October 27, 2021

KCI, a part of 3M Health Care Business Group
Margaret Marsh
Regulatory Affairs Advanced Specialist
6203 Farinon Drive
San Antonio, Texas 78249

Re: K203316
Trade/Device Name: V.A.C. Ulta Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 23, 2021
Received: September 27, 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); 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,

For 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K203316

Device Name
V.A.C.® Ulta Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
The V.A.C.® Ulta Negative Pressure Wound Therapy System is an integrated wound management system that provides Negative Pressure Wound Therapy (V.A.C.® Therapy) with an instillation option (Veraflo™ Therapy).

• 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.
• 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.

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.
• V.A.C.® Therapy in the absence of instillation may also be used for:
o The temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary and for open abdominal wounds with exposed viscera including, but not limited to, abdominal compartment syndrome. The intended care setting is a closely monitored area within the acute care hospital, such as the ICU. The abdominal dressing will most often be applied in the operating theater.
o The management of the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate 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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K203316
510(k) SUMMARY
V.A.C.® Ulta Negative Pressure Wound Therapy System

Date prepared	October 27, 2021
Submitter information [21 CFR 807.929(a)(1)]	
Name	KCI, now a part of 3M Health Care Business Group
Address	6203 Farinon Drive; San Antonio, Texas 78249
Fax number	210 255-6727
Establishment Registration Number	3009897021
Name of contact person	Margaret Marsh, Regulatory Affairs Advanced Specialist
Name of the device [21 CFR 807.92(a)(2)]	
Trade or proprietary name	V.A.C.® Ulta Negative Pressure Wound Therapy System
Common or usual name	Negative pressure wound therapy system with an instillation option
Classification name	Negative Pressure Wound Therapy Powered Suction Pump (and components)
Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]	
V.A.C.® Ulta Negative Pressure Wound Therapy System (K162790)	

K203316
510(k) SUMMARY
V.A.C.® Ulta Negative Pressure Wound Therapy System

Device description [21 CFR 807.92(a)(4)]
The V.A.C.® Ulta Negative Pressure Wound Therapy System is a negative pressure wound therapy system with an instillation feature which allows controlled delivery and drainage of topical wound treatment solutions and suspensions. The unit is comprised of a vacuum pump and an instillation pump. The vacuum pump delivers negative pressure therapy for the removal of wound exudate and instilled solutions when applied. The instillation pump provides controlled delivery of topical wound solutions and suspensions. Both pumps are software controlled. Instillation solutions and negative pressure are delivered through tubing to foam dressings in the wound covered by an occlusive drape. Software monitors both negative pressure during negative pressure wound therapy as well as positive pressure during instillation of fluids to the wound bed. Software also provides controls for setting therapy parameters as well as help and alarm functions.
Indications for Use [21 CFR 807.92(a)(5)]
The V.A.C.® Ulta Negative Pressure Wound Therapy System is an integrated wound management system that provides Negative Pressure Wound Therapy (V.A.C.® Therapy) with an instillation option (Veraflo™ Therapy). • 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. • 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. 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. • V.A.C.® Therapy in the absence of instillation may also be used for: o The temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary and for open abdominal wounds with exposed viscera including, but not limited to, abdominal compartment syndrome. The intended care setting is a closely monitored area within the acute care hospital, such as the ICU. The abdominal dressing will most often be applied in the operating theater. o The management of the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.

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510(k) SUMMARY
V.A.C.® Ulta Negative Pressure Wound Therapy System

Comparison To Predicate Table [21 CFR 807.92(a)(6)]		
Comparator	**Subject Device**	**Predicate Device**
Trade name	**V.A.C.® Ulta Negative Pressure Wound Therapy System**	**V.A.C.® Ulta Negative Pressure Wound Therapy System**
Therapy Unit Model number	Same as predicate	ULTDEV 01/US
510(k) Submitter/Holder	Same as predicate; however, KCI is now apart of 3M Health Care Business	KCI USA, Inc.
510(k) number	K203316	K162790
Indications for Use		
	Same as predicate: The V.A.C.® Ulta Negative Pressure Wound Therapy System is an integrated wound management system that provides Negative Pressure Wound Therapy (V.A.C.® Therapy) with an instillation option (Veraflo™ Therapy). • 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. • 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	The V.A.C.® Ulta Negative Pressure Wound Therapy System is an integrated wound management system that provides Negative Pressure Wound Therapy (V.A.C.® Therapy) with an instillation option (Veraflo™ Therapy). • 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. • 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

K203316
510(k) SUMMARY
V.A.C.® Ulta Negative Pressure Wound Therapy System

Comparator	Subject Device	Predicate Device
Indications for Use, continued	The V.A.C.® Ulta Negative Pressure Wound Therapy System with and without instillation is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial- thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), flaps and grafts. V.A.C.® Therapy in the absence of instillation may also be used for: • The temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary and for open abdominal wounds with exposed viscera including, but not limited to, abdominal compartment syndrome. The intended care setting is a closely monitored area within the acute care hospital, such as the ICU. The abdominal dressing will most often be applied in the operating theater. • The management of the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.	The V.A.C.® Ulta Negative Pressure Wound Therapy System with and without instillation is indicated for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial- thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), flaps and grafts. V.A.C.® Therapy in the absence of instillation may also be used for: • The temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary and for open abdominal wounds with exposed viscera including, but not limited to, abdominal compartment syndrome. The intended care setting is a closely monitored area within the acute care hospital, such as the ICU. The abdominal dressing will most often be applied in the operating theater. • The management of the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.

Components of the indication		
Care setting	Same as predicate	The V.A.C.® Ulta Negative Pressure Wound Therapy Unit is for acute care settings only; it is not intended for use in home care.
Duration of therapy	Same as predicate	Duration of therapy is determined by the instructions for use for the wound care dressing applied. • For V.A.C. ® Granufoam, V.A.C. Whitefoam and Veraflo™ Dressings, the typical duration is 3 days between dressing changes. • The AbThera™ Open Abdomen Dressing has a 3- day use life. • The Prevena™ Incision Management Dressings may be used for up to 7

		days.
Comparator	**Subject Device**	**Predicate Device**
Wound types	Same as predicate.	• V.A.C.® and Veraflo™ Therapies are intended for use with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure and venous insufficiency), flaps and grafts. • The AbThera™ Open Abdomen Dressing is intended for use in abdominal wall openings where primary closure is not possible and/or repeat abdominal entries are necessary and for open abdominal wounds with exposed viscera including, but not limited to, abdominal compartment syndrome. • The Prevena™ Incision Management Dressings are intended to be used on closed surgical incisions
Wound sizes	Same as predicate, except for the addition of a Large size of the Veraflo Cleanse Choice Dressing.	Dressings are provided in various sizes and shapes for wounds/incisions of various sizes and configurations.
Mechanisms of action	Same as predicate	NPWT (applies to all indicated wound types): • Helps hold the wound edges together • Removes wound exudates and infectious materials. • Reduces edema • V.A.C.® and Veraflo™ Therapies also promote granulation tissue formation and perfusion • Veraflo™ Therapy also cleanses the wound with appropriate topical wound solutions
Technology	Same as predicate	Software controlled application of negative pressure therapy via a vacuum pump and instillation therapy via an instillation pump.

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510(k) SUMMARY
V.A.C.® Ulta Negative Pressure Wound Therapy System

Comparator	Subject Device	Predicate Device
System design	**Therapy system consists of:**	
	Same as predicate	• Software controlled therapy unit
		• 500 and 1000 mL exudate canisters
		• Instillation cassette (Veraflo™ Therapy only)
		• Single pad tubing set for delivery of NPWT
		• Single and dual pad tubing sets for delivery of both instillation and negative pressure (Veraflo™ Therapy only)
	Same as predicate	• Dressings: o V.A.C.® Granufoam, Granufoam Silver, Whitefoam Dressings, o Veraflo™, Veraflo Cleanse™, and Veraflo Cleanse Choice™ Dressings o Prevena™ Incision Management Dressings o AbThera™ Open Abdomen Dressings
Operating Principle	Same as predicate	Therapy unit delivers software controlled negative pressure to the wound site. The 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, while the tubing transfers accumulated fluids to the canister. Therapy unit also provides automated delivery of instillation fluids into the wound bed via an instillation pump between negative pressure therapy cycles. After a user-selected soak time, fluids are removed into the canister via application of negative pressure in the next negative pressure wound therapy cycle.
	The operating principle for the determination of the instill volume provided by the new Smart Instill™ Feature is based on the decay in pressure after application of negative pressure to the dressed wound site.	

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V.A.C.® Ulta Negative Pressure Wound Therapy System

Comparator	Subject Device	Predicate Device
Performance Specifications		
V.A.C. Negative Pressure Wound Therapy (for V.A.C. Therapy Cycle)	Same as predicate	• Continuous mode and intermittent ("DPC") modes • Continuous negative pressure range: -25 to -200 mmHg in 25 mmHg increments • DPC mode: 1 to 10 minutes to rise up and 1 to 10 minutes to fall down (in 1 minute increments each); target negative pressure range: -50 to-200 mmHg in 25 mmHg increments
Prevena™ Therapy Cycle	Same as predicate	Continuous negative pressure at -125 mmHg,
AbThera™ Therapy Cycle	Same as predicate	Continuous negative pressure at -100, 125, and 150 mmHg
Veraflo™ Therapy Cycle	Same as predicate	• Volume delivered by pump: 6 mL to 500 mL • Instill hold time (time in wound bed, called "soak time"): 1 sec to 30 min • Instillation solution pressure limit: 3 psi • Negative pressure time: 3 min to 12 hrs • Negative pressure mode: continuous or DPC • Negative pressure range: -50 to -200 mmHg in 25 mmHg increments
	Smart Instill™ Feature: Dressing Saturation must be achieved for the instilled volume within 12 hours, without creating an overfill condition.	Not provided
Performance testing	Same as predicate.	Verification data confirms that the specified negative pressure and instillation performance specifications have been met.

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V.A.C.® Ulta Negative Pressure Wound Therapy System

Comparator	Subject Device	Predicate Device		
Therapy Unit				
• **Dimensions – with empty canister (inches)**	Same as predicate	Width	Length	Depth
		8.55	10.25	7.25
• **Weight – with empty 500 mL canister**	Same as predicate	8 lbs (without cassette)		
• **User interface**	Same as predicate	Touch screen		
• **Software Level of Concern**	Same as predicate	Moderate		

Comparator	Subject Device	Predicate Device
• **Software Controls**	Same as predicate	The embedded software accepts user instructions for initiating and modifying therapy via a touch screen.
	Same as predicate	Software controls include the user selection of negative pressure therapy parameters as well as negative pressure therapy application and monitoring. It also controls user selection of instillation therapy parameters as well as application and monitoring of therapy.
	Same as predicate, with the addition of: • Smart Instill™ Feature provides the clinician an additional option to select the solution volume setpoint (applicable to Veraflo™ Therapy only). • On-Screen Help Animations are now provided for the most frequent alarm/alert states (applicable to V.A.C.® Therapy, Veraflo™ Therapy, Prevena™ Therapy, and AbThera™ Therapy). • Postponement Feature allows for the postponement of Veraflo™ Therapy for up to 60 hours while still providing V.A.C.® Therapy. • Therapy Inactive Alarm Delay allows for dressing changes to occur without triggering a Therapy Inactive Alarm (applicable to both V.A.C.® and Veraflo™ Therapies).	The software also provides controls for alarms and a variety of optional features for the user, such as: • Seal Check Leak Detector • Dressing Soak Tool (Veraflo™ Therapy only) • Fill Assist Tool (Veraflo™ Therapy only) • Test Cycle Tool (Veraflo ™Therapy only) • Wound Imaging Tool for viewing uploaded wound images and calculating wound area/volume • History Tool for alarm, therapy and patient history logs • Utilities Tool to set system preferences such as language, unit measures, dates, etc. • Help Tool to provide on screen help. This tool provides additional information regarding alarms/alerts and how to resolve them, operation of therapies and cleaning instructions. • Information Tool to allow access to the current therapy settings and the therapy summary tabs.

Comparator	Subject Device	Predicate Device
Alarms		
• **System Notifications**		
	Same as predicate	Battery Exhausted
• **V.A.C. Therapy Alerts/Alarms**		
	Same as predicate	System Error Alarm (at Power ON)
		V.A.C.® Therapy Blockage Alarm (Therapy Interrupted)
		V.A.C.® Therapy Canister Full Alarm (Therapy Interrupted)
		V.A.C.® Therapy Canister Not Engaged Alarm
		V.A.C.® Therapy – Therapy Inactive Alarm
		V.A.C.® Therapy Leak Alarm
		V.A.C.® Therapy Leak Alarm – Therapy Interrupted
		V.A.C.® Therapy Low Pressure Alarm (Therapy Interrupted)
		V.A.C.® Therapy Battery Low Alert
		V.A.C.® Therapy Battery Critical Alarm
		V.A.C.® Therapy Internal Temperature Alert
		V.A.C.® Therapy System Error Alarm (Therapy Interrupted)
• **PREVENA Therapy Alerts**		
	Same as predicate	PREVENA™ Therapy Blockage Alert*
		PREVENA™ Therapy Blockage Alert (Therapy Interrupted)
		PREVENA™ Therapy Canister Full Alert* (Therapy Interrupted)
		PREVENA™ Therapy Canister Not Engaged Alert
		PREVENA™ Therapy - Therapy Inactive Alert
		PREVENA™ Therapy Leak Alert*
		PREVENA™ Therapy Battery Low Alert*
		PREVENA™ Therapy Battery Critical Alert*
		PREVENA™ Therapy Internal Temperature Alert
		PREVENA™ Therapy System Error Alert (Therapy Interrupted)

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V.A.C.® Ulta Negative Pressure Wound Therapy System

Comparator	Subject Device	Predicate Device
• **ABTHERA Therapy Alerts**		
.	Same as predicate	ABTHERA™ Therapy Blockage Alert*
		ABTHERA™ Therapy Blockage Alert (Therapy Interrupted)
		ABTHERA™ Therapy Canister Full Alert*
		ABTHERA™ Therapy Canister Not Engaged Alert
		ABTHERA™ Therapy - Therapy Inactive Alert
		ABTHERA™ Therapy Leak Alert*
		ABTHERA™ Therapy Battery Low Alert*
		ABTHERA™ Therapy Battery Critical Alert
		ABTHERA™ Therapy Internal Temperature Alert
		ABTHERA™ Therapy System Error Alert (Therapy Interrupted)
• **V.A.C. VERAFLO Therapy Alerts/Alarms**		
	Same as predicate, except for the addition of **Smart Instill Inactive Alert**	VERAFLO™ Therapy Blockage Alert
		VERAFLO™ Therapy Blockage Alarm(Therapy Interrupted
		VERAFLO™ Therapy Canister Full Alarm(Therapy Interrupted)
		VERAFLO™ Therapy Canister Not EngagedAlarm
		VERAFLO™ Therapy - Therapy InactiveAlarm
		VERAFLO™ Therapy Leak Alarm
		VERAFLO™ Therapy Leak Alarm (Therapy Interrupted)
		VERAFLO™ Therapy Low Pressure Alarm (Therapy Interrupted)
		VERAFLO™ Therapy V.A.C. VERALINKNot Engaged Alert
		VERAFLO™ Therapy Solution Bag / BottleEmpty Alert
		VERAFLO™ Therapy Fill Assist InactiveAlert
		VERAFLO™ Therapy Pressure DeviationAlarm (Therapy Interrupted)
		VERAFLO™ Therapy Instill Tube BlockageAlert (Therapy Interrupted)
		VERAFLO™ Therapy Battery Low Alert
		VERAFLO™ Therapy Battery Critical Alarm
		VERAFLO™ Therapy Internal TemperatureAlert
		VERAFLO™ Therapy System Error Alarm(Therapy Interrupted)

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510(k) SUMMARY
V.A.C.® Ulta Negative Pressure Wound Therapy System

Comparator	Subject Device	Predicate Device
• **Energy source**	Same as predicate	AC and battery
• **Battery type**	Same as predicate	Custom lithium battery
• **Use life**	Same as predicate	Indefinite, with routine servicing and repair
Canisters	Same as predicate	• 500 mL capacity canister with charcoal (odor control) and membrane filters (fluid barrier) • 1000 mL capacity canister with charcoal (odor control) and membrane filters (fluid barrier)
Instillation Cassette	Same as predicate	The instillation cassette is comprised of a solution container holder which connects to the V.A.C.® Ulta instillation pump via tubing on the back of the holder. The cassette has a spike that is used to connect to the solution container as well as tubing that delivers solution to the dressing.
Negative Pressure Tubing	Same as predicate	All therapies have tubing sets constructed from PVC.
Instillation Tubing	Same as predicate	PVC tubing; approximately 9 feet in length from dressing to canister.
Dressing System Configuration	Same as predicate	V.A.C.®, Veraflo™ and AbThera™ Dressings: All have multiple dressing components designed for use over open wounds. In typical orderof application: • Foam dressing (s) • Polyurethane drape • Pressure sensing pad and tubing • Instillation pad and tubing (Veraflo™Therapy only) Prevena™ Dressings have similar components, except that the foam dressing has a bonded interface fabric that contacts the incision site.

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510(k) SUMMARY

V.A.C.® Ulta Negative Pressure Wound Therapy System

Performance Data [21 CFR 807.92(b)]
Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]
• Software has been assessed in accordance with FDA Guidance, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document* issued on May 11, 2005**.** • A cybersecurity assessment of the V.A.C.® Ulta Negative Pressure Wound Therapy Unit, based on FDA Draft Guidance: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff,* October 2018**,** indicates that the risk of patient harm resulting from device exploitability is at a controlled level and is considered acceptable and that the V.A.C.® Ulta Negative Pressure Wound Therapy Unit is sufficiently trustworthy, reasonably resilient to uncontrolled cybersecurity threats that can lead to patient harm, reasonably suited to perform its intended functions and provides a reasonable level of availability, reliability, and correct operation. • Performance testing has documented that the Smart Instill™ Feature meets its design specification of delivering instillation fill volumes that will saturate the applied dressing within 12 hours of initiating instillation without underfilling or overfilling the dressed wound.
Summary of clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(2)]
No clinical tests were necessary. However, a human factors engineering assessment, per FDA Guidance, *Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff, issued February 2016* was conducted with 30 subject nurses and doctors. The results indicated that the new features could be safely and effectively used by all test subjects.
Conclusions drawn [21 CFR 807.92(b)(3)]
• There has been no change to the intended use of the V.A.C.® Ulta Negative Pressure Wound Therapy System. • There has been no change to the technology delivering negative pressure and instillation therapy. Performance specifications for provided therapies remain unchanged. • Human factors engineering assessment documents that the changes to the therapy unit software and its associated labeling to provide ease of use features are safe and effective for their intended use. The subject device is substantially equivalent to the predicate device with respect to indications for use and technological characteristics. There are no different questions regarding safety or effectiveness.