January 11, 2019

Applied Tissue Technologies LLC
% Michele Lucey
Regulatory Affairs Manager
Lakeshore Medical Device Consulting LLC
128 Blye Hill Landing
Newbury, New Hampshire 03255

Re: K182409
Trade/Device Name: Applied Tissue Technologies PWD™ Platform Wound Dressing
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: December 7, 2018
Received: December 12, 2018

Dear Michele 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kimberly Ferlin -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182409

Device Name
Applied Tissue Technologies PWD™ Platform Wound Dressing

Indications for Use *(Describe)*

The Applied Tissue Technologies PWD™ 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 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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:	Michele Lucey
Telephone:	603-748-1374

Date Prepared:	January 11, 2019
Device Trade Name:	Applied Tissue Technologies PWD™ Platform Wound Dressing
Classification:	Class II
Product Code(s):	OMP
Regulation Number(s):	21 CFR 878-4780 Powered Suction Pump
Predicate Device:	Medela Ag Invia Foam Dressing Kit, K170088

Intended Use:

The Applied Tissue Technologies PWD™ 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 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.

Device Description/Technological Characteristics:

The Applied Tissue Technologies PWD™ Platform Wound Dressing is a single use device. Its transparency permits the healthcare practitioner to observe the progress of the wound healing without removing the wound dressing. There is an access port to administer negative pressure wound therapy. The PWD is intended to be used for a maximum of 3 days. Therapy duration may be less than indicated if clinical practice or other factors require more frequent dressing changes.

The PWD will be marketed in four different shapes and sizes, all having the same intended use. The four sizes are identified as follows.

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

Performance Data:

Bench testing of the PWD™ Platform Wound Dressing was performed to evaluate device vapor transmission characteristics, ability to maintain negative pressure, and the ability to remove exudate. Biocompatibility testing was conducted according to the ISO 10993 standard series. Test results of all nonclinical testing were acceptable and demonstrate that the subject device is substantially equivalent to the predicate device

Substantial Equivalence:

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

Substantial Equivalence Comparison Chart			
Feature / Specification	**PWD™ Platform Wound Dressing**	**Invia Foam Dressing Kit (Medela Ag,)**	**Comparison**
Regulatory Clearance/ Approval Reference	K182409	K170088	N/A
Product Code	OMP	OMP	Same
Regulation Number	21 CFR 878.4780	21 CFR 878.4780	Same
Regulation Name	Powered Suction Pump (accessory)	Powered Suction Pump (accessory)	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.	Same
Maximum Duration of a single dressing	72 Hours	72 Hours	Same
Negative Pressure to the wound surface requirements in mmHg	80 mmHg (nominal) +/- 20mmHG to the wound surface	125 mmHg to the wound surface	This constitutes a nominal recommended setting, pump settings range from -40 to -175. This difference in recommended nominal setting

Substantial Equivalence Comparison Chart			
Feature / Specification	**PWD™ Platform Wound Dressing**	**Invia Foam Dressing Kit (Medela Ag,)**	**Comparison**
			does not range new questions of safety.
Multiple Shapes for Wound Sizes up to 400cc (Surface Area x depth)	400cc	240 - 2700c	PWD is within the range of the predicate device.
Dressing Configuration	Clear polyurethane embossed occlusive drape with tubing	Clear polyurethane occlusive drape dressing with foam insert negative pressure/instillation tubing – dressing is cut to size	Similar materials and configuration, the PWD uses a embossed layer to allow for fluid transfer, the predicate uses a foam. This difference does not raise new questions of safety.
Access Port	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 PWD tubing is connected to the Medela Invia Motion 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.	The Invia Foam Dressing Tubing is connected to the Medela Invia Motion 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	Same.
Pump	To be used with the Medela Invia® Motion™ Negative Pressure Wound Therapy System	To be used with the Medela Invia® Motion™ Negative Pressure Wound Therapy System	Same
How Supplied	PWD is Sterile Single Use Only	Dressing is Sterile Single Use Only	Same

Substantial Equivalence Comparison Chart			
Feature / Specification	**PWD™ Platform Wound Dressing**	**Invia Foam Dressing Kit (Medela Ag,)**	**Comparison**
Tissue Contact Materials	Polymers and Adhesive	Polymers Adhesive and dressing	Similar, differences do not introduce new questions of safety
Additives - antimicrobial, animal origin	No	No	Same
Sterilization	Eto	Eto	Same

The PWD™ Platform Wound Dressing is substantially equivalent to the predicate device, the Invia Foam Dressing Kit (K170088) and does not raise different questions of safety and effectiveness.