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 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

PRODUCT DESCRIPTION
Promogran Prisma™ is comprised of a sterile freeze-dried composite of 44% oxidized regenerated cellulose (ORC), 55% collagen and 1% silver- ORC with 25% w/w ionically bound silver ("0.017 mg/cm² total silver").

IMPORTANT INFORMATION FOR USERS
In the presence of exudate, Promogran Prisma™ transforms into a soft, conformable, biodegradable gel and thus allows contact with all areas of the wound. Promogran Prisma™, when covered with a semi-occlusive dressing, maintains a physiologically moist environment at the wound surface

Promogran Prisma™ can be used:
- As a primary dressing, in combination with a secondary dressing without application of 3M™ ActiV.A.C.™ Negative Pressure Wound Therapy System .

OR

- In combination with the ActiV.A.C. Negative Pressure Wound Therapy System and associated foam dressings, 3M™ V.A.C.® Granufoam™ Dressing and 3M™ V.A.C.® Simplace™ Dressing. Instructions specific to use **with** the ActiV.A.C. Negative Pressure Wound Therapy System are presented in a grey box.

When Promogran Prisma™ is used **WITHOUT** ActiV.A.C. Negative Pressure Wound Therapy System:

Promogran Prisma™ is a primary dressing that can be cut to fit the wound with scissors and used in combination with either a semi-occlusive or non-occlusive secondary dressing. Prior to application in dry wounds, saline solution should be used to hydrate Promogran Prisma™. It creates an environment that is conducive to granulation tissue formation, epithelialization and wound healing. Promogran Prisma™ provides an effective antibacterial barrier as demonstrated by the *in vitro* reduction of bacterial growth with common wound pathogens such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli* and Streptococcus pyogenes. Reduction of bacterial bioburden in the dressing may result in reduced risk of infection. Literature reports of *in-vitro* testing indicate that collagen fibers provide a biodegradable matrix for cellular invasion and capillary growth. In laboratory testing, Promogran Prisma™ has been shown to absorb components of wound exudate

INDICATIONS FOR USE WITHOUT ACTIV.A.C. THERAPY SYSTEM
Promogran Prisma™, when used without 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™ 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™ may be used under compression therapy with healthcare professional supervision.

CONTRAINDICATIONS
Promogran Prisma™ is not indicated for third-degree burns, or patients with known sensitivity to silver, ORC or collagen.

PRECAUTIONS
1. Promogran Prisma™ may be used when visible signs of infection are present in the wound area, only when proper medical treatment addresses the underlying cause. Promogran Prisma™ is not intended to be a substitute for appropriate treatment of infection.
2. Clinicians/Healthcare Professionals should be aware that there are very limited data on prolonged and repeated use of silver containing dressings, particularly in children and neonates.
3. **The Promogran Prisma™ is MR Unsafe. Do not use on patients during MRI (Magnetic Resonance Imaging) examination.**

INSTRUCTIONS FOR USE
Application
1. Prepare wound bed per your standard wound care protocol and debride when necessary. For optimal effect, apply Promogran Prisma™ directly to the whole wound bed.
2. For a wound with low or no exudate, apply Promogran Prisma™ and hydrate with saline solution. This will initiate the transformation of the Promogran Prisma™ into a gel.
3. After hydration, through exposure to wound exudate or saline, the Promogran Prisma™ gel will come into contact with the wound surface.
4. The biodegradable Promogran Prisma™ gel is absorbed into the body over time.
5. In order to maintain a moist wound healing environment, Promogran Prisma™ must be covered with a semi-occlusive dressing or a non-occlusive secondary dressing and fixed to the skin with a non-irritating tape.
6. After initial application, reapply Promogran Prisma™ to the wound daily or per physician recommendation. It is not necessary to remove any residual Promogran Prisma™ during dressing changes.

INSTRUCTIONS FOR USE WITH ACTIV.A.C. THERAPY SYSTEM
The information below only pertains to the combined use of Promogran Prisma™ and the **ActiV.A.C. Negative Pressure Wound Therapy System** and associated foam dressings, **V.A.C.® Granufoam™ Dressings** and **V.A.C.® Simplace™ Dressings**.

INDICATIONS for Promogran Prisma™ when used in conjunction with ActiV.A.C. Negative Pressure Wound Therapy System.

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 System** 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

. CONTRAINDICATIONS
Compression therapy may **not** be used when Promogran Prisma™ is used with ActiV.A.C. Negative Pressure Wound Therapy System

PRECAUTIONS
- **Important safety information exists for the ActiV.A.C. Negative Pressure Wound Therapy System components, including Contraindications, Warnings and Precautions. Before using ActiV.A.C. Negative Pressure Wound Therapy System, refer to the Instructions for Use that accompany the ActiV.A.C. Negative Pressure Wound Therapy System components for complete safety information and application instructions.**
- **When Promogran Prisma™ is slit for use with the ActiV.A.C. Negative Pressure Wound Therapy System, the Promogran Prisma™ will not provide a bacterial barrier.**

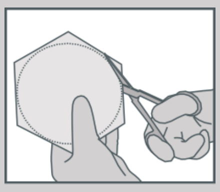
WARNINGS
- **It is not recommended to use Promogran Prisma™ with ActiV.A.C. Negative Pressure Wound Therapy System on the following wound types**:
  - Mixed vascular etiologies
  - Donor sites and other bleeding surface wounds
  - Abrasions
- **Ensure adequate hemostasis has been achieved before using ActiV.A.C. Negative Pressure Wound Therapy System.**
- **Bleeding:** With or without using ActiV.A.C. Negative Pressure Wound Therapy System, certain patients are at high risk of bleeding complications. The following types of patients are at increased risk of bleeding, which, if uncontrolled, could be potentially fatal:
  - Patients who have weakened or friable blood vessels or organs in or around the wound as a result of, but not limited to:
    - Suturing of the blood vessel (native anastamoses or grafts)/organ
    - Infection
    - Trauma
    - Radiation
  - Patients without adequate wound hemostasis
  - Patients who have been administered anticoagulants or platelet aggregation inhibitors
  - Patients who do not have adequate tissue coverage over vascular structures.

  Refer to the ActiV.A.C. Negative Pressure Wound Therapy System Safety Information for detailed instructions on how to manage risk of bleeding.
- **Do not use Promogran Prisma™ with ActiV.A.C. Negative Pressure Wound Therapy System over closed incisions.**
- **When Promogran Prisma™ is used in conjunction with ActiV.A.C. Negative Pressure Wound Therapy System, select a pressure setting of -125 mmHg as a minimum and use continuous mode (do not use intermittent mode).**
- **V.A.C.® Granufoam Silver™ Dressing should not be used in conjunction with Promogran Prisma™ due to unknown potential cumulative effect of silver.**

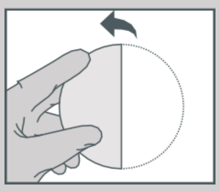
DIRECTIONS FOR USE
Promogran Prisma™ may be used in conjunction with the ActiV.A.C. Negative Pressure Wound Therapy System and with any size or configuration of the V.A.C.® Granufoam™ Dressing and V.A.C.® Simplace™ Dressings.

APPLICATION INSTRUCTIONS
- **For detailed instructions on how to apply the V.A.C.® Granufoam™ Dressing or V.A.C.® Simplace™ Dressing and set up the ActiV.A.C. Negative Pressure WoundTherapy System, refer to the Instructions for Use provided in the foam dressing cartons. A summary of those instructions is provided below. Note: V.A.C.® Granufoam Silver™ Dressing should not be used in conjunction with Promogran Prisma™ due to unknown potential cumulative effect of silver.**

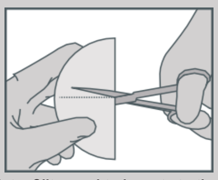
1. Prepare the wound bed as per your standard wound care protocol and debride when necessary.
2. Ensure adequate hemostasis has been achieved.
3. **The healthcare professional must cut seven (7) parallel slits into Promogran Prisma™ in order for the dressing to be used in conjunction with the ActiV.A.C. Negative Pressure Wound Therapy System. The slits allow for effective exudate removal and negative pressure delivery. A description of the cutting locations and procedure is shown below:**



a. Trim the Promogran Prisma™ with scissors to fit the wound. ***Ensure the Promogran Prisma™ remains dry before cutting.***

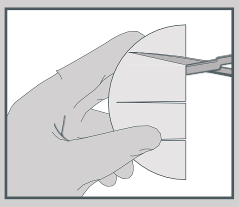


b. Fold the Promogran Prisma™ in half.

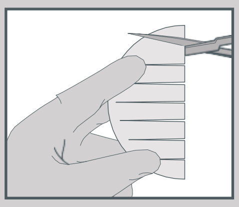


c. Starting from the folded edge, cut a slit through the center of the Promogran Prisma™ as far as possible, but do not cut the dressing into two pieces.

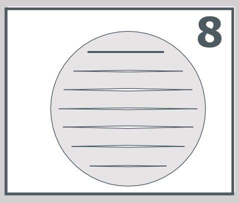
Note: Slits need to be cut starting from the folded edge to ensure the product remains in one piece.



d. Make an additional two parallel cuts halfway between the center cut and the bottom and top of the dressing, again making sure not tocut the dressing in half.



e. Make an additional 4 parallel slits halfway between each of the three existing slits.



f. The 7 slits result in the Promogran Prisma™ that has 8 sections which are equally spaced apart.

4. **Protect Periwound skin:** Consider use of skin preparation product to protect periwound skin. Do not allow Promogran Prisma™ or foam dressing to overlap onto intact skin. **Protect fragile/friable periwound skin with additional 3M™ V.A.C.® Drape, hydrocolloid or other transparent film.**
5. Either side of the Promogran Prisma™ may be applied to the wound bed.
6. Cut V.A.C.® Granufoam™ Dressing or V.A.C.® Simplace™ Dressing to dimensions that will allow it to be placed in the wound without overlapping onto intact skin.
7. Gently place the dressing over the Promogran Prisma™ and nonadherent dressing, if used. Do not force the dressing into any area of the wound or use in unexplored tunnels.
   Note: Ensure foam-to-foam contact between adjacent pieces of the dressing for even distribution of negative pressure.
   Note: Record the total number of pieces of foam in the wound on the V.A.C.® Drape, and patient's chart to ensure complete removal by the next treating clinician.

8. Trim the V.A.C.® Drape to cover both the foam dressing and an addition 3 to 5 cm border of intact peri-wound tissue. V.A.C.® Drape may be cut into multiple pieces for easier handling, retaining a portion of the Blue Handling Tab on each piece. Use any excess V.A.C.® Drape to seal any difficult areas, if needed.
   a. Partially pull back one side of Layer 1 of the drape to expose adhesive.
   b. Place the adhesive face down over the dressing and apply V.A.C.® Drape to cover the dressing and intact skin. Remove remaining Layer 1 backing material and pat V.A.C.® Drape to ensure an occlusive seal.
   c. Remove green-striped stabilization Layer 2 and Blue Handling Tabs.
9. Choose 3M™ SensaT.R.A.C™ Pad application site. Give particular consideration to fluid flow and tubing positioning to allow for optimal flow and avoid placement over bony prominences or within creases in the tissue.
10. Pinch V.A.C.® Drape and cut a 2.5 cm hole through drape (not a slit) at the site chosen for application of the SensaT.R.A.C Pad. The hole should be large enough to allow for fluid removal.
11. Apply SensaT.R.A.C Pad.
12. Remove the 3M™ActiV.A.C.™ Canister from the packaging and insert into the ActiV.A.C. Negative Pressure Wound Therapy System Unit until it locks in place.
13. Connect the SensaT.R.A.C. Pad tubing to the canister tubing and ensure clamp on each tube is open.
14. a.Turn on power to the 3M™ ActiV.A.C.™ therapy unit . **As a requirement, select Continuous mode and a minimum pressure setting of -125mmHg.**
    Note: The default therapy setting for the ACTIV.A.C. Therapy Unit is **Continuous** mode at-125mmHg.
    Note: If the ActiV.A.C. Therapy Unit has been set to **Intermittent** Mode, as displayed on the screen, change to **Continuous** Mode as described below:
    - From the Clinician Home Screen, press "**Therapy", then "Next", then "Settings".**
    - Select **"Continuous".** A **green** light indicates that the mode is active.
    - Press **"Exit"** to go to the **"Confirm Screen."**

    Note: Refer to the User Manual provided with the ActiV.A.C. Therapy Unit for detailed instructions on setting therapy parameters, monitoring therapy and responding to alarms.

14.b. Initiate negative pressure wound therapy.

15. The length of combined therapy for Promogran Prisma™ with ActiV.A.C. Negative Pressure Wound Therapy System should not exceed 30 days. During this therapy interval, the V.A.C.® Granufoam™ Dressings must be changed at a minimum 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.
16. Dressing changes
    a. To remove the V.A.C® Drape from skin, gently stretch drape horizontally and not vertically.
    b. Ensure removal of all pieces of the foam dressing and meshed nonadherent dressing if used, as were recorded on the V.A.C® Drape or in the patient's chart. Foam left in the wound for greater than the recommended time period may foster ingrowth of tissue into the foam, create difficulty in removing foam from the wound or lead to infection or other adverse events. If dressing adheres to wound, consider introducing sterile water or normal saline into the dressings, waiting 15-30 minutes then gently removing the dressing from the wound.
    c. If desired, reapply Promogran Prisma™ to the wound at each foam dressing change. Should there be any residual Promogran Prisma™ remaining in the wound, remove it before applying new dressings.

STORAGE
Promogran Prisma™ should be stored away from direct light. Overexposure to light may cause some discoloration, however, this does not affect the release of silver from the dressing. Store below 25°C/77°F.

Do not use if the package is damaged.

The use-by date of this product is printed on the packaging.

Do not re-sterilize.

Caution: Federal law (USA) restricts this device to sale by or on the order of a properly trained healthcare practitioner. This Caution is not applicable outside the U.S

NOTES
Please report a serious incident occurring in relation to the device to 3M.

Symbol Glossary

Symbol Title	Symbol	Description and Reference
Manufacturer		Indicates the medical device manufacturer. Source: ISO 15223, 5.1.1
Date of manufacture		Indicates the date when the medical device was manufactured. Source: ISO 15223, 5.1.3
Use-by date		Indicates the date after which the medical device is not to be used. Source: ISO 15223, 5.1.4
Batch code	LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified. Source : ISO 15223, 5.1.5
Catalogue number	REF	Indicates the manufacturer's catalogue number so that the medical device can be identified. Source : ISO 15223, 5.1.6
Sterilized using irradiation	STERILE R	Indicates a medical device that has been sterilized using irradiation. Source: ISO 15223, 5.2.4
Do not re-sterilize	STERILIZE	Indicates a medical device that is not to bere-sterilized. Source: ISO 15223, 5.2.6
Do not use if package is damaged and consult instructions for use		Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information. Source: ISO 15223, 5.2.8
Keep away from sunlight		Indicates a medical device that needs protection from light sources. Source: ISO 15223, 5.3.2

Upper limit of temperature	25°C (77°F)	Indicates the upper limit of temperature to which the medical device can be safely exposed. Source: ISO 15223, 5.3.6
Do not re-use		Indicates a medical device that is intended for one single use only. Source: ISO 15223, 5.4.2
Consult instructions for use or consult electronic instructions for use		Indicates the need for the user to consult the instructions for use. Source: ISO 15223, 5.4.3
Medical Device	MD	Indicates the item is a medical device. Source: ISO 15223, 5.7.7
Contains a medicinal substance		Indicates a medical device that contains or incorporates a medicinal substance. Source: ISO 15223, 5.4.7
Contains biological material of animal origin	BIO	Indicates a medical device that contains biological tissue, cells, or their derivatives, of animal origin. Source: ISO 15223, 5.4.8
Unique device identifier	UDI	Indicates a carrier that contains unique device identifier information. Source: ISO 15223, 5.7.10
Single sterile barrier system		Indicates a single sterile barrier system. Source: ISO 15223, 5.2.11
Rx Only	Rx Only	Indicates that U.S. Federal Law restricts this device to sale by or on the order of a healthcare professional. 21 Code of Federal Regulations (CFR) sec. 801.109(b)(1)
MR Unsafe	MR	An item which poses unacceptable risks to the patient, medical staff or other persons within in the MR environment. Source: ASTM F2503-20 Fig. 9
Recycle		Indicates trash bin or container is for materials to be recycled

For more information see, HCBGregulatory.3M.com

MD

3M Deutschland GmbH
Health Care Business
Carl-Schurz-Str. 1
41453 Neuss, Germany
3M.com
For more information,
see HCBGregulatory.3M.com

3M | Promogran Prisma™

Collagen Matrix with ORC and Silver
Matriz de colágeno con ORC y Plata

SGS
9300 Winnetka Ave. N
Brooklyn Park, MN 55445
(763) 488-5700

3M

CUST ID#	PRINT METHOD	SGS#	ROUND
		6563362-1	4

Production Art

Description: 3MIKCI™ Promogran Prisma
Base File Name:
PA: Promogran Prisma_IFU.indd
GA:
Software: InDesign 2020
SGS Contact:
Email:
Printer:
Printer Location:
Supplier:

Item Spec#: Promogran Prisma_IFU
Supersedes#:
Structure#:
Cat/Product#:
Reference: N/A
Requester: Debra Doyle
Die # / Doc. Size: 64.125mm (H) x 87mm (W)

DATE	CHANGE LOG	INT
10.06.21	New Build	SV
12.02.21	Amend as per Annotation	GV
12.06.21	Amend as per Annotation	SM
12.14.21	Amend as per Annotation	SR

INKS
PROCESS BLACK
PANTONE Cool Gray 11
MATCH
SPECIAL

PDF Scaled at 100.0%

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)]

<table>
<tr><th>Comparator</th><th colspan="2">Subject Device
(Promogran Prisma™ Used without and with the ActiV.A.C.™ Negative Pressure Wound Therapy System)</th><th>Predicate Device
(INTEGRA Meshed Bilayer Wound Matrix)</th></tr>
<tr><td rowspan="2">Indications for Use</td><td>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.</td><td>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.</td><td rowspan="2">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.</td></tr>
<tr><td colspan="2">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.</td></tr>
<tr><td>Care Setting</td><td colspan="2">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.</td><td>Care setting not indicated in labeling</td></tr>
</table>

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.

<table>
<tr><th>Comparator</th><th colspan="2">Subject Device
(Promogran Prisma™ Used without and with the ActiV.A.C.™ Negative Pressure Wound Therapy System)</th><th>Predicate Device
(INTEGRA Meshed Bilayer Wound Matrix)</th></tr>
<tr><td>Wound Sizes</td><td colspan="3">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.</td></tr>
<tr><td>Wound Contact Dressing Material</td><td colspan="2">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)</td><td>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</td></tr>
<tr><td>Dressing Size</td><td colspan="2">The dressing is hexagonal in shape and is provided in two sizes:
• The small dressing is 28 cm²
• The large dressing is 123 cm²</td><td>• 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)</td></tr>
<tr><td>Sterilization</td><td colspan="2">Gamma Irradiation</td><td>Gamma Irradiation</td></tr>
<tr><td>System Design</td><td>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.</td><td>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.</td><td>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.</td></tr>
</table>

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.