March 13, 2026

Solventum Germany GmbH
Bernadette Rauch
Senior Regulatory Affairs Specialist
Edisonstrasse 6
Kamen, North-Rhine Westphalia 59174
Germany

Re: K251999
Trade/Device Name: Promogran Prisma™ Collagen Matrix with ORC and Silver
Regulatory Class: Unclassified
Product Code: FRO, OMP
Dated: February 13, 2026
Received: February 13, 2026

Dear Bernadette Rauch:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251999

Device Name
Promogran Prisma™ Collagen Matrix with ORC and Silver

Indications for Use *(Describe)*
Indications for use WITHOUT ActiV.A.C. Therapy System

Promogran Prisma™ Collagen Matrix with ORC and Silver, 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™ Collagen Matrix with ORC and Silver may be used for the management of:
• Diabetic ulcers
• Venous ulcers
• Pressure ulcers
• Ulcers caused by mixed vascular etiologies
• Full thickness and partial thickness wounds
• Donor sites and other bleeding surface wounds
• Abrasions
• Traumatic wounds healing by secondary Intention
• Dehisced surgical wounds
Promogran Prisma™ Collagen Matrix with ORC and Silver may be used under compression therapy with healthcare professional supervision.

Indications for Promogran Prisma™ Collagen Matrix with ORC and Silver when used in conjunction WITH the ActiV.A.C. Negative Pressure Wound Therapy System.

Promogran Prisma™ Collagen Matrix with ORC and Silver, 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™ Collagen Matrix with ORC and Silver with the ActiV.A.C. Negative Pressure Wound Therapy System may be used for the management of:
• Venous ulcers
• Pressure ulcers
• Diabetic ulcers
• Partial-thickness burns
• Traumatic wounds healing by secondary intention
• Dehisced surgical wounds

Indications for Promogran Prisma™ Collagen Matrix with ORC and Silver, when used with V.A.C.® Peel and Place Dressings and the ActiV.A.C. Negative Pressure Therapy System.

Promogran Prisma™ Collagen Matrix with ORC and Silver, when used with the V.A.C.® Peel and Place Dressings and ActiV.A.C. Negative Pressure Wound Therapy System, is intended for the management of exuding wounds. Under the supervision of a health care professional, the V.A.C.® Peel and Place Dressing and ActiV.A.C. Negative Pressure Therapy System may be used for the management of:
• Venous ulcers
• Pressure ulcers
• Diabetic ulcers
• Partial-thickness burns

• Traumatic wounds healing by secondary intention
• Dehisced surgical wounds

Note: Compression therapy may only be used with Promogran Prisma™ Collagen Matrix with ORC and Silver under professional healthcare supervision. Compression therapy may not be used when Promogran Prisma™ Collagen Matrix with ORC and Silver is used with V.A.C.® Peel and Place Dressing and 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.

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510(k) Summary
[AS REQUIRED BY 21 CFR 807.92]

I. SUBMITTER

Name	Solventum Germany GmbH
Address	Edisonstrasse 6, 59174 Kamen, Germany
Establishment registration number	3032911850
Name of contact person	Bernadette Rauch, Principal Regulatory Affairs Specialist Email: bernadette.rauch@solventum.com
Name of US correspondent	Mark Burville, Director, Regulatory Affairs Email: mcburville@solventum.com
Date prepared	March 13, 2026

II. DEVICE

Trade or Proprietary name	Solventum™ Promogran Prisma™ Collagen Matrix with ORC and Silver
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

III. PREDICATE DEVICE

Predicate Device Name:	Promogran Prisma™
510(k) number:	K210135
Device Classification:	Unclassified
Product Code:	FRO/OMP

IV. DEVICE DESCRIPTION

Promogran Prisma™ Collagen Matrix with ORC and Silver 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").

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

Promogran Prisma™ Collagen Matrix with ORC and Silver can be used:

- As a primary dressing, in combination with a secondary dressing **without** application of ActiV.A.C.™ Negative Pressure Wound Therapy System.

OR

- In combination **with** the ActiV.A.C. Negative Pressure Wound Therapy System and associated dressings. Associated dressings include:
    - The V.A.C.® Granufoam™ Dressings and V.A.C.® Simplace™ Dressings with either V.A.C.® Drape or Dermatac™ Drape, or
    - V.A.C.® Peel and Place Dressings.

As a primary dressing, Promogran Prisma™ Collagen Matrix with ORC and Silver is cut with scissors to fit the wound 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™ Collagen Matrix with ORC and Silver. In laboratory testing, Promogran Prisma™ Collagen Matrix with ORC and Silver has been shown to absorb components of wound exudate.

Promogran Prisma™ Collagen Matrix with ORC and Silver is packaged in a hexagonal PETG tray with a foil and paper lid.

Promogran Prisma™ Collagen Matrix with ORC and Silver is sterilized by gamma irradiation following ISO 11137, providing a sterility assurance level of 10^{-6}.

V. INDICATIONS FOR USE

Indications for use <u>WITHOUT</u> ActiV.A.C. Therapy System
Promogran Prisma™ Collagen Matrix with ORC and Silver, when used **<u>without</u>** 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™ Collagen Matrix with ORC and Silver may be used for the management of:

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

Promogran Prisma™ Collagen Matrix with ORC and Silver may be used under compression therapy with healthcare professional supervision.

Indications for Promogran Prisma™ Collagen Matrix with ORC and Silver when used in conjunction WITH the ActiV.A.C. Negative Pressure Wound Therapy System.
Promogran Prisma™ Collagen Matrix with ORC and Silver, when used **<u>with</u> 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™ Collagen Matrix with ORC and Silver **with the ActiV.A.C. Negative Pressure Wound Therapy System** may be used for the management of:

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

Indications for Promogran Prisma™ Collagen Matrix with ORC and Silver, when used with V.A.C.® Peel and Place Dressings and the ActiV.A.C. Negative Pressure Therapy System.

Promogran Prisma™ Collagen Matrix with ORC and Silver, when used **with the V.A.C.® Peel and Place Dressings and ActiV.A.C. Negative Pressure Wound Therapy System,** is intended for the management of exuding wounds. Under the supervision of a health care professional, **the V.A.C.® Peel and Place Dressing and ActiV.A.C. Negative Pressure Therapy System** may be used for the management of:

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

Note: Compression therapy may only be used with Promogran Prisma™ Collagen Matrix with ORC and Silver under professional healthcare supervision. Compression therapy may not be used when Promogran Prisma™ Collagen Matrix with ORC and Silver is used with V.A.C.® Peel and Place Dressing and ActiV.A.C.™ Negative Pressure Wound Therapy.

VI. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

At a high level, the subject and the predicate device are based on the following same technological elements:

- Indications for use
- 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)
- Wound types and sizes
- Operating principle
- Sterilization type
- Packaging
- Shelf-life (2 years)

The indications for use, technological characteristics and principles of operation have not changed.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Comparator	Subject Device	Predicate Device (K210135)	Comparison
Trade Name	Promogran Prisma™ Collagen Matrix with ORC and Silver	• Promogran Prisma™ Matrix Dressing, Large • Promogran Prisma™ Matrix Dressing, Small	N/A
Promogran Prisma Dressing sizes	Same as predicate	28 cm^2 (4.34 in^2) 123 cm^2 (19.1 in^2)	Identical for predicate and subject device
Model Numbers	Same as predicate	Promogran Prisma: MA028, MA123	Identical for predicate and subject device
510(k) Submitter/Holder	Solventum Germany GmbH	3M Deutschland GmbH	N/A *Note: The spin-off of 3M's Health Care Business into two independent companies resulted in the Health Care Business of 3M being transformed into Solventum (specifically for this product: Solventum Germany GmbH).*
Product Code	Same as predicate	• FRO (when used without NPWT) • OMP (when used with NPWT)	FRO and OMP are identical for predicate and subject device.
Indications for use	**Indications for Promogran Prisma™ Collagen Matrix with ORC and Silver, when used with V.A.C.® Peel and Place Dressings and the ActiV.A.C. Negative Pressure Wound Therapy System.** Promogran Prisma™ Collagen Matrix with ORC and Silver, when used with the V.A.C.® Peel and Place Dressings and ActiV.A.C. Negative Pressure Wound Therapy System, is intended for the management of exuding wounds. Under the supervision of a health care professional, the V.A.C.® Peel and Place Dressing and ActiV.A.C. Therapy System may be used for the management of: • Venous ulcers • Pressure ulcers • Diabetic ulcers	**Indications for Promogran Prisma™ Collagen Matrix with ORC and Silver, when used with V.A.C.® Granufoam and V.A.C.® Simplace Dressings and the ActiV.A.C. Negative Pressure Wound Therapy System**. Promogran Prisma™ Collagen Matrix with ORC and Silver 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™ Collagen Matrix with ORC and Silver with the ActiV.A.C. Negative Pressure Wound Therapy System may be used for the management of: • Venous ulcers • Pressure ulcers • Diabetic ulcers • Partial-thickness burns • Traumatic wounds healing by secondary intention	Identical for predicate and subject device except for the dressing type applied over the Promogran Prisma™ Collagen Matrix with ORC and Silver dressing. *Note: For Promogran Prisma™ Collagen Matrix with ORC and Silver when used alone (FRO code), the indications for use are the same as were cleared under the initial Promogran Prisma 510(K) K033523.*

Comparator	Subject Device	Predicate Device (K210135)	Comparison
	• Partial-thickness burns • Traumatic wounds healing by secondary intent • Dehisced surgical wounds	• Dehisced surgical wounds	
Care Setting	Same as predicate	Dressing can be applied in the acute, extended, or the homecare setting under the supervision of a healthcare professional.	Identical for predicate and subject device.
Duration of Use	The length of the combined therapy for Promogran Prisma™ Collagen Matrix with ORC and Silver with ActiV.A.C. Therapy System should not exceed 30 days. During this therapy interval, in a monitored, non-infected wound, the V.A.C.® Peel and Place Dressings may be left in place for up to 2-3 days with the frequency adjusted by the clinician as appropriate. Dressing change intervals should be based on a continuing evaluation of the wound condition and the patient's clinical presentation, rather than a fixed schedule.	The length of combined therapy for Promogran Prisma™ Collagen Matrix with ORC and Silver with ActiV.A.C. Therapy System should not exceed 30 days. During this therapy interval, the V.A.C.® Granufoam™ Dressings should be changed every 48-72 hours but no less than 3 times per week. Dressing change intervals should be based on a continuing evaluation of the wound condition and the patients' clinical presentation, rather than a fixed schedule.	The duration of use of the subject device and predicate device is derived from the secondary dressing. *Note: When Promogran Prisma™ Collagen Matrix with ORC and Silver is used without the ActiV.A.C. Therapy System the duration of therapy is the same as was cleared under the initial Promogran Prisma 510(k) K033523.*
Wound Types	Same as predicate	Promogran Prisma™ Collagen Matrix with ORC and Silver when used in conjunction with the ActiV.A.C. Negative Pressure Wound Therapy System: • Venous ulcers • Pressure ulcers • Diabetic ulcers • Partial-thickness burns • Traumatic wounds healing by secondary intention • Dehisced surgical wounds	Identical for predicate and subject device when Promogran Prisma™ Collagen Matrix with ORC and Silver is used in combination with ActiV.A.C. Therapy unit.
Wound Sizes	Same as predicate for Promogran Prisma™ Collagen Matrix with ORC and Silver	There are no wound size restrictions for either Promogran Prisma™ Collagen Matrix with ORC and Silver, V.A.C.® Granufoam or V.A.C.® Simplace Dressings. The dressings are sized to cover the entire wound bed.	Identical for predicate and subject device.
System Design	• Promogran Prisma™ Collagen Matrix with ORC and Silver is slit per labeling instructions and placed into the prepared wound bed.	• Promogran Prisma™ Collagen Matrix with ORC and Silver is slit per labeling instructions and placed into the prepared wound bed.	The subject device is a combination of the predicate device (Promogran Prisma™ Collagen Matrix with ORC and Silver application) and the

Comparator	Subject Device	Predicate Device (K210135)	Comparison
	• V.A.C.® Peel and Place Dressing is placed over the Promogran Prisma™ Collagen Matrix with ORC and Silver. • The SensaT.R.A.C. Pad is adhered over the pre-cut hole in the drape and connected to the ActiV.A.C. Therapy Unit Canister and negative pressure wound therapy is initiated.	• V.A.C.® Granufoam Dressing foam or V.A.C.® Simplace Dressing is cut to fill the wound and cover the Promogran Prisma™ Collagen Matrix with ORC and Silver. • The provided adhesive drape is placed over the foam dressing in the wound bed. A hole is cut into the drape for placement of the SensaT.R.A.C. Pad • The SensaT.R.A.C. Pad is adhered to the drape and connected to the ActiV.A.C. Therapy Unit Canister and negative pressure wound therapy is initiated.	V.A.C.® Peel and Place Dressing application.
Operating Principle	Same as predicate	The ActiV.A.C. Therapy Unit delivers software controlled negative pressure wound therapy to the dressed wound bed. The drape is designed to provide a sealed negative pressure environment while the dressing material facilitates delivery of negative pressure across the wound bed and removal of wound exudates into the therapy unit canister.	Identical for predicate and subject device.
Dressing Material (System Design)	Same as predicate for Promogran Prisma™ Collagen Matrix with ORC and Silver	<u>Promogran Prisma™ Collagen Matrix with ORC and Silver:</u> • 44% oxidized regenerated cellulose (ORC) • 55% collagen • 1% silver-ORC (silver-ORC contains 25% w/w ionically bound silver) <u>V.A.C.® Granufoam Dressing Kits:</u> • Dermatac Drape: Polyurethane film with silicone and acrylic adhesives or • V.A.C.® Drape: Polyurethane film coated with acrylic adhesive • Granufoam foam: Polyurethane ether	Identical for predicate and subject device with respect to Promogran Prisma™ Collagen Matrix with ORC and Silver.
Sterilization of Promogran Prisma	Gamma irradiation (SAL 10^{-6})	Gamma irradiation (SAL 10^{-6})	Identical for predicate and subject device

Comparator	Subject Device	Predicate Device (K210135)	Comparison
Packaging Configuration of Promogran Prisma	Same as predicate	REF code MA028 and MA123: 10 trays/carton	Identical for predicate device
Sterile Packaging of Promogran Prisma	Same as predicate	PETG tray with tray lid (paper, polyethylene and aluminum foil)	Identical for predicate device
Shelf Life of Promogran Prisma	Same as predicate	2 years	Identical for predicate device

VIII. PERFORMANCE DATA

Summary of non-clinical tests conducted for determination of substantial equivalence

The extension of indications for use to include the use of V.A.C.® Peel and Place Dressing Kit does not require new biocompatibility testing. Promogran Prisma™ Collagen Matrix with ORC and Silver was previously tested for biocompatibility under 510(k) K033523 and tests included cytotoxicity, sensitization, irritation, material mediated pyrogenicity, systemic toxicity and implantation endpoints. V.A.C.® Peel and Place Dressing Kit was tested for biocompatibility under 510(k) K222859.

Delivery of ActiV.A.C.™ Negative Pressure Wound Therapy with V.A.C.® Peel and Place Dressing Kit placed over the Promogran Prisma™ Collagen Matrix with ORC and Silver dressing was assessed in the same type of simulated use test that was conducted with the V.A.C.® Peel and Place Dressing Kit (K222859) and the predicate product under 510(k) K210135. The study used simulated wound exudate, maximum air leak rate, and under worst case dressing configuration. The results document that the Promogran Prisma™ Collagen Matrix with ORC and Silver does not inhibit delivery of negative pressure wound therapy.

Human Factors testing was conducted with the revised Promogran Prisma™ Collagen Matrix with ORC and Silver instructions for use (IFU) that addresses the concomitant use of Promogran Prisma™ Collagen Matrix with ORC and Silver with the ActiV.A.C.™ Negative Pressure Wound Therapy when using V.A.C.® Peel and Place Dressing Kits. The revised labeling has been found to be safe and effective for the intended users, its uses, and use environments.

Summary of clinical tests conducted for determination of substantial equivalence

No clinical tests were required to demonstrate acceptable use of the Promogran Prisma™ Collagen Matrix with ORC and Silver with ActiV.A.C.™ Negative Pressure Wound Therapy and V.A.C.® Peel and Place Dressing Kit.

IX. CONCLUSION DRAWN

The subject device Promogran Prisma™ Collagen Matrix with ORC and Silver is substantially equivalent to the predicate device with respect to indications for use, system design and principal of operation when used in combination with ActiV.A.C.™ Negative Pressure Wound Therapy System.

The performance data indicate that there are no new questions regarding safety and effectiveness of use of the V.A.C.® Peel and Place Dressing Kit with Promogran Prisma™ Collagen Matrix with ORC and Silver and the ActiV.A.C.™ Negative Pressure Wound Therapy System.