510(k) Summary

JUN 19 2014

Submitters Name and Address: The Hymed Group Corporation
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Establishment Number: 2530949

User Fee ID Number: MD6070502-956733

Date of Summary Preparation: May 28, 2014

Name of Device:

Proprietary: Hydrolyzed Collagen/Ag Wound Gel with Silver
Common: Moist wound gel
Classification Name: Dressing, Wound, Drug

Medical Device Classification: Unclassified

Product Code: FRO (Dressing, Wound, Drug)

Purpose of this submission: This submission seeks approval for Collagen/Ag to be available also as an Over-The-Counter (OTC) wound care product substantially equivalent to SilverMed Antimicrobial Wound Gel which was approved for OTC and Rx use via K073019.

Identification of predicate devices to which substantial equivalence is being claimed and for which approval was granted for both Rx and OTC: SilverMed™ Antimicrobial Hydrogel (Rx & OTC), K073019

Description of the Device: Hydrolyzed Collagen/Ag Wound Gel for OTC use is a change in label of the previously approved Hydrolyzed Collagen/Ag Wound Gel with Silver (K061227), for Rx use, to permit its use by the general public without the need for a physician's prescription. The proposed Hydrolyzed Collagen/Ag Wound Gel for OTC use is the identical hydrolyzed collagen wound gel formulation manufactured using the same manufacturing process and conforming to the same specifications as the Collagen Ag Wound Gel (K061227) with elemental silver as a preservative that reduces the growth of bacteria within the dressing.

The addition of the silver preservative to hydrolyzed collagen formulation does not affect the safety or efficacy of Collagen/Ag gel for use by the general public. Hydrolyzed Collagen/Ag Wound Gel contains a high concentration of water bound to the hydrolyzed collagen which maintains a moist wound environment as it manages wound healing. The high concentration of hydrolyzed collagen in the gel provides for greater moisture absorption capacity into the gel supporting silver retention within the gel. Hydrolyzed Collagen/Ag Wound gel is provided in a patient ready, one (1) ounce, collapsible tube.

Intended use of the Device: Hydrolyzed Collagen/Ag Wound Gel (Rx) is currently approved for use in partial and full thickness wounds including pressure ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions, lacerations, skin tears, grafted wounds, donor sites and surgical wounds.
Hydrolyzed Collagen/Ag Wound Gel for OTC use is an absorbent hydrogel wound dressing that is indicated for the management of minor burns, superficial cuts, lacerations, abrasions and minor irritation of the skin.

Technology Characteristics: Hydrolyzed Collagen/Ag Wound Gel for OTC use is an aqueous, hydrogel identical in formulation to Hydrolyzed Collagen/Ag Wound Gel with silver (K061227) and substantially equivalent to SilverMed Antimicrobial Hydrogel (073019) which is approved for Rx & OTC market and whose market approval references the sponsors Collagen/Ag Wound Gel (K061227) as substantially equivalent to SilverMed. Hydrolyzed Collagen/Ag Wound Gel contains, as a preservative, elemental silver for the purpose of controlling bacterial bioburden within the gel dressing as does SilverMed Antimicrobial Hydrogel (K073019) currently in commercial distribution. The label use change to OTC availability does not alter the fundamental scientific technology of the device.

Non-Clinical Performance Data: Hydrolyzed Collagen/Ag Wound Gel has been evaluated in accordance with Part 10-993 of the International Standard Organization (ISO). Standard tests which include:

- Cytotoxicity (Exhibit I) indicated a grade 1 cytotoxic grade,
- ISO Guinea Pig Maximization Sensitization (Exhibit II) wherein a negative sensitization incidence was interpreted for all test animals and
- ISO intracutaneous reactivity (Exhibit III) which indicated that the product would be considered a non-irritant.
- Microbial control within the hydrogel claims are supported by *in-vitro* evaluation. Collagen/Ag gel was found to control bacterial growth within the hydrogel.
- Collagen/Ag gel has not been studied in a clinical setting. Hydrolyzed Collagen/Ag Wound Gel with Silver (K061227) has been marketed as a Prescription wound dressing since 2007.

Hydrolyzed Collagen/Ag Wound Gel – SilverMed Antimicrobial Wound Gel
Device Comparison Table

Parameters	Hydrolyzed Collagen/Ag Wound Gel (K132891)	SilverMed Antimicrobial Wound Gel (K073019)
Indications for use	Indications for OTC Use: Collagen/Ag Wound Gel is indicated for the management of minor burns, superficial cuts, lacerations, abrasions and minor irritation of the skin. Rx: Under the supervision of a healthcare professional, it is indicated for partial and full thickness wounds including pressure ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions, lacerations, skin tears, grafted wounds, donor sites and surgical wounds.	Indications for OTC Use: SilverMed Gel is indicated for the management of minor burns, superficial cuts, lacerations, abrasions and minor irritation of the skin. Rx: Under the supervision of a healthcare professional, it is indicated for partial and full thickness wounds including pressure ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions, lacerations, skin tears, grafted wounds, donor sites and surgical wounds.
Product Code	FRO	FRO
Rx	Yes	Yes
OTC*	No (hence the purpose of this submission*)	Yes
Physical	Hydrogel	Hydrogel
Product Description	Type I Bovine Collagen	Type I Bovine Collagen
Animal Tissue	Dermis	Dermis
Preserved	Yes	Yes
Dermal Irritant	No	No
Cytotoxic	No	No
Dermal Sensitizer	No	No
Product Classification	Dressing, wound, drug, unclassified	Dressing, wound, drug, unclassified

Conclusion: These data support the safe use of the Hydrolyzed Collagen/Ag Wound Gel in contact with breached or compromised skin.

End of Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 19, 2014

The Hymed Group Corporation
Mr. George Petito
President
1890 Bucknell Drive
Bethlehem, Pennsylvania 18015

Re: K132891
Trade/Device Name: Hydrolyzed Collagen Ag Wound Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 12, 2014
Received: May 13, 2014

Dear Mr. Petito:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132891

Device Name
Hydrolyzed Collagen Ag Wound Gel

Indications for Use *(Describe)*

Indications for Over-the-Counter Use: Hydrolyzed Collagen/Ag Wound Gel is indicated for the management of minor burns, superficial cuts, lacerations, abrasions and minor irritation of the skin.

Indications for Prescription Use: Under the supervision of a healthcare professional, it is indicated for partial and full thickness wounds including pressure ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions, lacerations, skin tears, grafted wounds, donor sites and surgical wounds.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jiyoung Dang -S

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