July 19, 2018

Medline Industries, Inc.
Bethany Benoit-DiMaria
Senior Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K173911
Trade/Device Name: Medline Burn and Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 13, 2018
Received: June 14, 2018

Dear Bethany Benoit-DiMaria:

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.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173911

Device Name
Medline Burn and Wound Dressing

Indications for Use *(Describe)*
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.

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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K173911
510(k) Summary
[AS REQUIRED BY 21CFR807.92(c)]

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

Registration Number: 1417592

Contact Person
Bethany Benoit-DiMaria
Senior Regulatory Affairs Specialist
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Summary Preparation Date
December 21, 2017

Type of 510(k) Submission
Traditional

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

Primary Predicate Device
Prontosan Wound Gel
K101882

Secondary Predicate Device
Manuka Fill
K131796

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Device Description

Medline Burn and Wound Dressing is a translucent, biocompatible, odorless, semisolid gel intended to cleanse and moisten the wound bed. The dressing maintains moisture in the wound and protects the wound from dessication to provide an optimal moist wound environment conducive to wound healing. Medline Burn and Wound Dressing 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 is provided non-sterile for single patient use. Polyhexanide (PHMB) acts as a preservative to inhibit the growth of microorganisms within the product.

Indications for Use

For Prescription 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.

Summary of Technological Characteristics

Medline Burn and Wound Dressing 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.

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	Prontosan Wound Gel	Manuka Fill	N/A
510(k) Reference	K173911	K101882	K131796	N/A
Product Code	FRO	FRO	FRO	**Same** as Primary Predicate (K101882) **Same** as Secondary Predicate (K131796)
Intended Use	Professional Use: Medline Burn and Wound Dressing is intended to cleanse and moisten the	Professional Use: Prontosan Wound Gel is intended to cleanse and moisten the wound bed and	Under the supervision of a healthcare professional, Manuka Fill wound dressing is	**Same** as Primary Predicate

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	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.	for the management of ulcers, 1st and 2nd degree burns, partial and full thickness wounds, and surgical incisions. It can be used during wound dressing changes to soften encrusted wound dressings.	indicated for the management of: Leg Ulcers, Pressure Ulcers, 1st and 2nd Degree Burns, Diabetic Foot Ulcers, Surgical Wounds, Trauma Wounds. Manuka Fill wound dressing provides a moist wound environment. A moist wound environment allows autolytic debridement of necrotic tissue	(K101882) **Same** as Secondary Predicate (K131796)
Regulation Number	Unclassified	Unclassified	Unclassified	**Same** as Primary Predicate (K101882) **Same** as Secondary Predicate (K131796)
Configurations	1.75 oz tube	30 ml tube	Individual tubes in a variety of sizes	**Similar** to Primary Predicate (K101882) **Similar** to Secondary Predicate (K131796)
Design Features	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	Wound gel with honey, helps maintain a moist wound environment conducive to wound healing	**Similar** to Primary Predicate (K101882) **Similar** to Secondary Predicate (K131796)
Materials	Poloxamer, Purified Water, Glycerin, Sucrose, Sodium Phophate Dibasic, Citric Acid, PHMB	Purified Water, Glycerol, Hydroxyethylcellulose, Undecylenamidopropyl Betaine, PHMB	100% Leptospermum scoparium honey from New Zealand	**Similar** to Primary Predicate (K101882) **Different** than

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				Secondary Predicate (K131796)
Non-Clinical Testing	-Biocompatibility in accordance to 10993-1 -Shelf Life -USP<51>Antimicrobial Effectiveness -Wound Healing Study	-Biocompatiblity in accordance to 10993-1 (breached or compromised surfaces with prolonged contact (>24h to 30d) -Shelf Life -USP<51>Antimicrobial Effectiveness -USP<85> Bacterial Endotoxin Testing	-Biocompatibility in accordance to 10993-1 (breached or compromised surfaces with prolonged contact (>24h to 30d) -Sterilization Validation -Packaging Validation -Shelf Life -Wound Healing Study	**Similar** to Primary Predicate (K101882) **Similar** to Secondary Predicate (K131796)
Sterile vs. Non-Sterile	Non-sterile	Sterile by aseptic filtration until first opened	Sterile by gamma irradiation	**Different** than Primary Predicate (K101882) **Different** than Secondary Predicate (K131796)
Reusable vs. Single Use	Single patient, multiple use	Single patient, multiple use	Single use	**Same** as Primary Predicate (K101882) **Similar** to Secondary Predicate (K131796)

Summary of Non-Clinical Testing

Medline Burn and Wound Dressing and the predicate device have the same intended use, and similar technological characteristics that do not raise different questions of safety and effectiveness. In order to address the same questions of safety and effectiveness and demonstrate that the differences in technological characteristics do not introduce new issues 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).

Summary of Clinical Testing

Not applicable.

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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 is as safe and as effective for its intended use as the predicate devices [Prontosan Wound Gel (K101882) and Manuka Fill (K131796)].