March 8, 2019

Medline Industries, Inc.
Claire Pigman
Regulatory Affairs Associate Manager
Three Lake Drive
Northfield, Illinois 60093

Re: K190224
Trade/Device Name: Medline Burn and Wound Dressing (OTC)
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 31, 2019
Received: February 5, 2019

Dear Claire Pigman:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lixin Liu -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190224

Device Name
Medline Burn and Wound Dressing (OTC)

Indications for Use *(Describe)*
Over-the-Counter Use:
Medline Burn and Wound Dressing is intended to moisten the wound and for the management of minor cuts, minor abrasions, minor lacerations and minor burns.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Medline Industries, Inc.
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SECTION 5
510(k) Summary – K190224
[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor
Medline Industries, Inc.
Three Lakes Drive
Northfield, IL 60093
Registration Number: 1417592

Contact Person
Claire Pigman
Regulatory Affairs Associate Manager
Phone: 847-643-4071
Email: CPigman@medline.com

Summary Preparation Date
January 31, 2019
(Updated March 7, 2019)

Type of 510(k) Submission
Traditional

Device Name / Classification
Name of Device: Medline Burn and Wound Dressing (OTC)
Proprietary Name: Medline Burn and Wound Dressing (OTC)
Common Name: Wound Dressing
Classification Name: Dressing, Wound, Drug
Product Code: FRO
Classification Panel: General & Plastic Surgery
Regulatory Class: Unclassified

Primary Predicate Device
Medline Burn and Wound Dressing
K173911

Secondary Predicate Device
Prontosan Wound Gel (OTC)
K101882

Medline Industries, Inc.
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Modification to the Predicate Device

The intent of this traditional 510(k) is to expand the intended use of the previously cleared Medline Burn and Wound Dressing (K173911) in order to include an over-the-counter (OTC) use. The device that is the subject of this submission is the same device as the Medline Burn and Wound Dressing cleared under K173911, but rather than being intended for prescription use only, is instead intended for over-the-counter use. According to the FDA guidance document, "Deciding When to Submit a 510(k) for Change to an Existing Device," a change from a prescription to OTC use requires directions for use necessary for lay users to use that same device safely and effectively. Therefore, changing a device labeled for prescription use only to a device that is labeled for OTC use requires a submission of a new 510(k). The subject device, Medline Burn and Wound Dressing (OTC) is an identical device in all other respects, including its technological characteristics, materials, manufacturing process, and FDA classification. Therefore, the Medline Burn and Wound Dressing (K173911) will be utilized as the primary predicate device in this submission.

Device Description

Medline Burn and Wound Dressing (OTC) is a translucent, biocompatible, odorless, semisolid gel intended to moisten the wound. The dressing protects the wound and provides a moist wound environment conducive to healing. Medline Burn and Wound Dressing (OTC) contains a gentle surfactant and is water soluble to aid in the removal of wound debris in between dressing changes.

Medline Burn and Wound Dressing (OTC) is provided non-sterile for single patient use. The subject device is comprised of the following ingredients: Poloxamer, Purified Water, Glycerin, Sucrose, Sodium Phosphate Dibasic, Citric Acid, and Polyhexanide (PHMB). The Medline Burn and Wound Dressing (OTC) contains a concentration of 0.1% w/w of PHMB, which acts as a preservative to inhibit the growth of microorganisms within the product. The proposed device will be available in the following design configuration:

Medline Item Number	Description	Size
CST50TUBE	Medline Burn and Wound Dressing (OTC)	1.75 oz. tube

Indications for Use

Over-the-Counter Use: Medline Burn and Wound Dressing is intended to moisten the wound and for the management of minor cuts, minor abrasions, minor lacerations and minor burns.

Summary of Technological Characteristics

Medline Burn and Wound Dressing (OTC) was developed for the management of wounds that benefit from a moist wound environment and cleansing without unnecessary mechanical or chemical trauma. Polyhexanide (PHMB) acts as a preservative to inhibit the growth of microorganisms within the product. Refer to Table 1 below for a comparison of the proposed and predicate devices.

Table 1 Proposed and Predicate Device(s) Comparison

DEVICE CHARACTERISTIC	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	SECONDARY PREDICATE DEVICE	COMPARISON ANALYSIS
Product Name	Medline Burn and Wound Dressing (OTC)	Medline Burn and Wound Dressing	Prontosan Wound Gel (OTC)	**N/A**
510(k) Number	K190224	K173911	K101882	**N/A**
Product Code	FRO	FRO	FRO	**Same**
Intended Use	Over-the-Counter Use: Medline Burn and Wound Dressing is intended to moisten the wound and for the management of minor cuts, minor abrasions, minor lacerations and minor burns.	Professional Use: Medline Burn and Wound Dressing is intended to cleanse and moisten the wound bed and for the management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1st and 2nd degree burns, partial and full thickness wounds, and surgical incisions. It can be used to provide a moist environment that supports autolytic debridement of necrotic tissue.	Over-the-Counter Use: Prontosan Wound Gel is intended to cleanse and moisten the wound bed and for the management of minor cuts, abrasion, laceration, and minor bums.	**Different (**Primary Predicate) **Similar** (Secondary Predicate)
Regulation Number	Unclassified	Unclassified	Unclassified	**Same**
Rx vs. OTC	OTC	Rx	OTC	**Different** (Primary Predicate) **Same** (Secondary Predicate)
Configurations	1.75 oz tube	1.75 oz tube	30 ml tube	**Same** (Primary Predicate) **Similar** (Secondary Predicate)
Design Features	Clear to translucent, water soluble, virtually odorless, amorphous wound gel with a surfactant and PHMB as a preservative	Clear to translucent, water soluble, virtually odorless, amorphous wound gel with a surfactant and PHMB as a preservative	Clear, colorless, and virtually odorless aqueous wound gel with a surfactant and PHMB as a preservative	**Same**
Materials	Poloxamer, Purified Water, Glycerin, Sucrose, Sodium Phophate Dibasic, Citric Acid, PHMB	Poloxamer, Purified Water, Glycerin, Sucrose, Sodium Phophate Dibasic, Citric Acid, PHMB	Purified Water, Glycerol, Hydroxyethylcellulose, Undecylenamidopropyl Betaine, PHMB	**Same** (Primary Predicate) **Similar** (Secondary Predicate)
Non-Clinical Testing	-Biocompatibility in accordance to 10993-1 (breached or compromised surfaces with prolonged contact (>24h to 30d)	-Biocompatibility in accordance to 10993-1 (breached or compromised surfaces with prolonged contact (>24h to 30d) -Shelf Life	-Biocompatiblity in accordance to 10993-1 (breached or compromised surfaces with prolonged contact (>24h to 30d) -Shelf Life	**Same** (Primary Predicate)

Table 1 Proposed and Predicate Device(s) Comparison

	-Shelf Life -USP<51>Antimicrobial Effectiveness -USP<61>Microbial Limits -USP<62>Microbiological Examination of Non-sterile Products -Wound Healing Study	-USP<51>Antimicrobial Effectiveness -USP<61>Microbial Limits -USP<62>Microbiological Examination of Non-sterile Products -Wound Healing Study	-USP<51>Antimicrobial Effectiveness -USP<85> Bacterial Endotoxin Testing	**Similar** (Secondary Predicate)
Sterile vs. Non-Sterile	Non-sterile	Non-sterile	Sterile by aseptic filtration until first opened	**Same** (Primary Predicate) **Different** (Secondary Predicate)
Reusable vs. Single Use	Single patient, multiple use	Single patient, multiple use	Single Patient Use, multiple use	**Same**

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Summary of Non-Clinical Testing

Medline Burn and Wound Dressing (OTC) and the primary predicate device (K173911) are the same device; these devices share the same formulation, design, manufacturing process and technological characteristics. The subject device does not raise different questions of safety and effectiveness. Biocompatibility testing in accordance to ISO 10993-1, shelf-life testing to finished product specifications, and non-clinical performance testing (animal wound healing study) were conducted in accordance with GLP (21 CFR 58) and previously submitted and cleared under K173911. The only difference between the primary predicate and the proposed device is the intended use of the proposed device is for OTC use, while the predicate is for prescription use only. There are no other changes besides the OTC indication and labeling; therefore, all testing information that was provided in the primary predicate submission (K173911) will be referenced to address the required components for this traditional 510(k) submission. Please refer to Appendix H, Supporting Documents, for a copy of an email correspondence with FDA, which confirms that testing can be referenced rather than submitted.

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, Inc. concludes that the Medline Burn and Wound Dressing (OTC) is as safe and as effective for its intended use as the predicate devices, Medline Burn and Wound Dressing (K173911) and Prontosan Wound Gel, OTC (K101882).