March 23, 2023

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

Re: K221585
Trade/Device Name: 3M V.A.C. Veraflo Cleanse Choice Dressing Kit, 3M Veraflo Cleanse Choice Complete Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: January 20, 2023
Received: January 24, 2023

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); 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
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)*
510k K221585

Device Name
3M™ V.A.C. Veraflo Cleanse Choice™ Dressing Kit
3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit

Indications for Use *(Describe)*
The 3M™ V.A.C. Veraflo Cleanse Choice™ 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. It provides hydromechanical removal of infectious materials, non-viable tissue and wound debris which reduces the number of surgical debridements required, while promoting granulation tissue formation, creating an environment that promotes wound healing.
The 3M™ V.A.C. Veraflo Cleanse Choice™ 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.

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. It provides hydromechanical removal of infectious materials, non-viable tissue and wound debris which reduces the number of surgical debridements required, while promoting granulation tissue formation, creating an environment that promotes wound healing.
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.

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510(k) K221585 Summary
3M™ V.A.C. Veraflo Cleanse Choice™ Dressing Kit
3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit

Date prepared March 9, 2023

Submitter information [21 CFR 807.929(a)(1)]

Name	3M Health Care Business Group
Address	6203 Farinon Dr, San Antonio TX 78249, United States of America
Establishment Registration Number	3009897021
Name of contact person	Margaret Marsh, Regulatory Affairs Advanced Specialist
Contact E-mail	mlmarsh@mmm.com

Name of the device [21 CFR 807.92(a)(2)]

Trade or proprietary name	• **3M™ V.A.C. Veraflo Cleanse Choice™ Dressing Kit** • **3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit**
Common or usual name	Components of a negative pressure wound therapy system
Classification name	878.4780 - Powered suction pump
Product code	OMP

Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]

- **3M™ V.A.C. Veraflo Cleanse Choice™ Dressing Kit,** cleared most recently under 510(k) K200390
- **3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit,** cleared under 510(k) K211521

Device description [21 CFR 807.92(a)(4)]

Both dressing kits are intended to be used with the 3M™ V.A.C.® Ulta Therapy Unit and its associated canisters and cassette for the delivery of 3M™ Veraflo™ Therapy that provides Negative Pressure Wound Therapy coupled with controlled delivery and drainage of topical wound treatment solutions and suspensions over the wound bed. The dressing kits provide sterile disposable components needed for delivery of 3M™ Veraflo™ Therapy.

Each kit contains a wound dressing with 10 mm diameter holes specifically designed for use with 3M™ Veraflo™ Therapy (either the 3M™ V.A.C. Veraflo™ Cleanse Choice™ or the 3M™ Veraflo™ Cleanse Choice Complete™ Dressing), an occlusive drape covering the dressing (either the 3M™ V.A.C. Advanced Drape or the V.A.C. Dermatac™ Drape), a tubing set for connecting the dressing to the negative pressure and instillation pumps (either the 3M™ V.A.C. VeraT.R.A.C.™ Pad or the 3M™ VeraT.R.A.C. Duo™ Tube Set, depending on dressing size) and a wound measuring ruler.

The subject dressings differ only in color, in the number of dressing pieces provided in the kit, in the drape materials of construction and in the method of sterilization:

- The 3M™ V.A.C. Veraflo™ Cleanse Choice™ Dressing Kit is gray in color, has three dressing layers (one with holes, one thin cover layer and one thick cover layer without holes), has a drape constructed of a polyurethane film with acrylic adhesive and is sterilized by irradiation.
- The 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit is blue in color, has only one dressing piece (which consists of a combination of the layer with holes and the thin cover layer without holes in the 3M™ V.A.C. Veraflo™ Cleanse Choice™ Dressing), has a drape constructed of a polyurethane film with acrylic adhesive and a perforated silicone layer, and is sterilized by ethylene oxide (ETO).

Indications for Use

The 3M™ V.A.C. Veraflo Cleanse Choice™ 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. It provides hydromechanical removal of infectious materials, non-viable tissue and wound debris which reduces the number of surgical debridements required, while promoting granulation tissue formation, creating an environment that promotes wound healing.

The 3M™ V.A.C. Veraflo Cleanse Choice™ 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.

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. It provides hydromechanical removal of infectious materials, non-viable tissue and wound debris which reduces the number of surgical debridements required, while promoting granulation tissue formation, creating an environment that promotes wound healing.

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)]

See Table on following pages.

510(k) Summary
3M™ V.A.C. Veraflo Cleanse Choice™ Dressing Kit
3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit

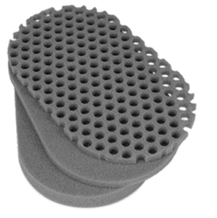
Comparison to Predicates Table

Comparator	Predicate Device (per K200390) V.A.C. Veraflo Cleanse Choice™ Dressing System	Subject Device 3M™ V.A.C. Veraflo Cleanse Choice™ Dressing Kit	Predicate Device (per K211521) 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit	Subject Device 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit	Comparison
Indications for Use	The V.A.C. Ulta™ Negative Pressure Wound Therapy System is an integrated wound management system that provides Negative Pressure Wound Therapy with an instillation option.	The 3M™ Veraflo™ Cleanse Choice 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.	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.	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.	Identical, except for minor name changes
	• Negative Pressure Wound 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.	• 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. It provides hydromechanical removal of infectious materials, non-viable tissue and wound debris which reduces the number of surgical debridements required, while promoting granulation tissue formation, creating an environment that promotes wound healing.	• 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.	• 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. It provides hydromechanical removal of infectious materials, non-viable tissue and wound debris which reduces the number of surgical debridements required, while promoting granulation tissue formation, creating an environment that promotes wound healing.	Identical, except for minor name changes, and addition of the new hydromechanical indication text

Comparator	Predicate Device (per K200390) V.A.C. Veraflo Cleanse Choice™ Dressing System	Subject Device 3M™ V.A.C. Veraflo Cleanse Choice™ Dressing Kit	Predicate Device (per K211521) 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit	Subject Device 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit	Comparison
	The V.A.C.ULTA™ Negative Pressure Wound Therapy System 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.	The 3M™ Veraflo™ Cleanse Choice 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.	The 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.	The 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.	Except for minor name changes, text is identical.
Wound Types	Chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), flaps and grafts.	Same as predicate	Chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), flaps and grafts.	Same as predicate	Identical
Care Setting	Acute and extended care settings	Same as predicate	Acute and extended care settings	Same as predicate	Identical

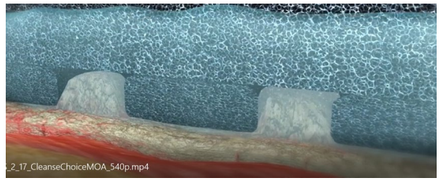
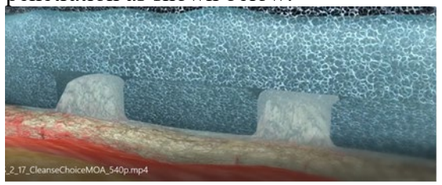
Comparator	Predicate Device (per K200390) V.A.C. Veraflo Cleanse Choice™ Dressing System	Subject Device 3M™ V.A.C. Veraflo Cleanse Choice™ Dressing Kit	Predicate Device (per K211521) 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit	Subject Device 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit	Comparison
Dressing Kit Components	• V.A.C. Veraflo Cleanse Choice Dressing (3 piece design) • V.A.C. Advanced Drape • VeraT.R.A.C. or VeraT.R.A.C. Duo Tube Set • Ruler • 3M ™ Cavilon™ Skin Prep	Same as predicate	• Veraflo Cleanse Choice Dressing (1 piece design) • Dermatac Drape • VeraT.R.A.C. or VeraT.R.A.C. Duo Tube Set • Ruler	Same as predicate	Identical type of components, except for Cavilon Skin Prep
Dressing Dimensions/ Geometry	See nested table below	Same as predicate	**Medium Dressing:** single piece consisting of an oval shaped, 180 x 125 x 16mm foam with holes (10 mm in diameter and 8 mm deep) **Large Dressing**: single piece consisting of an oval shaped, 256 x 150 x 16mm foam with holes (10 mm in diameter and 8 mm deep) **Note**: holes in the dressing penetrate one-half the thickness of the dressing.	Same as predicate	Identical. There is no change between each subject device and its predicate device

	Component	Description
Medium Dressing	Perforated Contact Layer	Oval shaped, 180 x 125 x 8 mm foam with holes (10 mm in diameter through holes)
	Thin Cover Layer	Oval shaped, 180 x 125 x 8 mm foam without holes
	Thick Cover Layer	Oval shaped, 180 x 125 x 16mm foam without holes
Large Dressing	Perforated Contact Layer	Oval shaped layer, 256 x 150 x 8 mm, with holes (10 mm in diameter through holes)
	Thin Cover Layer	Oval shaped layer, 256 x 150 x 8 mm, without holes

Comparator	Predicate Device (per K200390) V.A.C. Veraflo Cleanse Choice™ Dressing System	Subject Device 3M™ V.A.C. Veraflo Cleanse Choice™ Dressing Kit	Predicate Device (per K211521) 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit	Subject Device 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit	Comparison
	Thick Cover Layer: Oval shaped layer, 256 x 150 x 16 mm, without holes				
Dressing Drawing		Same as predicate		Same as predicate	Identical. There is no change between each subject device and its predicate device
Patient Contacting Materials	• The dressing is constructed of a felted polyurethane ester foam colored with carbon black.	Same as predicate	• The dressing is constructed of the same felted polyurethane ester foam as in 3M V.A.C. Veraflo Cleanse Choice Dressing, except that it is colored with blue and violet dyes.	Same as predicate.	Identical. There is no change between each subject device and its predicate device
	• The drape is constructed of a polyurethane film with acrylic adhesive Note: Optionally, the user can apply the drape constructed of polyurethane film with acrylic adhesive and a perforated silicone layer (provided separately)	Same as predicate	• The drape is constructed of a polyurethane film with acrylic adhesive and a perforated silicone layer.	Same as predicate	
NPWT System Design	The V.A.C. Veraflo Cleanse Choice™ Dressing System is intended for use with the V.A.C. Ulta NPWT system. The NPWT system consists of:	Same as predicate	The Veraflo Cleanse Choice Complete Dressing System is intended for use with the 3M™ V.A.C.® Ulta NPWT system. The NPWT System consists of:	Same as predicate	Identical, except for the subject dressing name.

Comparator	Predicate Device (per K200390) V.A.C. Veraflo Cleanse Choice™ Dressing System	Subject Device 3M™ V.A.C. Veraflo Cleanse Choice™ Dressing Kit	Predicate Device (per K211521) 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit	Subject Device 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit	Comparison
	• Software controlled therapy unit: 3M™ V.A.C.® Ulta Therapy Unit • Exudate canister (either 500 or 1000 mL capacity) • Negative pressure tubing and sensing pad • Instillation cassette, tubing and pad • Foam wound dressing • Occlusive drape		• Software controlled therapy unit: 3M™ V.A.C.® Ulta Therapy Unit • Exudate canister (either 500 or 1000 mL capacity) • Negative pressure tubing and sensing pad • Instillation cassette, tubing and pad • Foam wound dressing • Occlusive drape		

Comparator	Predicate Device (per K200390) V.A.C. Veraflo Cleanse Choice™ Dressing System	Subject Device 3M™ V.A.C. Veraflo Cleanse Choice™ Dressing Kit	Predicate Device (per K211521) 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit	Subject Device 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit	Comparison
Operating Principle	At a **system** level (with which the kit is used): The 3M™ V.A.C.® Ulta Therapy System delivers software controlled negative pressure to the wound site during the negative pressure cycle. It also provides automated delivery of user selected topical wound solutions into the wound bed between negative pressure therapy cycles. At the **kit component** level: • The reticulated open cells of the foam dressing to which the therapy unit is connected enable distribution of the negative pressure across the surface of the wound and allows for instillation solution to contact the wound bed. The 10 mm diameter and 8 mm through holes in the dressing facilitate removal of thick wound exudate during the negative pressure cycle. • The tubing set allows for delivery of negative pressure and instillation solutions to the wound bed and for transfer of accumulated fluids to the canister in the negative pressure cycle. • The drape provides a sealed environment for delivery of negative pressure wound therapy and protects from fluid leakage during instillation therapy.	Same as predicate	At a **system** level (with which the kit is used): The 3M™ V.A.C.® Ulta Therapy System delivers software controlled negative pressure to the wound site during the negative pressure cycle. It also provides automated delivery of user selected topical wound solutions into the wound bed between negative pressure therapy cycles. At the kit **component** level: • The reticulated open cells of the foam dressing to which the therapy unit is connected enable distribution of the negative pressure across the surface of the wound and allows for instillation solution to contact the wound bed. The 10 mm diameter and 8 mm deep holes in the dressing facilitate removal of thick wound exudate during the negative pressure cycle. • The tubing set allows for delivery of negative pressure and instillation solutions to the wound bed and for transfer of accumulated fluids to the canister in the negative pressure cycle. • The drape provides a sealed environment for delivery of negative pressure wound therapy and protects from fluid leakage during instillation therapy.	Same as predicate	Identical

Comparator	Predicate Device (per K200390) V.A.C. Veraflo Cleanse Choice™ Dressing System	Subject Device 3M™ V.A.C. Veraflo Cleanse Choice™ Dressing Kit	Predicate Device (per K211521) 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit	Subject Device 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit	Comparison
Operating Principle, continued	At the **dressing** level: • The unique structure of the dressing with 10 mm diameter through holes in the contact layer facilitate removal of thick wound exudate during the negative pressure cycle. The holes induce mechanical stress and strain on the wound tissue and wound debris layer. Under negative pressure, fracture points are created as the wound materials are drawn up into the holes in the dressing, allowing topical solution penetration as shown below.  • Hydromechanical removal of infectious materials, non-viable tissue and wound debris is achieved through the dressing's mechanical action in conjunction with the process of instilling and allowing topical solutions to soak in the wound bed for up to 30 minutes during the Instillation Cycle of Veraflo Therapy. The instillation and soaking action allows for diluting, softening, and solubilizing infectious materials, non-viable tissue and wound debris	Same as predicate	At the **dressing** level: • The unique structure of the dressing with 10 mm diameter holes facilitate removal of thick wound exudate during the negative pressure cycle. The holes induce mechanical stress and strain on the wound tissue and wound debris layer. Under negative pressure, fracture points are created as the wound materials are drawn up into the holes in the dressing, allowing topical solution penetration as shown below.  • Hydromechanical removal of infectious materials, non-viable tissue and wound debris is achieved through the dressing's mechanical action in conjunction with the process of instilling and allowing topical solutions to soak in the wound bed for up to 30 minutes during the Instillation Cycle of Veraflo Therapy. The instillation and soaking action allows for diluting, softening, and solubilizing infectious materials, non-viable tissue and wound debris to	Same as predicate	The two device systems have the same operating principles.

Comparator	Predicate Device (per K200390) V.A.C. Veraflo Cleanse Choice™ Dressing System	Subject Device 3M™ V.A.C. Veraflo Cleanse Choice™ Dressing Kit	Predicate Device (per K211521) 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit	Subject Device 3M™ Veraflo™ Cleanse Choice Complete™ Dressing Kit	Comparison
	to facilitate their removal under the negative pressure cycle of Veraflo Therapy.		facilitate their removal under the negative pressure cycle of Veraflo Therapy.		
Design V/V	• Verification of delivery of negative pressure at nominal, high- and low-pressure settings during the negative pressure phase under worse case simulated use conditions for 72 hours. • Verification of delivery and removal of instillation solutions to the wound bed. • The dressing kit shall have a minimum shelf-life of 1 year. • After exposure to worst case conditions of sterilization, system components must meet all relevant FDA biocompatibility requirements and be sterile at a SAL of 10^{-6}.	Same as predicate	• Verification of delivery of negative pressure at nominal, high- and low-pressure settings during the negative pressure phase under worse case simulated use conditions for 72 hours. • Verification of delivery and removal of instillation solutions to the wound bed. • The dressing kit shall have a minimum shelf-life of 1 year. • After exposure to worst case conditions of sterilization, system components must meet all relevant FDA biocompatibility requirements and be sterile at a SAL of 10^{-6}.	Same as predicate	Identical
Sterilization	Gamma irradiation	Same as predicate	Ethylene Oxide Sterilization	Same as predicate	Respective subject devices are identical to their predicates.
Sterile Packaging	Thermoformed tray of PETG with a Tyvek lid	Same as predicate	Thermoformed tray of PETG with a Tyvek lid	Same as predicate	Identical except for geometry of tray
Shelf-Life	Two years	Same as predicate	Two years	Two years	Identical
Labeling Format	Paper Instructions for Use provided in the dressing carton	Same as predicate	Electronic copy of Instructions for Use available on the web. QR code provided on kit and carton labels	Same as predicate	Respective subject devices are identical to their predicates.

Performance data [21 CFR 807.92(b)]

- **Sterilization:** There is no change in the design of these dressing kits that impacts sterilization. Only labeling has been changed; thus data from the predicates have been leveraged to demonstrate equivalence in terms of sterilization.
- **Biocompatibility:** There is no change in the design of these dressing kits that impacts biocompatibility. Only labeling has been changed; thus data from the predicates have been leveraged to demonstrate equivalence in terms of biocompatibility.
- **Shelf life:** Stability testing was conducted to confirm that the stability indicating parameters for delivery of hydromechanical removal of infectious materials, non-viable tissue and wound debris were within specification for production equivalent samples accelerated aged to the proposed shelf life.
- **Hydromechanical removal of infectious materials, non-viable tissue and wound debris:** Bench tests and evaluations comparing the 3M™ Veraflo™ Cleanse Choice Complete™ Dressing to the 3M™ V.A.C. Veraflo Cleanse Choice™ Dressing Kit were conducted to establish functional equivalence of the two dressings with respect to performing hydromechanical removal of infectious materials, non-viable tissue and wound debris. The results of this testing indicate that the two dressings are functionally equivalent and that the literature-reported clinical data for the 3M™ V.A.C.™ Veraflo Cleanse Choice™ Dressing demonstrating hydromechanical removal of infectious materials, non-viable tissue and wound debris are also applicable to the 3M™ Veraflo™ Cleanse Choice Complete™ Dressing.

  The testing consisted of the following:
  - A comparison of materials of construction
  - A comparison of material physical properties, such as pore size, density, tensile, tear, elongation, compression, hole size, hole pattern, and geometry
  - Finite element modeling of expected strain profiles
  - Foam changes under negative pressure as measured by surface area and hole size contraction.

- **Summary of literature-reported clinical data used to demonstrate performance**

  Real World Data: A literature search was conducted to examine available real-world clinical evidence supporting the use of 3M™ V.A.C. Veraflo™ Therapy with 3M™ V.A.C. Veraflo Cleanse Choice™ Dressing for hydromechanical removal of infectious materials, non-viable tissue and wound debris. The evidence consisted of clinically relevant case reports which were sufficiently well described so that individual patient wound data at an initial time point could be compared to that after therapy has been applied. The required outcome measure was evidence of reduction in non-viable wound tissue (such as slough, fibrotic tissue, necrotic tissue, or other unspecified non-viable tissue) after the stated period of therapy.

  The 21 retrieved reference publications (see below) included a total of 177 patients treated with 3M™ V.A.C. Veraflo™ Therapy and 3M™ V.A.C. Veraflo Cleanse Choice™ Dressings. Recommended use in general included instilling saline or a hypochlorous solution with a 1-minute to 10-minute dwell time followed by 2 to 3.5 hours of negative pressure (-125 mm Hg or -150 mm Hg). Dressing changes were performed every 2 to 3 days and duration was based upon wound size and other patient factors. These patients presented with a variety of the indicated wound types. The direct endpoint in the included studies was reduction in non-viable tissue.

When this endpoint was not directly stated, indirect endpoints were also included such as decrease in the need for surgical debridement or visible evidence of reduction of nonviable tissue in photographs. Each case report was also assessed for impact on granulation tissue formation. The collection of 177 patients treated with 3M™ V.A.C. Veraflo Cleanse Choice™ Dressings included in the examined studies represent real-world evidence across a variety of wound types for patients with a range in age and a variety of comorbidities.

This body of evidence supports that the adjunctive use of 3M™ V.A.C. Veraflo™ Therapy with 3M™ V.A.C. Veraflo Cleanse Choice™ Dressing can provide hydromechanical removal of infectious materials, non-viable tissue and wound debris and promote granulation tissue development in a variety of complex wounds when areas of non-viable tissue are present on the wound surface.

Conclusions drawn [21 CFR 807.92(b)(3)]

Both the subject and predicate device kits have the same technology in that they are sterile, single use, components that are required for use with the 3M™ V.A.C.® Ulta Therapy Unit for delivery of 3M™ Veraflo™ Therapy. They both contain a wound dressing with 10 mm diameter holes, an occlusive drape, and tubing set. The mechanisms of action of each kit component are unchanged. Except for the proposed labeling change that includes the hydromechanical indication, there is no change to the materials of construction and design, methods of manufacturing, intended use population and wound types.

The results of the bench testing support the functional equivalency of the 3M™ Veraflo™ Cleanse Choice Complete™ Dressing to the 3M™ V.A.C. Veraflo Cleanse Choice™ Dressing. Published clinical data supports the ability of the 3M™ V.A.C. Veraflo Cleanse Choice™ Dressing to provide hydromechanical removal of infectious materials, non-viable tissue and wound debris which reduces the number of surgical debridements required, while promoting granulation tissue formation creating an environment that promotes wound healing.

In conclusion, the intended use of the device kits is the same as the predicates and the minor changes to labeling do not raise new questions of safety and effectiveness. Further, the performance data provided demonstrates substantial equivalence to the predicates and support for the devices' use in hydromechanical removal of infectious materials, non-viable tissue and wound debris while promoting granulation tissue. The subject device kits are substantially equivalent to the predicate device kits.

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