



March 26, 2024

Medline Industries, LP
Dinah Rincones
Sr. Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K233151

Trade/Device Name: PluroGel® Antimicrobial Burn and Wound Dressing, PluroGel® Burn and Wound Dressing (OTC)

Regulatory Class: Unclassified

Product Code: FRO

Dated: September 26, 2023

Received: September 27, 2023

Dear Dinah Rincones:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

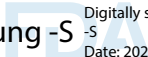
Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kathleen Young -S  Digitally signed by Kathleen Young
Date: 2024.03.26 10:17:51 -04'00'

For Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K233151

Device Name

PluroGel® Antimicrobial Burn and Wound Dressing
PluroGel® Burn and Wound Dressing (OTC)

Indications for Use (Describe)

Rx Indications for Use: PluroGel® Antimicrobial Burn and Wound Dressing is indicated for the management of full and partial thickness wounds including surgically created wounds, dermal ulcers (pressure ulcers), leg ulcers (diabetic foot ulcers), superficial wounds, first degree burns, partial thickness burns, and donor sites. PluroGel® Antimicrobial Burn and Wound Dressing maintains a moist wound and skin environment that supports autolytic debridement of necrotic tissue.

OTC Indications for Use: PluroGel® Burn and Wound Dressing (OTC) is indicated for the management of minor cuts, minor burns, and minor lacerations. PluroGel® Burn and Wound Dressing (OTC) maintains a moist wound and skin environment.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Registration Number: 1417592

Contact Person

Dinah Rincones
Sr. Regulatory Affairs Specialist
Phone: 847-949-2687
Email: DRincones@medline.com

Summary Preparation Date

March 25th, 2024

Type of 510(k) Submission

Traditional

Device Information

- | | |
|-----------------------------|--|
| • Type of 510(k) Submission | - Traditional |
| • Device Common Name | - Wound Dressing |
| • Trade Name | - PluroGel [®] Antimicrobial Burn and Wound Dressing
- PluroGel [®] Burn and Wound Dressing (OTC) |
| • Classification Name | - Dressing, Wound, Drug |
| • Regulatory Class | - Unclassified |
| • Review Panel | - General & Plastic Surgery |
| • Product Code | - FRO |

Predicate Device Information

Sonafine Wound Dressing - K110172 (Predicate)

Reference Device Information

Epiceram Skin Barrier Emulsion - K052643 (Reference device 1)
Medline Burn and Wound Dressing - K173911 and Medline Burn and Wound Dressing (OTC) - K190224 (Reference device 2).

Device Description

PluroGel[®] Antimicrobial Burn and Wound Dressing and PluroGel[®] Burn and Wound Dressing (OTC) is a translucent, biocompatible, odorless, semisolid gel intended to provide and maintain a clean and moist wound environment that is conducive to healing. The dressing maintains moisture in the wound and protects the wound from desiccation to provide an optimal moist wound environment conducive to wound

healing. PluroGel® Antimicrobial Burn and Wound Dressing and PluroGel® Burn and Wound Dressing (OTC) is non-cytotoxic, contains a surfactant, and is water soluble to aid in the removal of wound debris in between dressing changes.

PluroGel® is provided non-sterile and contains phenoxyethanol and potassium sorbate as antimicrobial preservative agents to inhibit the growth of microorganisms within the product during shelf storage before and after opening.

Indications for Use

Rx Indications for Use: PluroGel® Antimicrobial Burn and Wound Dressing is indicated for the management of full and partial thickness wounds including surgically created wounds, dermal ulcers (pressure ulcers), leg ulcers (diabetic foot ulcers), superficial wounds, first degree burns, partial thickness burns, and donor sites. PluroGel® Antimicrobial Burn and Wound Dressing maintains a moist wound and skin environment that supports autolytic debridement of necrotic tissue.

OTC Indications for Use: PluroGel® Burn and Wound Dressing (OTC) is indicated for the management of minor cuts, minor burns, and minor lacerations. PluroGel® Burn and Wound Dressing (OTC) maintains a moist wound and skin environment.

Summary of Technological Characteristics

PluroGel® Antimicrobial Burn and Wound Dressing and PluroGel® Burn and Wound Dressing (OTC) is substantially equivalent in function and intended use to the following legally marketed device: Sonafine Wound Dressing - K110172.

Refer to **Table 1** for a comparison and discussion of similarities and differences between the subject device, predicate device, and reference devices.

Table 1: Comparison of the Subject Device with the Predicate Device

	Subject Device	Predicate Device Sonafine	Comparison Analysis
510(k) Number	K233151	K110172	N/A
Applicant	Medline Industries, LP	STRATUS PHARMACEUTICAL	N/A
Regulation Number	Unclassified	Unclassified	Same as Predicate Device
Product Code	FRO	FRO	Same as Predicate Device
Rx Indications for Use	PluroGel® Antimicrobial Burn and Wound Dressing is indicated for the management of full and partial thickness wounds including surgically created wounds, dermal ulcers (pressure ulcers), leg ulcers (diabetic foot ulcers), superficial wounds, first degree burns, partial thickness burns, and donor sites. PluroGel® Antimicrobial Burn and Wound Dressing maintains a moist wound and skin environment that	Indicated for the management of full and partial thickness wounds including dermal ulcers, leg ulcers, superficial wounds, first and second degree burns and donor sites, including: -Radiation Dermatitis -Various types of dermatoses -Atopic dermatitis -Allergic contact dermatitis -Dry waxy skin	Similar to Predicate Device. <i>Note:</i> <i>The subject device and the predicate device are intended to maintain a moist wound and skin environment and for the management of various types of wounds and burns that would benefit from a moist environment. Additional wound type listed for the subject device do not result in a new intended use.</i> Similar to Reference Device 2. <i>Note:</i>

	Subject Device	Predicate Device Sonafine	Comparison Analysis
	supports autolytic debridement of necrotic tissue.	SONAFINE® Wound Dressing maintains a moist wound and skin environment.	<i>The subject device and reference device 2 contain Poloxamer P-188 and are used for maintaining a moist wound healing environment that supports autolytic debridement of necrotic tissue.</i>
OTC Indications for Use	PluroGel® Burn and Wound Dressing (OTC) is indicated for the management of minor cuts, minor burns, and minor lacerations. PluroGel® Burn and Wound Dressing (OTC) maintains a moist wound and skin environment.	SONAFINE® Wound Dressing is indicated for the management of minor cuts, minor burns, and minor lacerations. SONAFINE® Wound Dressing maintains a moist wound and skin environment. Contraindicated for individuals with a known sensitivity to the components contained in the formulation.	Same as Predicate Device
Ingredients	Poloxamer, Purified Water, Phenoxyethanol (antimicrobial preservative), Sodium Phosphate Dibasic, Potassium Sorbate (antimicrobial preservative), Citric Acid.	Avocado oil, cetyl palmitate, ethylene glycol monostearate, fragrance, liquid paraffin, methyl paraben, paraffin wax, propylene glycol, propyl paraben, purified water, sodium alginate, sodium hydroxide, sorbic acid (potassium salt) , squalene, stearic acid and trolamine.	Similar to Predicate Device <u>Note:</u> <i>The subject device and the predicate device comprise ingredients that act as surfactants, diluents, buffers, humectants and preservatives (to inhibit the growth of microorganisms within the product). The predicate device (K110172) contains one of the same preservatives as the subject device (Potassium Sorbate), and reference device 1 (K052643) contains the other preservative (Phenoxyethanol). The subject device, the predicate device and reference devices all meet biocompatibility safety requirements in accordance with to ISO 10993-1.</i>
Configurations	50g jars	28g, 45g and 90g tubes.	Different to Predicate Device <u>Note:</u> <i>The predicate device is provided in 28g, 45g and 90g tubes while the proposed device is provided in 50g jars. This difference does not affect the subject device safety or effectiveness. In addition, the FDA has cleared semisolid dressings for the same intended use offered in the same type and size of jars (K150985).</i>
Overall Design	Semisolid burn and wound dressings with the following features: <ul style="list-style-type: none"> • Preserved formulation. • Semisolid form. • Water-soluble. 	Semisolid burn and wound dressings with the following features: <ul style="list-style-type: none"> • Preserved formulation. • Semisolid form. • Water-soluble. 	Same as Predicate Device
Sterile vs. Non-sterile	Non-sterile	Non-sterile	Same as Predicate Device

Summary of Non-Clinical Testing

Biocompatibility Testing

PluroGel[®] Antimicrobial Burn and Wound Dressing and PluroGel[®] Burn and Wound Dressing (OTC) is categorized as a surface device for breached or compromised skin with prolonged contact (>24 hours to 30 days). The biological evaluation of the PluroGel[®] Antimicrobial Burn and Wound Dressing and PluroGel[®] Burn and Wound Dressing (OTC) was conducted in accordance with FDA guidance document, “*Use of International Standard ISO 10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”* and ISO 10993-1 *Biological Evaluation of the Medical Devices – Part 1: Evaluation of Testing within a Risk Management Process*.

Shelf Life and Sterilization

The PluroGel[®] Antimicrobial Burn and Wound Dressing and PluroGel[®] Burn and Wound Dressing (OTC) is a non-sterile device. Stability testing has been performed on the final finished product to support its shelf life.

Period of Use after Opening

Period of Use testing was conducted to ensure that preservative effectiveness is maintained throughout the intended use-life of the device.

Performance Testing (Animal)

A wound healing study was conducted following Good Laboratory Practice (GLP) as indicated in 21 CFR Part 58 and in accordance to established in vivo test systems.

Performance Testing (Clinical)

Not applicable.

Summary of Clinical Testing

Not applicable.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, LP. concludes that PluroGel[®] Antimicrobial Burn and Wound Dressing and PluroGel[®] Burn and Wound Dressing (OTC) is as safe and as effective for its intended use as the predicate device, Sonafine Wound Dressing cleared in K110172.