July 2, 2019

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

Re: K191460
Trade/Device Name: PWD™ Platform Wound Dressing 3" x 5" Oblong
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: May 29, 2019
Received: June 3, 2019

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/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,

Cynthia Chang, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191460

Device Name
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.

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Special 510(k) Summary
Per 21 CFR 807.92

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 603-748-1374
Date Prepared	June 27, 2019
Device Trade Name	PWD™ Platform Wound Dressing
Classification	Class II
Product Code	OMP
Regulation Number	21 CFR 878.4780, Powered Suction Pump
Predicate Device	PWD™ Platform Wound Dressing,

K182409 **Intended Use:**

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 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:

The Applied Tissue Technologies PWDTM 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 five different shapes and sizes, all having the same intended use. The five sizes are identified as follows.

PWDTM Platform Wound Dressing	
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

Comparison to Predicate Device(s):

The subject device is the same design as the predicate device. The only difference is the addition of a larger footprint, 3”x5” product variant.

Nonclinical Performance Data:

In consideration of design control activities including risk analysis, non-clinical performance testing was conducted to demonstrate that the additional dressing size has the same performance characteristics as the predicate device.

SE Determination:

Based on the supporting documentation within this premarket notification, the subject device demonstrates substantial equivalence to the listed predicate device.