December 20, 2021

3M Health Care Business Group
Margaret Marsh
Regulatory Affairs Advanced Specialist
6203 Farinon Dr
San Antonio, Texas 78249

Re: K211521
Trade/Device Name: 3M Veraflo Cleanse Choice Complete Dressing Kit (Medium Dressing Kit: VFCCC05MD, Large Dressing Kit: VFCCC05LG)
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: October 28, 2021
Received: October 29, 2021

Dear Margaret Marsh:

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 and Part 809); 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., RAC
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

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)*
K211521

Device Name
3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit (Medium Dressing Kit VFCCC05MD, Large Dressing Kit: VFCCC05LG)

Indications for Use *(Describe)*
The 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit is used as part of an integrated wound management system that provides 3M™ Veraflo™ Therapy, which consists of negative pressure wound therapy (3M™ V.A.C.® Therapy) with an instillation option.
- 3M™ V.A.C.® Therapy in the absence of instillation 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.
- The instillation option 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.
The 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit with and without instillation is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure and 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.

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510(k) Summary

K211521

Date prepared	December 6, 2021
Submitter information [21 CFR 807.929(a)(1)]	
Applicant Name	3M Health Care Business Group
Applicant Address	6203 Farinon Dr San Antonio TX 78249 United States of America
Applicant Contact Telephone	210 255 6481
Applicant Contact	Margaret Marsh, Regulatory Affairs Advanced Specialist
Applicant Contact Email	mlmarsh@mmm.com
Name of the device [21 CFR 807.92(a)(2)]	
Trade or proprietary name	3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit : Medium Dressing Kit: VFCCC05MD Large Dressing Kit: VFCCC05LG)
Common or usual name	Component of a powered suction pump
Classification name	Negative Pressure Wound Therapy Powered Suction Pump
Regulation Number	878.4780
Product Code	OMP
Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]	
Predicate: 3M™ V.A.C. Veraflo Cleanse Choice™ Dressing Kit, cleared under 510(k) K160451 Reference: 3M™ V.A.C. Dermatac™ Drape, cleared for use with 3M™ V.A.C. Veraflo™ Therapy under 510(k) K200390.	
Device description summary [21 CFR 807.92(a)(4)]	
The Veraflo™ Cleanse Choice Complete Dressing Kit is intended to be used with the separately provided V.A.C.® Ulta Therapy Unit and its associated canisters and cassette for the delivery of Veraflo Therapy that provides V.A.C.® Therapy Negative Pressure Wound Therapy with an instillation option. The system kit provides sterile disposable components needed for delivery of Veraflo Therapy. The kit contains the wound dressing (Veraflo Cleanse Choice Complete Dressing), drape (V.A.C. Dermatac Drape), tubing set (3M™ V.A.C. VeraT.R.A.C.™ Pad or 3M™ V.A.C. VeraT.R.A.C. Duo™ Tube Set) and a wound measuring ruler. The kit components are intended to simplify wound dressing applications by replacing the multiple grey foam dressing pieces in the predicate kit with a single blue foam piece and to provide the V.A.C. Dermatac Drape in the same package with the dressing. Because V.A.C. Dermatac Drape can only be sterilized by ethylene oxide, the kit must also be sterilized by this method.	

510(k) Summary

K211521

Indications for Use **21 CFR 807.92(a)(5)**
Both the subject and predicate device kit have same intended use and indications for use. The 3M™ V.A.C. Veraflo™ Cleanse Choice Complete™ Dressing Kit is used as part of an integrated wound management system that provides 3M™ Veraflo™ Therapy, which consists of negative pressure wound therapy (3M™ V.A.C.® Therapy) with an instillation option. • 3M™ V.A.C.® Therapy in the absence of instillation 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. • The instillation option 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. The 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit with and without instillation is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), flaps and grafts.
Comparison of the technological characteristics with the predicate device [21 CFR 807.92(a)(6)]
The subject and predicate device kits both have the same technology in that they are sterile, single use, components that are required for use with the V.A.C.® Ulta Therapy Unit for delivery of Veraflo Therapy. They both contain a wound dressing, drape and tubing set; the mechanism of action of each kit component is unchanged. The changes in the subject kit components relate to the color of the dressing, reduction of the required pieces of dressing to only one, incorporation of a separately cleared drape for use with Veraflo Therapy and ETO sterilization. These changes have been verified to have no impact on the predicate requirements for biocompatibility, system performance in delivering negative pressure and removing fluid from the wound bed into the canister or usability.
Performance data [21 CFR 807.92(b)]
Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]
The following tests were performed to verify compliance with the predicate design requirements: • A biological safety evaluation was performed on Veraflo Cleanse Choice Complete Dressing Kit as an externally communicating device with tissue/bone/dentin contact for a prolonged duration (>24 hours to ≤30 days). The biological safety evaluation was conducted in accordance with FDA Guidance: *Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process - Guidance for Industry and Food and Drug Administration Staff.* • A system performance test was performed to verify that the Veraflo Cleanse Choice Complete Dressing Kit when used with the V.A.C.® Ulta Therapy Unit was able to maintain negative pressure and remove fluid from the wound site over the three-day use life of the dressing and under worst case and/or clinically relevant simulated use conditions of testing.

• A usability assessment was conducted to determine if the design changes had an impact of the predicate usability profile. As there are no changes to the intended users, intended use environment or the context of use, and no new application tasks compared to the predicate, the assessment concluded that no supplemental usability validation is required and that its market introduction does not negatively impact use-safety.
Summary of clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(2)]
No clinical tests were necessary for a determination of substantial equivalence.
Conclusions drawn [21 CFR 807.92(b)(3)]
Although minor changes were made to the predicate design, these changes have been verified to have no impact on the predicate design requirements for biocompatibility, system performance or usability. Thus, there are no new questions of safety and effectiveness. The subject device kit is substantially equivalent to the predicate device kit.