March 23, 2023

3M
Melanie Avila
Regulatory Affairs Manager
6203 Farinon Drive
San Antonio, Texas 78249

Re: K222859
Trade/Device Name: 3M V.A.C. Peel and Place Dressing Kit, Small (EZ10SML), 3M V.A.C. Peel and Place Dressing Kit, Medium (EZ10MED), 3M V.A.C. Peel and Place Dressing Kit, Large (EZ10LRG)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: March 25, 2022
Received: September 22, 2022

Dear Melanie Avila:

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
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and Infection Control Devices
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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)*
K222859

Device Name
3M™ V.A.C. ® Peel and Place Dressing

Indications for Use *(Describe)*
The 3M™ V.A.C.® Peel and Place Dressing is intended to be applied in an acute, extended, or home care setting where product application is conducted by or under the supervision of a qualified healthcare professional. It is an accessory to the 3M™ Negative Pressure Wound Therapy System.

When used on open wounds, the 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.

When used on closed surgical incisions, they are 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.

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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Date Prepared: March 15, 2023

Name of Subject Device: 3M™ V.A.C.® Peel and Place Dressing
Predicate Device: V.A.C. DERMATAC™ Drape and V.A.C. Granufoam Dressing (K212320
Reference Device: Pico Single Use NPWT System (K180698)
Common or Usual Name: Dressing component of Negative Pressure Wound Therapy (NPWT) System
Classification Name: Negative Pressure Wound Therapy Powered Suction Pump (and components)
Regulatory Number: 21 CFR 878.4780
Regulatory Class: Class II
Product Code: OMP

Device Description

The 3M™ V.A.C.® Peel and Place Dressing Kit is a sterile, single use all in one dressing comprised of a semi-occlusive drape and foam dressing kitted together with a SensaTRAC Pad and Tubeset. The perforations in the silicone layer expose the acrylic adhesive coated on the polyurethane film. The acrylic adhesive secures the drape to the periwound and the silicone layer primarily provides a seal for negative pressure. The polyurethane foam assists with manifolding negative pressure across the wound and periwound.

The one-piece all-in-one dressing and drape are similar to the Dermatac Drape and Granufoam Dressing, most recently cleared under 510(k) K212320, which are provided in a two piece design.

Intended Use / Indications for Use

The 3M™ V.A.C.® Peel and Place Dressing is intended to be applied in an acute, extended, or home care setting where product application is conducted by or under the supervision of a qualified healthcare professional. It is an accessory to the 3M™ Negative Pressure Wound Therapy System.

When used on open wounds, the 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.

When used on closed surgical incisions, they are 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.

The 3M™ V.A.C.® Peel and Place Dressing Kit is a sterile, single use all in one dressing comprised of a semi-occlusive drape and foam dressing kitted together with a SensaTRAC Pad and Tubeset (not the subject of this 510(k)). They are accessories to the V.A.C.® Therapy System, which is comprised of the following components:

- Software controlled therapy unit that provides negative pressure
- Semi-occlusive drape and foam dressing
- Disposable canister which collects wound exudate and stores it away from the wound
- SensaTRAC Pad and Tube Set

Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)]			
Characteristic	**Subject Device:** 3M™ V.A.C. ® Peel and Place Dressing	**Predicate Device:** Dermatac Drape and Granufoam Dressing, K212320	**Reference Device:** Pico Single Use NPWT System K180698
Indicated Wound Types	Identical	• Chronic • Acute • Traumatic • Subacute • Dehisced wounds • Partial-thickness burns • Ulcers (such as diabetic, pressure or venous insufficiency) • Flaps and grafts Surgically closed incisions (For V.A.C. Therapy only)	N/A
V.A.C. Negative Pressure Wound Therapy Units	Identical	• 3M™ ActiV.A.C.™ • 3M™ V.A.C.® Simplicity • 3M™ V.A.C.Via™ • V.A.C.ULTA™ V.A.C.RX4™	N/A
Use environment/Care Setting of dressing kit	Identical	Acute, extended and home care settings	Hospital and homecare setting
System Design	The all-in-one, peel and place drape and dressing	The individual drape and dressings are components	PICO 7 consists of a pump and sterile

	are components of a NPWT system that includes: • Therapy unit providing negative or instillation therapy • A canister to collect wound exudate and/or instillation fluids A tubing set that connects the dressing to the canister	of a NPWT system that includes: • Therapy unit providing negative or instillation therapy • A canister to collect wound exudate and/or instillation fluids A tubing set that connects the dressing to the canister	dressing(s). The PICO 7 pump maintains negative pressure wound therapy at 80 mmHg (nominal) to the wound surface. Exudate is managed by the dressing through a combination of absorption and evaporation of moisture through the outer film.

Performance Data

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

- V.A.C.® Negative Pressure Maintenance System Test demonstrates the 3M™ V.A.C.® Peel and Place Dressing maintains negative pressure within specifications and manages fluid exudate without unexpected alarms.
- Package Integrity testing to ensure the sterile barrier is maintained throughout its labeled shelf life.
- Product performance testing of dressing components after Ethylene Oxide (ETO) sterilization to verify the product functions as intended throughout its labeled shelf life.
    - Dressing Extensibility
    - Moisture Vapor Transmission Rate
    - Peel Adhesion Force
    - Release Liner Testing
- The 3M™ V.A.C. ® Peel and Place Dressing and associated labeling was evaluated via simulated-use testing with users representative of the use specification and has been found to be safe and effective for the intended users, uses and use environments.
- Summary of Biocompatibility Testing

Endpoint	Study Type (Test System)	Guidelines
Cytotoxicity	MEM Elution (L-929 Mouse Fibroblast Cells)	USFDA GLP 21CFR58 ISO 10993-5 (2009) ISO 10993-12 (2007)
Sensitization	Guinea Pig Maximization Sensitization (Hartley guinea pigs)	USFDA GLP 21CFR58 ISO 10993-10 (2010) ISO 10993-12 (2012)
Irritation	Intracutaneous Reactivity (New Zealand White Rabbit)	USFDA GLP 21CFR58 ISO 10993-10 (2010) ISO 10993-12 (2012)
Acute Systemic Toxicity	Acute Systemic Injection (Swiss Mice)	USFDA GLP 21CFR58 ISO 10993-11 (2006) ISO 10993-12 (2012)
Material-mediated pyrogenicity	Rabbit pyrogenicity test (New Zealand White Rabbits)	USFDA GLP 21CFR58 ISO 10993-11 (2006) ISO 10993-12 (2012)
Subacute Systemic Toxicity	32-day Repeated Dose Subacute Toxicity (Sprague Dawley rats)	US FDA GLP 21CFR58 ISO 10993-11 (2006) ISO 10993-12 (2012)
Genotoxicity	Bacterial Mutagenicity – Ames Assay (Salmonella typhimurium [TA97a, TA98, TA100 and TA1535] and Escherichia coli [WP2-uvrA])	USFDA GLP 21CFR58 ISO 10993-3 (2014) ISO 10993-12 (2012)
Implantation	In Vitro Mouse Lymphoma with Extended Treatment (L5178Y cells)	USFDA GLP 21CFR58 ISO 10993-6 (2016)

The product had favorable biocompatibility test data for all relevant endpoints.

In all instances, the 3M™ V.A.C.® Peel and Place Dressing functioned as intended and all test results observed were as expected.

The 3M™ V.A.C.® Peel and Place Dressing and associated labeling was evaluated via simulated-use testing with users representative of the use specification. The testing generated strong evidence that the 3M™ V.A.C.® Peel and Place Dressing has been found to be safe and effective for the intended users, uses and use environments

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

Conclusions

The minor differences in technology do not raise any new questions of safety and efficacy and the performance data established by the predicate, including biocompatibility, shelf-life testing and bench testing demonstrate substantial equivalence to the predicate.

The subject device's fundamental technology and principles of operation are unchanged compared to the predicate device. The subject device's Intended Use remains the same from the predicate device as cleared under K212320.

The subject device is as safe and effective as the predicate device.