September 28, 2021

3M Health Care Business Group
Teri Feeley
Sr. Regulatory Associate
6203 Farinon Dr.
San Antonio, Texas 78249

Re: K212320

Trade/Device Name: Dermatac™ Drape and V.A.C. Granufoam Dressings Featuring SensaT.R.A.C. Technology-Small (5 pack), Dermatac Drape and V.A.C. Granufoam Dressings Featuring SensaT.R.A.C. Technology -Small (10 pack), Dermatac Drape and V.A.C. Granufoam Dressings Featuring SensaT.R.A.C. Technology - Medium(5 pack), Dermatac Drape and V.A.C. Granufoam Dressings Featuring SensaT.R.A.C. Technology -Medium (10 pack), Dermatac Drape and V.A.C. Granufoam Dressings Featuring SensaT.R.A.C. Technology- Large (5 pack), Dermatac Drape and V.A.C. Granufoam Dressings Featuring SensaT.R.A.C. Technology- Large (10 pack)

Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: July 22, 2021
Received: July 26, 2021

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General 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.

Submission Number *(if known)*

K212320

Device Name

Dermatac™ Drape and V.A.C.® Granufoam™ Dressings Featuring SensaT.R.A.C.™ Technology- Small (5 pack) (DTGF05PKS);
Dermatac™ Drape and V.A.C.® Granufoam™ Dressings Featuring SensaT.R.A.C.™ Technology - Small (10 pack) (DTGF10PKS);
Dermatac™ Drape and V.A.C.® Granufoam™ Dressings Featuring SensaT.R.A.C.™ Technology - Medium(5 pack) (DTGF05PKM);
Dermatac™ Drape and V.A.C.® Granufoam™ Dressings Featuring SensaT.R.A.C.™ Technology - Medium (10 pack) (DTGF10PKM);
Dermatac™ Drape and V.A.C.® Granufoam™ Dressings Featuring SensaT.R.A.C.™ Technology- Large (5 pack) (DTGF05PKL);
Dermatac™ Drape and V.A.C.® Granufoam™ Dressings Featuring SensaT.R.A.C.™ Technology- Large (10 pack) (DTGF10PKL)

Indications for Use *(Describe)*

The Dermatac™ Drape and V.A.C. Granufoam™ Dressing are accessories to the:

• ACTIV.A.C.™, V.A.C. SIMPLICITY™, V.A.C.VIA™ and V.A.C. FREEDOM™ Negative Pressure Wound Therapy Systems, which are integrated wound management systems for use in acute, extended and home care settings.

• V.A.C.ULTA™, INFOV.A.C.™, and V.A.C.RX4™ Negative Pressure Wound Therapy Systems, which are integrated wound management systems for use in acute care settings and other professional healthcare environments where product use is conducted by or under the supervision of a qualified healthcare professional.

When used on open wounds, they are 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.

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3M Health Care Business Group

510(k) Summary
3M™ Dermatac™ Drape and V.A.C. Granufoam™ Dressing

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

Contact Person: Teri Feeley
Email: tfeeley@mmm.com
Phone: 210-459-1952
Facsimile: 210-255-6727
Date Prepared: 22 July 2021

Name of Subject Device: 3M™ DERMATAC™ Drape and V.A.C.® GRANUFOAM™ Dressing
Predicate Device: V.A.C. DERMATAC™ Drape (K181505)
Reference Device: RX4™ NPWT System, (V.A.C. Granufoam™ Dressing components of system) (K160487)
Common or Usual Name: Dressing component of Negative Pressure Wound Therapy 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 Dermatac™ Drape and V.A.C. Granufoam™ Dressing kit is a component of the V.A.C.® Negative Pressure Wound Therapy (NPWT) Systems. The V.A.C. NPWT System is comprised of:
:

- Powered Negative Pressure Wound Therapy (NPWT) Unit
- A disposable canister which collects wound exudate
- A wound interface dressing
- Semi-occlusive wound drape
- Sensing pad and lumen

The Dermatac™ Drape and V.A.C. Granufoam™ Dressing kit provides sterile disposable components needed for delivery of negative pressure wound therapy. Dermatac™ Drape and V.A.C. Granufoam™ Dressing kit includes:

- (1) V.A.C.® Granufoam™ Dressings (small, medium, or large)
- (1 or 2) V.A.C. Dermatac™ Drapes
- (1) SensaT.R.A.C.™ Pad
- (1) Ruler

3M Health Care Business Group

510(k) Summary
3M™ Dermatac™ Drape and V.A.C. Granufoam™ Dressing

Intended Use / Indications for Use

The Dermatac™ Drape and V.A.C. Granufoam™ Dressing are accessories to the:

• ACTIV.A.C.™, V.A.C. SIMPLICITY™, V.A.C.VIA™ and V.A.C. FREEDOM™ Negative Pressure Wound Therapy Systems, which are integrated wound management systems for use in acute, extended and home care settings.

• V.A.C.ULTA™, INFOV.A.C.™, and V.A.C.RX4™ Negative Pressure Wound Therapy Systems, which are integrated wound management systems for use in acute care settings and other professional healthcare environments where product use is conducted by or under the supervision of a qualified healthcare professional.

When used on open wounds, they are 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.

Summary of Technological Characteristics

The V.A.C. Granufoam™ Dressing is a wound interface that is intended to be placed into the wound. The dressing has open reticulated pores to manifold negative pressure across the wound bed evenly and to facilitate the removal of exudate and infectious material. The Dermatac™ Drape is placed over the V.A.C.® Granufoam™ Dressings to provide a sealed environment for the application of negative pressure and maintain a moist wound environment. The SensaT.R.A.C. Pad connects the dressing to the canister connected to the negative pressure wound therapy unit and facilitates the removal of wound exudates.

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

- Intended use
- Indicated wound types
- Use environment is acute, extended and home care settings
- Intended for use as part of the V.A.C. Therapy Systems (ACTIV.A.C.™, V.A.C. SIMPLICITY™, V.A.C.VIA™ and V.A.C. FREEDOM™, V.A.C.ULTA™, INFOV.A.C.™, and V.A.C.RX4™ and associated canisters)

3M Health Care Business Group

510(k) Summary
3M™ Dermatac™ Drape and V.A.C. Granufoam™ Dressing

Changes associated with this submission:

- Package Dermatac™ Drape with V.A.C. Granufoam™ Dressing and SensaT.R.A.C.™ Pad as a dressing kit for use with V.A.C.® NPWT Systems rather than providing the dressings components separately.
- Change to the sterilization method of the legally marketed device V.A.C. Granufoam™ Dressing, SensaT.R.A.C.™ Pad and Ruler.
- Minor modifications to the labeling

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

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

Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)]		
Characteristic	**Subject Device:**	**Predicate Device:** Dermatac Drape, K181505 **Reference Device:** RX4 NPWT System, K160487
Intended Use	Identical	To deliver and maintain negative pressure wound therapy to the wound site.
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
V.A.C. Negative Pressure Wound Therapy Units	Identical	• ACTIV.A.C.™ Therapy Unit* • V.A.C. SIMPLICITY™ Therapy Unit* • V.A.C.VIA™ Therapy Unit* • V.A.C. FREEDOM™ Therapy Unit* • V.A.C.ULTA™ Therapy Unit* • INFOV.A.C.™ Therapy Unit* • V.A.C.RX4™ Therapy Unit* *and associated canisters
Use environment/Care Setting of dressing kit	Identical	Acute, extended and home care settings
Dressing Components	Identical	• V.A.C. Granufoam™ Dressing • Dermatac™ Drape

		• SensaT.R.A.C. Pad • Ruler

Performance Data

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

- V.A.C.™ Negative Pressure Maintenance System Test demonstrates the Dermatac™ Drape and V.A.C. Granufoam™ Dressing when used as part of the NPWT System maintains negative pressure within specifications and manages fluid exudate without unexpected alarms.
- Package Integrity testing to ensure the sterile barrier integrity is maintained throughout its labeled shelf life.
- Product performance testing of dressing components after ETO sterilization to verify the product functions as intended throughout its labeled shelf life.

In all instances, the Dermatac™ Drape and V.A.C. Granufoam™ Dressing functioned as intended and all test results observed were as expected.

Clinical and Pre-clinical testing were not necessary to demonstrate equivalence. In addition, human factors engineering testing was not required since the subject device has the same user interface and use environment as the predicate.

Conclusions

The subject device is as safe and effective as the predicate device. The subject device's fundamental technology and principles of operation are unchanged compared to the predicate and reference devices. The subject device's Intended Use remains the same from the predicate device as cleared under K181505.

The minor technological differences between the subject device and its predicate device do not significantly affect the safety or effectiveness of the device, nor did they represent a change in intended use safety. The performance data demonstrates that the Dermatac™ Drape and V.A.C. Granufoam™ Dressing is as safe and effective as the predicate. Thus, the Dermatac™ Drape and V.A.C. Granufoam™ Dressing is substantially equivalent to the predicate.