corp.
1150 Cleveland St
Clearwater, FL 33755
(727) 443 0530

Contact: Art W. Simonetti
(737) 443 0530

Recommendation:

The wound dressing under consideration is Class I, exempt. The sponsor should be sent an exempt letter.

Review:

The product under consideration was previously cleared for marketing under K970133 for certain indications for use (see K970133 for details). The sponsor through this pre-market notification, is seeking additional indications for use re: 1st and 2nd degree burns and post-surgical incisions.

The predicate device Carrasyn Hydrogel Wound Dressing (K962218) is also indicated for these two indications namely, 1st and 2nd burns and post surgical incisions in addition to other indications (see K970133). As both the subject device and the predicate device are hydrogels, there should not be any problem in allowing the subject device to have these two additional indications for use. Moreover, the sponsor does not intend to change the formulation of the dressing (existing one, K970133). Therefore, the subject device is substantially equivalent to the predicate device (Carrasyn Hydrogel Wound Dressing,

K962218). As the hydrogel wound dressings are Class I, exempt, the sponsor should be sent an exempt letter.

Sam Arepalli
Sam Arepalli, Ph.D.

8/11/00
Date

510(K) MEMORANDUM

TO: File

FROM: David B. Berkowitz, Reviewer
ODE/DGRND/Plastic and Reconstructive Surgery Devices Branch

DATE: October 24, 2002

SUBJ: **K020540**
Regenecare™ Wound Gel
MPM Medical, Inc.
Richard Hamer 817-294-3644

Recommendation:

Procode: MGQ

Class: Unclassified

Hydrogel Wound Dressing

REVIEW:

1. Does the product contain drugs or biologicals? If yes, what is the drug/biologic.

This 510(k) contains 3 drugs, lidocaine, aloe vera, and tocopherol acetate. The amounts are listed below. There are no claims or support for claims. The purpose of a small amount of peroxide should be explained.

1) The 510(k) identifies the drugs and amounts as listed below:

lidocaine

2%

Aloe vera gel

Tocopherol Acetate

Collagen

(b)(4) Confidential and Proprietary
Information

2) The claim for the purpose of the drugs is absent.

3) The supporting evidence for the claim is absent.

2. Indication and/or Intended Use Statement

Subject Device p. 7

Local management of skin wounds, including pressure ulcers, venous stasis ulcers, first and second degree burns, and superficial wounds and scrapes.

6 12

Predicate Device(s)

Identical to above.

Discussion of equivalency

The labeling is currently identical to the predicate, but it must be changed to reflect the drugs present. See the attached letter.

3. Technological Characteristics (Design, Materials, Sizes, etc.)
Subject Device

The device is a wound gel to be provided in a plastic tube. The sponsor said the device is identical to the predicate except for the addition of the 2% lidocaine, but this is not the case. There are several differences:

<u>Ingredient</u>	Amount of Ingredient (%)	
	Current 510(k)	Predicate (K992074)
water	(b)(4) Confidential and Proprietary Information	
Lidocaine	2.0	0
Hydrolyzed collagen	(b)(4) Confidential and Proprietary Information	
Sodium alginate		
Glycerin		
Aloe Vera gel		
Germaben II		
Cetyl hydroxyethylcellulose		
Sodium Hydroxymethyl Glycinate		
Citric acid		
Tocopheryl Acetate		
Hydrogen peroxide (Conc.)		
Natrosol Plus 330cs		
Suttocide A (Na hydroxymethyl - glycinate)		

Discussion of equivalency

K992074 The predicate is presented as the identical device without the lidocaine.

4. Comparative Performance Data (in vitro, animal and/or clinical)
Safety Data
Subject Device

We requested this in the letter, but the compositions of the predicate and the current are the same, except for the lidocaine. CDER has preparations of lidocaine with concentrations ranging up to 4%. Lidocaine is a well-established topical anesthetic, and is used within a safe range. No additional safety testing is required.

Predicate Devices

K992074 MPM Regenecare Wound Gel. This is identical to the current device except for the 2% lidocaine.

Cytotoxicity – mild reactivity – grade 1 Extracts were tested.

Dermal irritation – a potential for slight irritation

sensitization – non-sensitizing

Effectiveness Data

Subject Device

none – same as predicate, except for 2% lidocaine. CDER has approved topical lidocaine products with up to 4% lidocaine.

Predicate Device(s)

Discussion of Equivalency

The devices are equivalent. The only difference is the addition of lidocaine.

5. Sterilization p. 46

(b)(4) Confidential and Proprietary Information



6. Labeling p. 18

(OTC and/or Prescription) Prescription

Package Insert (page) Not yet available

Carton/Pouch Labels (page) p. 18 See facsimile transmission of Oct. 29, attached to this memo.

Directions require the use of other MPN products for use of the gel. The parameters of generic characterization should be used in addition to suggesting the MPN products. Specifically, what is the generic such as MPN wound cleaner? See facsimile transmission.

7. Claims

See facsimile transmission. The claims are:

Collagen – humectant
Aloe – moisturizer
Vitamin E – antioxidant
Lidocaine – topical anesthetic

8. Has sponsor provided all administrative requirements?

- Truthful and Accurate Statement (Page) 6
- 510(k) Summary or Statement (Page) 10
- Indication for Use Page (Page) 7

9. Summary

The dressing is identical to the predicate except for the addition of 2% lidocaine. CDER has approved topical lidocaine products at concentrations up to 4%, so there are no safety issues. The lidocaine does not affect the effectiveness of the device, and may provide some relief from pain or itching associated with the wound. Equivalence is not changed.

10. Contact History/Requests for More Information:

The AI letter requested the following information: **Summary of responses in bold.**

1. The composition of the device differs from the composition of the predicate. In addition to the lidocaine, other components have been added and others deleted. Please provide the following: **Statement is incorrect. The compositions are identical except for the lidocaine.**
 - a. A complete set of biocompatibility testing performed on the current product;
Not required. The composition is the same. Lidocaine is approved for topical use by CDER for levels up to 4%.
 - b. the source of the lidocaine and the accompanying labeling;
Provided. Is USP grade.
 - c. the sources and compositions of cetyl hydroxyethyl cellulose and sodium hydroxymethyl glycinate and the material safety data sheets for these components;
Provided
 - d. a clarification of the strength of the solution or amount of citric acid added to the gel;
Not provided, but not important – same as predicate.
 - e. Please explain the role of the hydrogen peroxide in the dressing.
To control bioburden prior to sterilization.

2. The requirements for the labeling of drugs in wound dressings have changed. Each drug component and the amount present (or concentration) should be included on the label. For each such component you should make a claim, and provide evidence to support the claim. This information should be provided for lidocaine, aloe vera gel, and tocopheryl acetate. **This is the only remaining issue. See below.**
3. In the directions for use on the label, you recommend the use of MPN Wound Cleaner, and the MPN Mult-Layered Dressing. Please provide evidence that these are legally marketed products. **These are legally marketed. Both are exempt. I have asked the tae labeling cite a generic equivalent.**
4. Please provide the anatomical parts of the cattle from which the collagen is obtained, and present your reasoning for your believe the radiation dose will inactivate bovine viruses. **Bone. Not an issue. From a US source.**

10/25 Remaining issues. Call Richard Hamer – 817 294-3644
10-28 call 817 721-6401

1. For the item below, the amounts and the purpose of each should be included on the labeling. The sponsor said that tocopherol and aloe are not drugs, but they are both in the pharmacopoeia.

lidocaine 2%
Aloe vera gel
Tocopherol Acetate
Collagen

(b)(4) Confidential and Proprietary Information

Lidocaine is a well-known anesthetic. Aloe vera may be claimed as a moisturizer, and tocopherol as an antioxidant or an excipient.

2. Please provide a generic equivalent of MPN wound cleanser in the labeling.
3. Change labeling to clarify that it is the moist wound environment, not the dressing that encourages autolytic debridement.

Mr. Hamer agreed to all of the above. Received facsimile transmission on October 29, 2002. .

YES NO

1. Is Product A Device	X		If NO = Stop
2. Is Device Subject To 510(k)?	X		If NO = Stop
3. Same Indication Statement?	X		If YES = Go To 5

4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	X		If YES = Stop NE
5. Same Technological Characteristics?		X	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?	X		If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?		X	If YES = Stop NE
9. Accepted Scientific Methods Exist?	X		If NO = Stop NE
10. Performance Data Available?	X		If NO = Request Data
11. Data Demonstrate Equivalence?	X		Final Decision:

EXPLANATIONS TO "YES" RESPONSES TO QUESTIONS 4, 6, 8, and 11 AND EVERY "NO" RESPONSE ON "SE" DECISION MAKING CHECKLIST, AS NEEDED:

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. ***Explain why there is or is not a new effect or safety or effectiveness issue:*** The compositions of the predicate dressings are very similar to this dressing.
5. Describe the new technological characteristics:
6. ***Explain how new characteristics could or could not affect safety or effectiveness:***
7. Explain how descriptive characteristics are not precise enough:
8. ***Explain new types of safety or effectiveness questions raised or why the questions are not new:***
9. Explain why existing scientific methods can not be used:
10. Explain what performance data are needed:
11. ***Explain how the performance data demonstrate that the device is or is not substantially equivalent:***

1. Intended Use: See Above

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement.

See Memorandum.

Is the device life-supporting or life sustaining? No

Is the device implanted (short-term or long-term)? No

Does the device design use software? No

Is the device sterile? Yes

Is the device for single use? Yes

Is the device for home use or prescription use? Rx

Does the device contain drug or biological product as a component? Yes Collagen

Is this device a kit? No.

Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

David B. Burkhardt

10/31/02

Name

Date

Plastic and Reconstructive Surgery Devices Branch