May 23, 2024

KCI USA, Inc.
Jacqulyn Rosinski
Regulatory Affairs Associate
6203 Farinon Dr.
San Antonio, Texas 78249

Re: K241134
Trade/Device Name: 3M™ ActiV.A.C.™ Canister - 300ml with Gel
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: April 24, 2024
Received: April 24, 2024

Dear Jacqulyn Rosinski:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mustafa A. Mazher -S

for Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241134

Device Name
3M™ ActiV.A.C.™ Canister - 300ml with Gel

Indications for Use *(Describe)*
The ACTIV.A.C.™ Negative Pressure Wound Therapy System is an integrated wound management system for use in acute, extended and home care settings.

When used on open wounds, it 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. 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, it is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudates via the application of negative pressure wound therapy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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3M Health Care Business Group
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Contact Person: Jacqulyn Rosinski
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Phone: 651-650-1545
Date Prepared: April 24, 2024

Name of Subject Device: 3M™ ActiV.A.C.™ Canister - 300ml with Gel
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
Predicate Device: ACTIV.A.C.™ Negative Pressure Wound Therapy System (K201571)

Device Description

The 3M™ ActiV.A.C.™ Canister – 300ml with Gel is a component of the ActiV.A.C.™ Negative Pressure Wound Therapy System, also referred to as the ActiV.A.C.™ Therapy System. The ActiV.A.C.™ Therapy System consists of:
• an ACTIV.A.C.™ Therapy Unit,
• a disposable canister which collects wound exudate (the subject of this submission),
• a wound interface dressing,
• a semi-occlusive wound drape, and
• a sensing pad and lumen.

The 3M™ ActiV.A.C.™ Canister - 300ml with Gel is a single use disposable component of the ActiV.A.C.™ Therapy System and is sold separately from the ActiV.A.C.™ Therapy Unit. It is provided in either a 5 pack or 10 pack configuration.

The Canister is attached to the side of the therapy unit and collects wound exudates. The distal end of the Canister tubing attaches to the dressing tube set using rigid connectors. The Canister has volume graduations and contains a gel pack for fluid solidification and a tubing pinch clamp.

The Canister is composed of MABS (Methylmethacrylate acrylonitrile butadiene styrene).

Most recently cleared under K201571.

Intended Use / Indications for Use

The ACTIV.A.C.™ Negative Pressure Wound Therapy System is an integrated wound management system for use in acute, extended and home care settings.

When used on open wounds, it 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. 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, it is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudates via the application of negative pressure wound therapy.

Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)]			
Characteristic	**Subject Device: 3M™ ActiV.A.C.™ Canister - 300ml with Gel**	**Predicate Device: ACTIV.A.C.™ Negative Pressure Wound Therapy System (K201571)**	**Comparison**
Description	The 3M™ ActiV.A.C.™ Canister - 300ml with Gel is single use and is sold separately from the ActiV.A.C.™ Therapy unit. The Canister is inserted inside the therapy unit. The Canister collects exudates, has volume graduations, and contains a gel pack for fluid solidification.	The 3M™ ActiV.A.C.™ Canister - 300ml with Gel is single use and is sold separately from the ActiV.A.C.™ Therapy unit. The Canister is inserted inside the therapy unit. The Canister collects exudates, has volume graduations, and contains a gel pack for fluid solidification. The canister is provided sterile fluid-path.	Different. The Canister will be provided entirely non-sterile. All other design features remain identical.
Indicated Wound Types	• Chronic • Acute • Traumatic • Subacute • Dehisced wounds • Partial-thickness burns • Ulcers (such as diabetic, pressure or venous insufficiency) • Flaps and grafts Surgically closed incisions (For V.A.C. Therapy only)	• Chronic • Acute • Traumatic • Subacute • Dehisced wounds • Partial-thickness burns • Ulcers (such as diabetic, pressure or venous insufficiency) • Flaps and grafts Surgically closed incisions (For	Identical

		V.A.C. Therapy only)	
Use environment/Care Setting of dressing kit	Dressing can be applied in the acute, extended and the homecare setting under the supervision of a healthcare professional.	Dressing can be applied in the acute, extended and the homecare setting under the supervision of a healthcare professional.	Identical
System Design	Disposable single use 300 mL canister designed for home use in conjunction with a sterile dressing system and a therapy unit *(dressing system and Therapy unit are provided separately from the canister)*	Disposable single use 300 mL canister designed for home use in conjunction with a sterile dressing system and a therapy unit *(dressing system and Therapy unit are provided separately from the canister)*	Identical

Performance Data

There was no performance data or biocompatibility performed to demonstrate equivalence.

Clinical and Pre-clinical testing were not necessary to demonstrate equivalence.

Conclusions

The subject device's intended use, indications for use, fundamental technology and principles of operation are unchanged compared to the predicate device as cleared under K201571.
The device modification was verified through the design control process and in all instances, risk analysis supported no new or increased risk to patient.

The subject device is as safe and effective as the predicate device, thus substantially equivalent.