September 21, 2022

Applied Tissue Technologies LLC
% Ms. Michele Lucey
President
Lakeshore Medical Device Consulting LLC
128 Blye HIll Landing
Newbury, New Hampshire 03255

Re: K212359
Trade/Device Name: PWD Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: August 19, 2022
Received: August 23, 2022

Dear Ms. Lucey:

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

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General 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)*
K212359

Device Name
PWD™ Platform Wound Dressing Negative Pressure System

Indications for Use *(Describe)*
The Applied Tissue Technologies PWD™ Platform Wound Dressing Negative Pressure System comprised of the; PWD™ Dressing, PWD™ Negative Pressure Wound Therapy Pump, and the PWD™ Wound Exudate Canister is indicated in patients who would benefit from a suction device (Negative Pressure Wound Therapy) as it creates an environment that may promote wound healing by removing excess wound exudate. The Applied Tissue Technologies Platform Wound Dressing is appropriate for use on the following wounds: exudating, chronic, acute, traumatic, sub-acute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, pressure and venous insufficiencies), flaps, grafts and closed surgical incisions.

PWD Negative Pressure Wound Therapy System is suitable for use both in a hospital and homecare setting.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K212359
Traditional
510(k) SUMMARY

Submitter Information

Submitters' Name:	Applied Tissue Technologies LLC
Address:	99 Derby Street, Suite 200 Hingham, MA 02043
Telephone:	781-366-3848
Contact Person:	Ms. Michele Lucey President, Lakeshore Medical Device Consulting LLC
Address	128 Blye Hill Landing, Newbury, NH 03255
Telephone	603-748-1374
Email	lucey_m@msn.com

Date Prepared:	September 20, 2022
Device Trade Name:	PWD™ Platform Wound Dressing Negative Pressure System
Classification:	Class II
Product Code(s):	OMP
Regulation Number(s):	21 CFR 878-4780 Powered Suction Pump
Predicate Device (Primary):	PICO 7 Single Use Negative Pressure Wound Therapy System K172005
Predicate Device (Secondary)	PWD™ Platform Wound Device K191460

Indications for Use:

The Applied Tissue Technologies PWD™ Platform Wound Dressing Negative Pressure System comprised of the; PWD™ Dressing, PWD™ Negative Pressure Wound Therapy Pump, and the PWD™ Wound Exudate Canister is indicated in patients who would benefit from a suction device (Negative Pressure Wound Therapy) as it creates an environment that may promote wound healing by removing excess wound exudate. The Applied Tissue Technologies Platform Wound Dressing is appropriate for use on the following wounds: exudating, chronic, acute,

traumatic, sub-acute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, pressure and venous insufficiencies), flaps, grafts and closed surgical incisions.

PWD Negative Pressure Wound Therapy System is suitable for use both in a hospital and homecare setting.

Device Description/Technological Characteristics:

The Applied Tissue Technologies PWD™ Platform Wound Dressing Negative Pressure System consists of the PWD™ Dressing, PWD™ Negative Pressure Wound Therapy Pump and the Wound exudate canister. The system provides a negative pressure wound dressing therapy in a moist environment to facilitate the wound healing process. The dressing has an access port through which fluids can be drawn from the wound site. The same port can also be utilized to administer negative pressure wound therapy using the negative pressure pump if required. The negative pressure pump is used with a collection cannister to collect the exudate. The PWD Platform Wound Dressing is supplied in five different shapes and sizes, all having the same intended use. The five sizes are identified as follows.

PWD™ Platform Wound Device Dressing Sizes	
Description	Catalog/REF #
1" Round	AT1070-01
2" Round	AT1071-01
3" Round	AT1072-01
1" x 3" Oblong	AT1073-01
3" x 5" Oblong	AT1074-01

Performance Data:

Bench testing of the PWD™ Platform Wound Dressing Negative Pressure System was performed to evaluate device vapor transmission characteristics, ability to maintain negative pressure, and the ability to remove exudate. Biocompatibility testing was conducted on the dressing component according to the ISO 10993 standard series. The Pump and the Cannister are not tissue contacting. Test results of all nonclinical testing were acceptable and demonstrate that the device is safe and effective for its intended use. A summary of the Non-clinical Bench tests is provided in the following Table:

Performance Test Summary				
Test Name	Description	Reference Standards	Acceptance Criteria	Results
Water Vapor Transmission Rate	Measures the passage of water vapor through the membrane/adhesive barrier	ASTM 1249	Must be at least equivalent to commercially available NPWT dressing	Pass
Exudate	Simulated Use	N/A	System must	Pass

Performance Test Summary				
Test Name	Description	Reference Standards	Acceptance Criteria	Results
Throughput Properties Under Negative Pressure	testing using various exudate types to confirm acceptable fluid flow when connected to the Pump and Canister system		demonstrate the ability to remove exudates of various types from the wound bed	
Maintenance of Negative Pressure	Simulated use testing from under moist conditions to demonstrate maintenance of negative pressure	NA	The PWD must maintain negative pressure at the wound bed for the test duration	Pass
Usability	Usability testing for both health care and home use environments	NA	Users must demonstrate the ability to correctly use the device	Pass
Electrical Safety	Complies with applicable safety standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11	Requirements for electrical safety per the applicable safety standards is met	Pass
Electro-magnetic Compatibility	Complies with applicable safety standards	Complies with IEC 60601-2-3	Requirements for electromagnetic compatibility per the applicable safety standards is met	Pass

Substantial Equivalence:

The Indications for Use statement for the PWD™ Platform Wound Dressing Negative Pressure System is the same as the PICO 7 Single Use Negative Pressure Wound Therapy System.

The following table provides the evidence to further support the claim for substantial equivalence:

Substantial Equivalence Comparison Chart				
Feature / Specification	**PWD™ Platform Wound Dressing Negative Pressure System**	**PICO 7 Single Use Negative Pressure Wound Therapy System**	**PWD™ Platform Wound Dressing**	**Comparison**
Regulatory Clearance/ Approval Reference	N/A	Primary K172005	Secondary K191460	N/A
Product Code	OMP	OMP	OMP	Same
Regulation Number	21 CFR 878.4780	21 CFR 878.4780	21 CFR 878.4780	Same
Regulation Name	Powered Suction Pump	Powered Suction Pump	Powered Suction Pump	Same
Anatomical location	Body surface where wound is present	Body surface where wound is present	Body surface where wound is present	Same
Where used (environment)	The Negative Pressure Wound Therapy System is suitable for use in both hospital and homecare settings.	The Negative Pressure Wound Therapy System is suitable for use in both hospital and homecare settings.	The Negative Pressure Wound Therapy System is suitable for use in both hospital and homecare settings.	Same
Indications for Use	The Applied Tissue Technologies PWD™ Platform Wound Dressing Negative Pressure System comprised of the; PWD™ Dressing, PWD™ Negative Pressure Wound Therapy Pump, and the PWD™ Wound Exudate Canister is indicated in patients who would benefit from a suction device (Negative Pressure Wound Therapy) as it creates an environment that may promote wound healing by removing excess wound	PICO 7 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	The Applied Tissue Technologies PWDTM Platform Wound Dressing is intended to be used in conjunction with the Invia Motion Negative Pressure Wound Therapy (NPWT) system and is indicated in patients who would benefit from a suction device (NPWT) as it creates an environment that may promote wound healing by	

Substantial Equivalence Comparison Chart				
Feature / Specification	**PWD™ Platform Wound Dressing Negative Pressure System**	**PICO 7 Single Use Negative Pressure Wound Therapy System**	**PWD™ Platform Wound Dressing**	**Comparison**
	exudate. The Applied Tissue Technologies Platform Wound Dressing is appropriate for use on the following wounds: exudating, chronic, acute, traumatic, sub-acute and dehisced wounds, partial thickness burns, ulcers (such as diabetic, pressure and venous insufficiencies), flaps, grafts and closed surgical incisions. PWD Negative Pressure Wound Therapy System are suitable for use both in a hospital and homecare setting.	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 a hospital and homecare setting.	removing excess wound exudate. The Applied Tissue Technologies Platform Wound Dressing is appropriate for use on the following wounds: exudating, chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as: diabetic, pressure and venous insufficiencies), flaps and grafts	
Maximum Duration of a single dressing	7 Days	7 Days	3 Days	Same as the primary predicate
Negative Pressure to the wound surface requirements in mmHg	Fixed setting at -80 mmHg (nominal) to the wound surface	Fixed setting at -80 mmHg to the wound surface	-80 mmHg	Same
Multiple Dressing Shapes for Wound Sizes (area = L x W)	1-3” Round 1 x 3” Oblong 3 x 5” Oblong	10 x 20 cm to 25 x 25 cm	1-3” Round 1 x 3” Oblong 3 x 5” Oblong	PWD is smaller than the predicate for overall dimensions. The dressing is sized for the wound

Substantial Equivalence Comparison Chart				
Feature / Specification	**PWD™ Platform Wound Dressing Negative Pressure System**	**PICO 7 Single Use Negative Pressure Wound Therapy System**	**PWD™ Platform Wound Dressing**	**Comparison**
				size. Same as the Secondary Predicate
Dressing Configuration	Clear polyurethane embossed occlusive drape with negative pressure/instillation tubing	Clear polyurethane occlusive drape dressing with foam or gauze filler, negative pressure/instillation tubing – filler is cut to size	Clear polyurethane embossed occlusive drape with negative pressure/instillation tubing	Same as the secondary predicate
Access Port	For attachment to the negative pressure pump. For removal of fluids.	For attachment to the negative pressure pump. For removal of fluids	For attachment to the negative pressure pump. For removal of fluids.	Same
Collection Pack	The dressing tubing is connected to the canister/tubing set during negative pressure wound therapy for collection of fluids. The fluids are removed from the wound site and secured within the cannister without requiring additional dressing changes	No Cannister, relies on dressing changes for removal of exudate, frequency dependent on the level of exudate	The dressing tubing is connected to the canister/tubing set during negative pressure wound therapy for collection of fluids. The fluids are removed from the wound site and secured within the cannister without requiring additional dressing changes	Same as the secondary predicate.
Pump	PWD™ Negative Pressure Wound Therapy Pump	PICO 7	NA	Same
Pump Type	Custom designed pump controlled by a microprocessor	Custom designed pump controlled by a microprocessor	NA	Same

Substantial Equivalence Comparison Chart				
Feature / Specification	**PWD™ Platform Wound Dressing Negative Pressure System**	**PICO 7 Single Use Negative Pressure Wound Therapy System**	**PWD™ Platform Wound Dressing**	**Comparison**
How Supplied	PWD Dressing is supplied Sterile Single Use Only. The pump and cannister are supplied non-sterile single use only	The system is supplied sterile, single use only	PWD Dressing is supplied Sterile Single Use Only.	The PWD pump and cannister are supplied nonsterile – similar to other systems with the same intended use. This difference does not raise new questions of safety.
Tissue Contact Materials	Polymers and Adhesive	Polymers and Adhesive	Polymers and Adhesive	Same as the secondary predicate
Additives - antimicrobial, animal origin	No	No	No	Same
Sterilization	Eto at an SAL 10^{-6}	Eto	Eto at an SAL 10^{-6}	Same.
Electrical Safety Testing	Complies with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11	Complies with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11	NA	Same
Electromagnetic Compatibility	Complies with IEC 60601-2-3	Complies with IEC 60601-2-3	NA	Same
MR Safety	Pump is MR Unsafe	Pump is MR Unsafe	NA	Same

Conclusion:

When considering design, feature, materials, and performance characteristics the PWD™ PNegPlatform Wound Dressing Negative Pressure System is substantially equivalent to the predicate device, the PICO 7 Single Use Negative Pressure Wound Therapy System K172005