February 13, 2023

3M
Teri Feeley
Sr. Regulatory Associate
6203 Farinon Dr.
San Antionio, Texas 78247

Re: K223263
Trade/Device Name: Prevena Plus 125 Therapy Unit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP, QFC
Dated: October 12, 2022
Received: October 24, 2022

Dear Teri Feeley:

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 A. 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)*
K223263

Device Name
Prevena Plus 125 Therapy Unit

Indications for Use *(Describe)*
Prevena Plus 125 Therapy Unit is indicated for use with both the Prevena™ Dressings and compatible V.A.C.® Dressings.

The Prevena Plus 125 Therapy Unit when used with the Prevena™ Dressings (Prevena Plus Incision Management System), manages the environment of closed surgical incisions and removes fluid away from the surgical incision via the application of -125mmHg continuous negative pressure. When used with legally marketed Prevena Dressings for up to seven days, Prevena Plus 125 Therapy Units are intended to aid in reducing the incidence of seroma and, in patients at high risk for post-operative infections, aid in reducing the incidence of superficial surgical site infection in Class I and Class II wounds.

The Prevena ™ Plus 125 Therapy Unit, when used with compatible V.A.C.® Dressings on open wounds (Prevena Plus Negative Pressure Wound Therapy System), is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

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.

510(k) Summary
Prevena™ Plus 125 Therapy Unit
K223263

1. Submitter Information:

3M Health Care Business Group
6203 Farinon Dr.
San Antonio, TX 78249

Contact Person: Teri Feeley
Email: tfeeley@mmm.com
Phone: 210-459-1952
Facsimile: 210-255-6727
Date Prepared: 08 Feb 2023

2. Device

Trade/Device Name: Prevena™ Plus 125 Therapy Unit
Regulation Number: 21 CFR 878.4783
Regulation Name: Negative pressure wound therapy device for reduction of wound complications
Regulatory Class: Class II
Product Code Primary: QFC, OMP
Dated: October 12, 2022
Received: October 24, 2022

3. Predicate Device

Predicate Device: Prevena™ Plus 125 Therapy Unit (DEN180013)
Predicate Device: Prevena™ Plus 125 Therapy Unit (K180855)
Reference Device: V.A.C. VIA NPWT System (K173447)

4. Device Description

The Prevena™ Plus 125 Therapy Unit may be used part of as either of these systems:

A) Prevena Incision Management System
Consist of:

- Prevena™ Therapy Unit
- Prevena 150mL Canister & adaptor
- Prevena Dressing kit

B) Prevena Plus Negative Pressure Wound Therapy System Consist of:

- Prevena™ Plus 125 Therapy Unit
- Prevena 150mL Canister & adaptor
- V.A.C. Dressing kit

The Prevena™ Plus Incision Management System (Prevena™ Plus Therapy Unit when used with Prevena Dressings) is designed for use over linear, non-linear, intersecting incisions.

The Prevena™ Plus Negative Pressure Wound Therapy System (Prevena™ Plus Therapy Unit when used with V.A.C. Dressings) is designed for use in a variety of open wound types such as: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

5. Intended Use / Indications for Use

Prevena™ Plus 125 Therapy Unit is indicated for use with both the Prevena Dressings and compatible V.A.C.® Dressings.

The Prevena™ Plus 125 Therapy Unit when used with the Prevena Dressings (Prevena™ Plus Incision Management System), manages the environment of closed surgical incisions and removes fluid away from the surgical incision via the application of -125mmHg continuous negative pressure. When used with legally marketed Prevena Dressings for up to seven days, Prevena™ Plus 125 Therapy Units are intended to aid in reducing the incidence of seroma and, in patients at high risk for post-operative infections, aid in reducing the incidence of superficial surgical site infection in Class I and Class II wounds.

The Prevena™ Plus 125 Therapy Unit, when used with compatible V.A.C.® Dressings on open wounds (Prevena™ Plus Negative Pressure Wound Therapy System), is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

6. Comparison of Technological Characteristics

The Prevena Plus 125 Therapy Units are negative pressure pumps that deliver -125mmHg continuously for up to 7 or 14 days.

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Prevena™ Plus 125 Therapy Unit
K223263

The Prevena Plus 125 Therapy Units may be used with Prevena Dressings for use over linear, non-linear, intersecting incisions on various anatomical locations as determined at the discretion of the healthcare provider.
Alternatively, the Prevena Plus 125 Therapy Units may be used with previously cleared small or medium V.A.C. Dressings for use in a variety of open wounds such as: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

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

- Intended use
- Indicated for closed incisions when used with Prevena Dressings
- Indicated for open wounds when used with V.A.C. Dressings
- Use environment is acute, extended and home care settings
- Intended for use with Prevena Dressings and V.A.C. Dressings

The subject device indications for use, technological characteristics and principles of operation are substantially equivalent to the predicates.

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Prevena™ Plus 125 Therapy Unit
K223263

A table comparing the key features of the subject and predicate devices is provided below.

Characteristic	**Subject Device:** Prevena™ Plus Therapy Unit	**Predicate Device:** Prevena™ Plus Therapy Unit; DEN180013	**Predicate Device:** Prevena™ Plus Therapy Unit; K180855	**Reference Device:** V.A.C. VIA NPWT System, K173447
Indications for Use	Identical to predicate DEN180013 & reference Device Prevena Plus 125 Therapy Unit is indicated for use with both the Prevena™ Dressings and compatible V.A.C.® Dressings. The Prevena Plus 125 Therapy Unit when used with the Prevena™ Dressings (Prevena Plus Incision Management System), manage the environment of closed surgical incisions and remove fluid away from the surgical incision via the application of -125mmHg continuous negative pressure. When used with legally marketed Prevena Dressings for up to seven days, Prevena Plus 125 Therapy Units are intended to aid in reducing the incidence of seroma and, in patients at high risk for post-operative infections, aid in reducing the incidence of superficial surgical site infection in Class I and Class II wounds. The Prevena ™ Plus 125 Therapy Unit, when used with	Prevena Plus 125 Therapy Units manage the environment of closed surgical incisions and remove fluid away from the surgical incision via the application of -125mmHg continuous negative pressure. When used with legally marketed compatible dressings, Prevena Plus 125 Therapy Units are intended to aid in reducing the incidence of seroma and, in patients at high risk for post-operative infections, aid in reducing the incidence of superficial surgical site infection in Class I and Class II wounds.	Prevena™ Plus Incision Management Systems is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.	The V.A.C.VIA Therapy System is an integrated wound management system for use in acute, extended and home care settings. When used on closed surgical incisions, the V.A.C. VIA ™ is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudates via the application of negative pressure wound therapy.

Characteristic	**Subject Device:** Prevena™ Plus Therapy Unit	**Predicate Device:** Prevena™ Plus Therapy Unit; DEN180013	**Predicate Device:** Prevena™ Plus Therapy Unit; K180855	**Reference Device:** V.A.C. VIA NPWT System, K173447
	compatible V.A.C.® Dressings on open wounds (Prevena™ Plus Negative Pressure Wound Therapy System), is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.			

Characteristic	**Subject Device:** Prevena™ Plus Therapy Unit	**Predicate Device:** Prevena™ Plus Therapy Unit; DEN180013	**Predicate Device:** Prevena™ Plus Therapy Unit; K180855	**Reference Device:** V.A.C. VIA NPWT System, K173447
				When used on open wounds, the V.A.C.VIA™ Therapy System is intended to create an environment that promotes wow1d healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudates and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure, or venous insufficiency), flaps and grafts.
Indicated Wound Types	Identical to Reference Device	• closed incisions	• closed incisions	• chronic • acute • traumatic • subacute • dehisced wounds • partial-thickness burns

510(k) Summary
Prevena™ Plus 125 Therapy Unit
K223263

Characteristic	**Subject Device:** Prevena™ Plus Therapy Unit	**Predicate Device:** Prevena™ Plus Therapy Unit; DEN180013	**Predicate Device:** Prevena™ Plus Therapy Unit; K180855	**Reference Device:** V.A.C. VIA NPWT System, K173447
				• ulcers (such as diabetic • pressure or venous insufficiency) • flaps • grafts • closed incisions
Prevena Dressings	Identical to Predicates DEN180013 & K180855	• Prevena Peel & Place Dressings • Prevena Customizable Dressing • Prevena Restor Dressings	• Prevena Peel & Place Dressings • Prevena Customizable Dressing • Prevena Restor Dressings	• V.A.C. VIA Granufoam Spiral Dressings • Dermatac Drape with V.A.C. Granufoam Dressing
V.A.C. Dressing	Similar to Reference • V.A.C. VIA Granufoam Spiral Dressings • Dermatac Drape with V.A.C. Granufoam Dressing • V.A.C. Granufoam Dressing • V.A.C. Simplace Dressing • V.A.C. Whitefoam Dressings • V.A.C. Granufoam Silver Dressing	N/A	N/A	• V.A.C. VIA Granufoam Spiral Dressings • Dermatac Drape with V.A.C. Granufoam Dressing
Use environment/Care Setting of dressing kit	Identical to Reference device	operating room/surgery center and then may transition home with the patient	operating room/surgery center and then may transition home with the patient	acute, extended or homecare setting

7. Performance Data

a. Summary of non-clinical tests conducted for determination of substantial equivalence:

- Prevena™ Plus Negative Pressure Wound Therapy System negative pressure test demonstrates the Prevena Plus Therapy Unit when used with small and medium V.A.C. Dressing as part of a system, maintains negative pressure within specifications.
- Human factors evaluation

In all instances, the Prevena™ Plus 125 Therapy Unit functioned as intended with V.A.C. Dressings and all test results observed were as expected.

b. Clinical and Pre-clinical testing were not necessary to demonstrate equivalence.

8. Conclusions

The subject device is substantially equivalate as the predicate devices. The subject device's Intended Use, indications for use, fundamental technology and principles of operation are unchanged compared to their respective predicates (DEN180013 & K180855).

The proposed modification to add the "open wound" indication to the subject devices is identical to the reference device (K173447) and does not raise different questions of safety or effectiveness of the subject device. The performance data demonstrates that the Prevena Plus 125 Therapy Unit when used with small and medium V.A.C. Dressing are substantially equivalent to the predicate devices.