July 1, 2021

Molnlycke Health Care US, LLC
Megan Bevill
Manager, Regulatory Affairs
5445 Triangle Parkway Suite 400
Peachtree Corners, Georgia 30092

Re: K203369
Trade/Device Name: Avance Solo Negative Pressure Wound Therapy (NPWT) System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: May 28, 2021
Received: June 1, 2021

Dear Megan Bevill:

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,

Lixin Liu, Ph.D.
Acting 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)*
K203369

Device Name
Avance Solo Negative Pressure Wound Therapy (NPWT) System

Indications for Use *(Describe)*
The Avance Solo NPWT System is indicated for patients who would benefit from wound management via the application of negative pressure wound therapy, particularly as the device may promote wound healing through the removal of exudate, infectious material.

Avance Solo NPWT System is indicated for removal of low to moderate amounts of exudates from chronic, acute, traumatic, subacute and dehisced wounds, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps, and grafts.

Avance Solo NPWT System is intended for use by healthcare professionals for therapy on patients in healthcare facilities and home care settings.

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

This 510(k) summary information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Date Prepared:	June 30, 2021
Applicant:	Mölnlycke Health Care US, LLC 5445 Triangle Parkway, Suite 400 Peachtree Corners, GA 30092 Registration Number: 3004763499 Owner/Operator Number: 8030877
Official Correspondent:	Megan Bevill Manager, Regulatory Affairs Tel: 770-547-9196 email: megan.bevill@molnlycke.com
Trade/Proprietary Names:	Avance Solo Negative Pressure Wound Therapy (NPWT) System
Regulation Name:	Negative Pressure Wound Therapy Powered Suction Pump
Device Class:	II
Regulation Number:	21 CFR 878.4780
Product Code:	OMP
Predicate Device Name(s):	PICO Single Use NPWT System (K163387) ActiVAC Therapy Unit (K120033)

Description of Device:
Avance Solo Negative Pressure Wound Therapy (NPWT) System consists of Avance Solo Pump, Avance Solo Canister 50 mL, Avance Solo Border Dressing and Avance Solo Foam which together form a system for wound management via the application of negative pressure wound therapy.

- Avance Solo Pump, a battery powered single patient use pump with a 14 day lifespan, single button operated with visual and audible alarms and notifications
- Avance Solo Canister 50 ml, a single use canister attached to the pump for collection of wound fluid and exudate
- Avance Solo Border Dressing, a single use breathable soft silicone absorbent dressing with acrylic fixation strips
- Avance Solo Foam, a single use polyurethane foam wound filler for cavity wounds

Avance Solo NPWT System maintains negative pressure nominally at -125 mmHg to the wound and enables exudate management by absorption and evaporation in Avance Solo Border Dressing. Excess exudate is collected in Avance Solo Canister 50 ml.

Avance Solo NPWT System is intended for adults.

Intended Use/Indication for Use:
The Avance Solo NPWT System is indicated for patients who would benefit from wound management via the application of negative pressure wound therapy, particularly as the device may promote wound healing through the removal of exudate, infectious material.

Avance Solo NPWT System is indicated for removal of low to moderate amounts of exudates from chronic, acute, traumatic, subacute and dehisced wounds, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps, and grafts.

Avance Solo NPWT System is intended for use by healthcare professionals for therapy on patients in healthcare facilities and home care settings.

Technological Characteristics:

Feature	Avance Solo NPWT System	PICO Single Use NPWT System	ActiVAC Therapy Unit	Substantial Equivalence Comments (comparison to primary predicate unless otherwise stated)
510(k) clearance	K203369 (subject device)	K163387	K120033	NA
Rationale for inclusion	Subject of submission	Primary predicate device	Secondary predicate device	NA
Manufacturer	Mölnlycke Health Care	Smith & Nephew Medical Inc.	KCI USA, Inc.	NA
Regulation	21 CFR 878.4780	21 CFR 878.4780	21 CFR 878.4780	Same
Class name	Negative Pressure Wound Therapy Powered Suction Pump	Negative Pressure Wound Therapy Powered Suction Pump	Negative Pressure Wound Therapy Powered Suction Pump	Same
Class	II	II	II	Same
Product Name	Avance Solo NPWT System	PICO Single Use NPWT System	ActiVAC Therapy Unit	NA
Product code	OMP	OMP	OMP	Same
Indication for use/Intended use	The Avance Solo NPWT System is indicated for patients who would benefit from wound management via the application of negative pressure wound therapy, particularly as the device may promote wound healing through the removal of exudate, infectious material. Avance Solo NPWT System is indicated for removal of low to moderate amounts of exudates from chronic, acute, traumatic, subacute and dehisced wounds, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps, and grafts. Avance Solo NPWT System is intended for use by healthcare professionals for therapy on patients in healthcare facilities and home care settings.	PICO is indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. Appropriate wound types include: - Chronic - Acute - Traumatic - Subacute and dehisced wounds - Partial-thickness burns - Ulcers (such as diabetic or pressure) - Flaps and grafts - Closed surgical incisions PICO Single Use Negative Pressure Wound Therapy System is suitable for use in both hospital and homecare setting.	The ActiVAC NPWT System is an integrated wound management system for use in acute, extended and home care settings. When used on open wound, 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 includes: 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 incision, they are also intended to manage the environment of surgical incisions that continue to	Minor differences in formatting with no impact on substantial equivalence; primary predicate device does not explicitly include venous ulcers in indicated wound types, but secondary predicate does

			drain following sutured or stapled closure by maintaining a closed environment and removing exudates via the application of negative pressure wound therapy.	
Use environment	Healthcare facilities and home care setting	Hospital and homecare setting	Hospital and homecare setting	Same
System components	Pump Canister Border dressing with fixation strips Foam	Pump Border dressing with fixation strips Foam	Pump Canister Transfer port Cover film Foam	Avance Solo NPWT System utilizes both the exudate absorption/evaporation properties of the border dressing as well as a canister for collection of excess exudate. PICO Single Use NPWT System handles exudate only through absorption/evaporation in the border dressing (i.e., it does not utilize a canister). In both systems, most of the wound fluids are handled through evaporation through the dressing; the Avance Solo Canister serves as a backup for excess exudate. Despite this difference, both systems are capable of delivering effective negative pressure wound therapy and removing excess wound exudate and are therefore substantially equivalent.
Performance specification	-125 mmHg (nominal)	-80 mmHg (nominal)	-125 mmHg (nominal) (default setting)	Preclinical and clinical literature suggests that delivery of negative pressure within the range of -50mmHg to -150

				mmHg induces safe and effective NPWT. Because both the Avance Solo NPWT System and PICO Single Use NPWT System are specified to deliver negative pressure within the clinically acceptable range, the performance specification difference does not impact substantial equivalence.
Pump useful life	14 days	7 days	NA (multiple patient use)	Differences in useful life do not impact substantial equivalence; the total time of treatment is not determined by the lifetime of the pumps, as continued therapy with either system can be provided by connecting a new pump.
Pump power source	Two AA Lithium batteries	Two AA Lithium batteries	Battery and AC powered	Same as primary predicate
Sterility	System components are supplied sterile; sterilization is achieved by EtO	System components are supplied sterile; sterilization is achieved by EtO	Pump is not supplied sterile Canister has a sterile fluid path; sterilization is achieved by radiation Transfer port, cover film, and foam are supplied sterile; sterilization is achieved by radiation	Same as primary predicate

Non-Clinical Testing:
(Biocompatibility) The subject devices have been evaluated in accordance with ISO 10993-1 and have been shown to meet the criteria for the relevant endpoints, based on the characterization of contact with respect to nature and duration. The results meet the relevant ISO 10993-XX criteria for their intended use. The endpoints included cytotoxicity, sensitization, irritation, acute systemic toxicity, material-mediated pyrogenicity, subacute/subchronic toxicity, implantation, and genotoxicity.

(Bench testing) Bench testing has been performed to demonstrate that the Avance Solo NPWT System is capable of effectively transporting fluid away from the wound and that pressure is delivered in accordance with the pump settings. Test setups addressed both low (0.6 g/cm^2/24 hours) and moderately (1.1 g/cm^2/24 hours) exuding wounds, with and without wound filler. In addition, alarm functionality, device lifetime, and pressure safety mechanism testing was conducted. The subject Avance Solo NPWT System performed as intended in the test setups, and all predefined acceptance criteria were met.

(Software validation) Software validation has been conducted in accordance with IEC 62304:2006 + A1:2015.

(Electromagnetic compatibility and electrical safety testing)
The Avance Solo NPWT System has been shown to comply with the relevant medical electrical equipment standards:

- AAMI ES 60601-1: 2005 +A2 +A1, Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014, Medical electrical equipment: General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests
- IEC 60601-1-6: 2010 + A1:2013, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-8: 2006 + A1:2012, Medical electrical equipment -- Part 1-8: General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-11: 2015, Medical electrical equipment: General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

(Human factors/usability) Summative usability testing has been performed with the two identified user groups (healthcare professionals and patients/lay persons).

Clinical Data:
No clinical data was provided to support substantial equivalence.

Conclusion:
Substantial equivalence has been demonstrated through a comparison of intended use, design, and technological characteristics as well as performance and electrical safety testing. The Avance Solo NPWT System is as safe and effective, and performs as well as the predicate devices.