July 14, 2022

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

Re: K220560
Trade/Device Name: Dermatac™ Drape
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: February 28, 2022
Received: February 28, 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 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)*
K220560

Device Name
Dermatac™ Drape

Indications for Use *(Describe)*
The Dermatac™ Drape is an accessory to the following V.A.C.® Therapy Negative Pressure Wound Therapy Systems:

- 3M™ ActiV.A.C.™, 3M™ V.A.C.® Simplicity, and 3M™ V.A.C.Via™ Negative Pressure Wound Therapy Systems, which are integrated wound management systems for use in acute, extended and home care settings.
- The V.A.C.ULTA™ and V.A.C.RX4™ Negative Pressure Wound Therapy Systems 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, these systems 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.

The Dermatac™ Drape is also an accessory to the V.A.C. VERAFLO™ Therapy (Instillation) provided by the V.A.C.ULTA™ Therapy Unit.

V.A.C. VERAFLO™ Therapy is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

V.A.C. VERAFLO™ Therapy is indicated for patients with chronic, acute, traumatic, sub-acute 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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3M Health Care Business Group
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Contact Person: Melanie Avila
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Phone: 210-275-5038
Date Prepared: 14 February 2022

**Name of Subject Device:** Dermatac™ Drape
**Predicate Device:** V.A.C. DERMATAC™ Drape (K200390)
**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 Dermatac™ Drape is a semi-occlusive wound drape that is used as an accessory to the V.A.C.® Therapy and V.A.C. VERAFLO™ Therapy Systems. The Dermatac™ Drape is a single-use, sterile covering that provides a sealed environment for delivery of these therapies. It also allows for a moist wound environment.

The drape consists of a polyurethane film with acrylic adhesive with a perforated silicone layer. The perforations in the silicone layer expose the acrylic adhesive coated on the polyurethane film. The acrylic adhesive secures the drape to the periwound skin, thus creating a sealed wound environment.

The therapy systems with which it is used are comprised of the following:

- Software controlled therapy unit that provides negative pressure and, in the case of V.A.C. VERAFLO™ Therapy, a pump for controlled delivery of topical wound solutions.
- Disposable canister which collects wound exudate and, in the case of V.A.C. VERAFLO™ Therapy, instilled solutions
- Foam dressing for placement into the wound
- Semi-occlusive drape that covers the dressing
- Tubing set that connects the dressing to the therapy unit.

**Intended Use / Indications for Use**

*The Dermatac™ Drape is an accessory to the following V.A.C.® Therapy Negative Pressure Wound Therapy Systems:*

*• 3M™ ActiV.A.C.™, 3M™ V.A.C.® Simplicity, and 3M™ V.A.C.Via™ Negative Pressure Wound Therapy Systems, which are integrated wound management systems for use in acute, extended and home care settings.*
*• The V.A.C.ULTA™ and V.A.C.RX4™ Negative Pressure Wound Therapy Systems 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, these systems 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.*

*The Dermatac™ Drape is also an accessory to the V.A.C. VERAFLO™ Therapy (Instillation) provided by the V.A.C.ULTA™ Therapy Unit.*

*V.A.C. VERAFLO™ Therapy is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.*

*V.A.C. VERAFLO™ Therapy is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers and venous insufficiency), flaps and grafts.*

**Summary of Technological Characteristics**

Comparison of subject and predicate device:

- Minor changes to the material formulation
- Minor changes to device packaging.
- Additional manufacturing location
- Minor changes to 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, K200390 |
|---|---|---|
| Indicated Wound Types | Identical | • Chronic<br>• Acute<br>• Traumatic<br>• Subacute<br>• Dehisced wounds<br>• Partial-thickness burns<br>• Ulcers (such as diabetic, pressure or venous insufficiency)<br>• Flaps and grafts<br>• Surgically closed incisions (For V.A.C. Therapy only) |
| V.A.C. Negative Pressure Wound Therapy Units | • 3M™ ActiV.A.C.™<br>• 3M™ V.A.C.® Simplicity<br>• 3M™ V.A.C.Via™<br>• V.A.C.ULTA™<br>• V.A.C.RX4™ | • ACTIV.A.C.™<br>• V.A.C. SIMPLICITY™<br>• V.A.C.VIA™<br>• V.A.C. FREEDOM™<br>• V.A.C.ULTA™,<br>• INFOV.A.C™<br>• V.A.C.RX4™ |
| Use environment/Care Setting of dressing kit | Identical | Acute, extended and home care settings |

**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 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.
    - Dressing Extensibility
    - Moisture Vapor Transmission Rate
    - Peel Adhesion Force
    - Wet Peel Adhesion Testing
    - Release Liner Testing
- Summary of biocompatibility Testing

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

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

In all instances, the Dermatac™ Drape 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 device. The subject device's Intended Use remains the same from the predicate device as cleared under K200390.

The minor differences between the subject device and its predicate do not significantly affect the safety or effectiveness of the device, nor did they represent a change in intended use. The performance data

demonstrates that the Dermatac™ Drape is as safe and effective as the predicate.  Thus, the Dermatac™ Drape is substantially equivalent to the predicate.