May 10, 2022

3M Health Care Business Group
Margaret Marsh
Regulatory Affairs Advanced Specialist
3M Centre, Cain Road
Berkshire, Bracknell Forest, RG12 8HT,
United Kingdom

Re: K210135
Trade/Device Name: PROMOGRAN PRISMA Matrix, Small Dressing, PROMOGRAN PRISMA Matrix, Large Dressing
Regulatory Class: Unclassified
Product Code: FRO

Dear Margaret Marsh:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 24, 2022. Specifically, FDA is updating this SE Letter as an administrative correction to the Indications for Use (IFU).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, julie.morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

February 24, 2022

3M Health Care Business Group
Margaret Marsh
Regulatory Affairs Advanced Specialist
3M Centre, Cain Road
Berkshire, Bracknell Forest, RG12 8HT,
United Kingdom

Re: K210135
Trade/Device Name: PROMOGRAN PRISMA Matrix, Small Dressing, PROMOGRAN PRISMA Matrix, Large Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 18, 2021
Received: January 19, 2021

Dear Margaret Marsh:

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/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 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 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,

Julie A. Morabito -S

Julie Morabito Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210135

Device Name
3M™ Promogran Prisma™

Indications for Use *(Describe)*

Promogran Prisma™, when used without ActiV.A.C.™ Negative Pressure Wound Therapy, is intended for the management of exuding wounds. Under the supervision of a health care professional, Promogran Prisma™ may be used for the management of:

- Diabetic ulcers
- Venous ulcers
- Pressure ulcers
- Ulcers caused by mixed vascular etiologies
- Full-thickness & partial thickness wounds
- Donor sites and other bleeding surface wounds
- Abrasions
- Traumatic wounds healing by secondary intention
- Dehisced surgical wounds.

Promogran Prisma™ when used with ActiV.A.C.™ Negative Pressure Wound Therapy is intended for the management of exuding wounds. Under the supervision of a health care professional, Promogran Prisma™ with ActiV.A.C.™ Negative Pressure Wound Therapy may be used only for the management of:

- Diabetic ulcers
- Venous ulcers
- Pressure ulcers
- Partial-thickness burns
- Traumatic wounds healing by secondary intention
- Dehisced surgical wounds.

Compression therapy may only be used with Promogran Prisma™ under professional healthcare supervision. Compression therapy may not be used when Promogran Prisma™ is used with ActiV.A.C.™ Negative Pressure Wound Therapy.

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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510(k) SUMMARY - K210135
3M™ Promogran Prisma™

Date prepared February 24, 2022

Submitter information [21 CFR 807.929(a)(1)]

Name Systagenix Wound Management Limited, now a part of 3M Health Care Business Group

Address 3M Deutschland GmbH Health Care Business, Carl-Schurz-Str.1, 41453 Neuss, Germany

Establishment registration number 3017375200

Name of contact person Margaret Marsh, Regulatory Affairs Advanced Specialist
e-mail: mlmarsh@mmm.com

Name of the device [21 CFR 807.92(a)(2)]

Trade or proprietary name 3M™ Promogran Prisma™, Small
3M™ Promogran Prisma™, Large

Common or usual name Wound Dressing with a Drug Component that can be used with or without Negative Pressure Wound Therapy

Classification name/code	• Primary Product Code: Wound Dressing with a Drug Component (Silver)/FRO • Secondary Product Code: When used with Negative Pressure Wound Therapy: Component of a Powered Negative Pressure Wound Therapy System/OMP
Classification regulation	Wound Dressing with a Drug Component (Silver): Unclassified
Classification panel	General and Plastic Surgery

Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]

Integra™ Meshed Bilayer Wound Matrix (Integra LifeSciences Corp.), cleared under 510(k) K081635 for use with Negative Pressure Wound Therapy.

Device description [21 CFR 807.92(a)(4)]

3M™ Promogran Prisma™ is comprised of a sterile, freeze-dried composite of 44% oxidized regenerated cellulose (ORC), 55% collagen and 1 % silver-ORC. Silver ORC contains 25% w/w ionically bound silver.

It is a primary dressing that can be cut with scissors to fit the wound and used in combination with either a semi-occlusive or non-occlusive secondary dressing. The dressing is hexagonal in shape, provided in two sizes (28 cm^2 and 123 cm^2) that are packaged in a hexagonal thermoformed tray and sterilized by gamma irradiation.

As described in the product labeling, when used with the ActiV.A.C.™ Negative Pressure Wound Therapy System, seven slits are cut into the 3M™ Promogran Prisma™ by the health care provider before applying the dressing and the components of the ActiV.A.C.™ Negative Pressure Wound Therapy System.

Indications for Use [21 CFR 807.92(a)(5)]

Promogran Prisma™, when used **without** ActiV.A.C.™ Negative Pressure Wound Therapy, is intended for the management of exuding wounds. Under the supervision of a health care professional, Promogran Prisma™ may be used for the management of:

- Diabetic ulcers
- Venous ulcers
- Pressure ulcers
- Ulcers caused by mixed vascular etiologies
- Full-thickness & partial thickness wounds
- Donor sites and other bleeding surface wounds
- Abrasions
- Traumatic wounds healing by secondary intention
- Dehisced surgical wounds.

Promogran Prisma™ when used **with** ActiV.A.C.™ Negative Pressure Wound Therapy is intended for the management of exuding wounds. Under the supervision of a health care professional, Promogran Prisma™ with ActiV.A.C.™ Negative Pressure Wound Therapy may be used only for the management of:

- Diabetic ulcers
- Venous ulcers
- Pressure ulcers
- Partial-thickness burns
- Traumatic wounds healing by secondary intention
- Dehisced surgical wounds.

Compression therapy may only be used with Promogran Prisma™ under professional healthcare supervision. Compression therapy may not be used when Promogran Prisma™ is used with ActiV.A.C.™ Negative Pressure Wound Therapy.

Comparison to predicate device [21 CFR 807.92(a)(6)]

Comparator	Subject Device (Promogran Prisma™ Used without and with the ActiV.A.C.™ Negative Pressure Wound Therapy System)		Predicate Device (INTEGRA Meshed Bilayer Wound Matrix)
Indications for Use	Promogran Prisma™ **when used without** the ActiV.A.C.™ Negative Pressure Wound Therapy is intended for the management of exuding wounds. Under the supervision of a health care professional, Promogran Prisma™ may be used for the management of: • Diabetic ulcers • Venous ulcers • Pressure ulcers • Ulcers caused by mixed vascular etiologies • Full-thickness & partial thickness wounds • Donor sites and other bleeding surface wounds • Abrasions • Traumatic wounds healing by secondary intention • Dehisced surgical wounds.	Promogran Prisma™ **when used with** the ActiV.A.C.™ Negative Pressure Wound Therapy System is intended for the management of exuding wounds. Under the supervision of a health care professional, Promogran Prisma™ with ActiV.A.C.™ Negative Pressure Wound Therapy may be used only for the management of: • Venous ulcers • Pressure ulcers • Diabetic ulcers • Partial-thickness burns • Traumatic wounds healing by secondary intention • Dehisced surgical wounds.	INTEGRA™ Meshed Bilayer Wound Matrix is indicated for the management of wounds including: • Partial and full-thickness wounds, • Pressure ulcers, • Venous ulcers, • Diabetic ulcers, • Chronic vascular ulcers, • Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), • Trauma wounds (abrasions, lacerations, second degree burns, and skin tears) and • Draining wounds. May be used in conjunction with negative pressure wound therapy. The device is intended for one-time use.
	Compression therapy may only be used with Promogran Prisma™ under professional healthcare supervision. Compression therapy may **not** be used when Promogran Prisma™ is used with ActiV.A.C.™ Negative Pressure Wound Therapy.		
Care Setting	Care setting: Acute and extended care settings; home care setting where the application of the dressing and therapy is by the clinician only and not by the patient.		Care setting not indicated in labeling

Comparator	Subject Device (Promogran Prisma™ Used without and with the ActiV.A.C.™ Negative Pressure Wound Therapy System)		Predicate Device (INTEGRA Meshed Bilayer Wound Matrix)
Duration of Therapy	Promogran Prisma™ when used **without** ActiV.A.C.™ Negative Pressure Wound Therapy can be reapplied to the wound daily or per physician recommendation.	The length of combined treatment for Promogran Prisma™ **with** ActiV.A.C.™ Therapy should not exceed 30 days. During this therapy interval, the V.A.C.® Granufoam™ Dressings must be changed at a minimum of every 72 hours. Dressing change intervals should be based on a continuing evaluation of the wound condition and the patients' clinical presentation, rather than a fixed schedule."	• Duration for use of the matrix not indicated in labeling. • "Change the secondary dressing as needed. Frequency of secondary dressing change will be dependent upon volume of exudate produced, type of dressing used and the clinician's need to inspect the wound bed for signs of infection or healing."
Wound Types	Promogran Prisma™ when used **without** ActiV.A.C.™ Negative Pressure Wound Therapy is intended for the management of: • Diabetic ulcers • Venous ulcers • Pressure ulcers • Ulcers caused by mixed vascular etiologies • Full-thickness & partial thickness wounds • Donor sites and other bleeding surface wounds • Abrasions • Traumatic wounds healing by secondary intention • Dehisced surgical wounds.	Promogran Prisma™ when used **with** the ActiV.A.C.™ Negative Pressure Wound Therapy System is intended for the management of • Venous ulcers • Pressure ulcers • Diabetic ulcers • Partial-thickness burns • Traumatic wounds healing by secondary intention • Dehisced surgical wounds.	Partial and full-thickness wounds, Pressure ulcers, Venous ulcers, Diabetic ulcers, Chronic vascular ulcers, Surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), Trauma wounds (abrasions, lacerations, second degree burns, and skin tears) and Draining wounds.

Comparator	Subject Device (Promogran Prisma™ Used without and with the ActiV.A.C.™ Negative Pressure Wound Therapy System)		Predicate Device (INTEGRA Meshed Bilayer Wound Matrix)
Wound Sizes	There are no labeled limitations pertaining to wound size for applying the dressing. The surface area of the selected dressing would necessarily limit the size of the wound to be managed.		
Wound Contact Dressing Material	Promogran Prisma™ is comprised of a sterile, freeze dried composite of: • 44% oxidized regenerated cellulose (ORC) • 55% bovine dermal collagen • 1% silver-ORC (Silver-ORC contains 25 % w/w ionically bound silver)		INTEGRA Bilayer Matrix Wound Dressing is comprised of: • a porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan and • a semi-permeable polysiloxane (silicone) layer
Dressing Size	The dressing is hexagonal in shape and is provided in two sizes: • The small dressing is 28 cm^2 • The large dressing is 123 cm^2		• 2 x 2 inch (5 x 5 cm) • 4 x 5 inch (10 x 12.5 cm) • 4 x 10 inch (10 x 25 cm) • 8 x 10 inch (20 x 25 cm)
Sterilization	Gamma Irradiation		Gamma Irradiation
System Design	When used **without** ActiV.A.C.™ Negative Pressure Wound Therapy, Promogran Prisma™ is placed into the wound and then covered with a user selected semi-occlusive dressing or a non-occlusive secondary dressing and fixed to the skin with a non-irritating tape.	When used **with** ActiV.A.C.™ Negative Pressure Wound Therapy, Promogran Prisma™ is placed into the wound over which is positioned the V.A.C.® Granufoam™ or V.A.C. ® Simplace™ Dressing. The V.A.C.® Drape is used to cover the dressed wound and is connected via a tubing set to the canister placed in the ActiV.A.C.™ Therapy Unit.	The INTEGRA™ Bilayer Matrix Wound Dressing is placed into the wound and covered with a secondary dressing (selected by the user) to maintain dressing adherence and protect the wound area.

Performance Data [21 CFR 807.92(b)]

Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]

Promogran Prisma™ was previously tested for biocompatibility under 510(k) K033523; tests included cytotoxicity, sensitization, irritation, material mediated pyrogenicity, systemic toxicity, and implantation end points. The design change to require the healthcare professional to slit the dressing before use with ActiV.A.C.™ Negative Pressure Wound Therapy does not require new biocompatibility testing.

Delivery of ActiV.A.C.™ Negative Pressure Wound Therapy to the wound under the Promogran Prisma™ was assessed in bench studies using simulated wound exudate, maximum air leak rate, and under worst case dressing configuration. The results document that the Promogran Prisma™ does not inhibit delivery of negative pressure within specification at the low and high end of the recommended therapy settings.

Summary of clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(2)]

No clinical tests were necessary to demonstrate acceptable use of the Promogran Prisma™ with ActiV.A.C.™ Negative Pressure Wound Therapy. However, human factors engineering assessment with 30 subject nurses and doctors documented that the changes to the labeling, to describe use with ActiV.A.C.™ Negative Pressure Wound Therapy, are safe and effective for their intended use.

Conclusions drawn [21 CFR 807.92(b)(3)]

The subject device is substantially equivalent to the predicate device with respect to indications for use and wound dressing characteristics. There are no new questions regarding safety or effectiveness for the combined use of Promogran Prisma™ with the ActiV.A.C.™ Negative Pressure Wound Therapy System.