DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 19, 2016

Molnlycke Health Care, Us LLC
Megan Bevill
Manager, Regulatory Affairs
5550 Peachtree Parkway
Suite 500
Norcross, Georgia 30092

Re: K161797
Trade/Device Name: Avance Tubing, Avance Y-connector, Avance Viewpad
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 19, 2016
Received: September 21, 2016

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161797

Device Name
Avance Tubing, Avance Y-Connector, and Avance View Pad

Indications for Use *(Describe)*
The Avance NPWT system, with associated products, are indicated for patients who would benefit from a suction device (negative pressure wound therapy), as it may promote wound healing via the removal of fluids, including irrigation and body fluids, wound exudate and infectious materials. Examples of appropriate wound types include: chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness bums, 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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510(k) SUMMARY

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

Date Prepared:	October 14, 2016
Applicant:	Mölnlycke Health Care US, LLC 5550 Peachtree Parkway, Suite 500 Norcross, GA 30092 Registration number: 3004763499 Owner/Operator Number: 8030877
Official Correspondent:	Megan Bevill Manager, Regulatory Affairs Tel: 470-375-0049 Fax: 678-245-7746 email: megan.bevill@molnlycke.com
Trade/Proprietary Names:	Avance® Tubing, Avance® Y-Connector, and Avance® ViewPad™
Common Name:	NPWT System Components
Regulation Name:	Powered Suction Pump
Device Class:	Class II
Regulation Number:	21 CFR 878.4780
Product Code:	OMP
Predicate Device Information:	Venturi Negative Pressure Wound Therapy System (K080897) Avance® Y-Connector S (K151872) Avance® Foam Dressing Kits (K141847)

Reason for 510(k) Submission:
This premarket notification has been prepared to obtain clearance for the following line additions to Mölnlycke's Avance Negative Pressure Wound Therapy (NPWT) System: Avance Tubing, Avance Y-Connector, and Avance ViewPad.

Description of Devices:
The subject Avance Tubing serves as the connecting link between the Avance NPWT pump and the Avance dressings, thereby delivering negative pressure wound therapy from the pump to the wound bed and facilitating the transport of fluid and exudate from the wound site to the canister. It consists of a 1.5 m length of tubing with connectors on each end to facilitate connection to other components of the Avance NPWT System.

The subject Avance Y-Connector allows connection of multiple Avance dressings to one Avance pump in order to accommodate large or multiple wounds. It consists of y-tubing with connectors on all ends to facilitate connection to other components of the Avance NPWT System. A maximum of one Avance Y-Connector may be used to connect up to two large dressing kits to a single pump.

The subject Avance ViewPad used in conjunction with the Avance dressings; it is placed on top of the wound cover (film), connected to the wound filler via a hole cut in the wound cover, and then connected to

the Avance NPWT pump tubing for delivery of NPWT and transport of fluids and exudate away from the wound. The subject Avance ViewPad is similar to the existing ViewPad component of the Avance Foam Dressing Kits (K141847), with the exception of a green colorant that has been added to the connector and a modification to the design of the slide clamp.

Indication for Use:
The Avance NPWT system, with associated products, are indicated for patients who would benefit from a suction device (negative pressure wound therapy), as it may promote wound healing via the removal of fluids, including irrigation and body fluids, wound exudate and infectious materials. Examples of appropriate wound types include: chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.

Technological Characteristics:

Subject Avance Tubing		
Feature	**Avance Tubing**	**Extension Tubing, as cleared within the Venturi Negative Pressure Wound Therapy System**
510(k) clearance	Subject device	K080897
Manufacturer	Mölnlycke Health Care	Talley Medical
Common name	Canister tubing for NPWT system	Canister tubing for NPWT system
Regulation	21 CFR 878.4780	21 CFR 878.4780
Class name	Powered Suction Pump	Powered Suction Pump
Class	II	II
Product code	OMP	OMP
Functionality within NPWT system	The Avance tubing serves as the connecting link between the Avance NPWT pump and the Avance dressings, thereby delivering negative pressure from the pump to the wound bed and facilitating the transport of fluid and exudate from the wound site to the canister.	The Extension Tubing connects an NPWT dressing to an NPWT pump, thereby delivering negative pressure from the pump to the wound bed and facilitating the transport of fluid and exudate from the wound site to the canister
Indication for use	The Avance NPWT system, with associated products, are indicated for patients who would benefit from a suction device (negative pressure wound therapy), as it may promote wound healing via the removal of fluids, including irrigation and body fluids, wound exudate and infectious materials. Examples of appropriate wound types include: chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.	The Talley Venturi system is intended for use for patients with acute or chronic wounds that may be benefited by the application of negative pressure therapy and the potential wound healing effects of removal of fluids including wound exudates, irrigation fluids, body fluids, and infectious materials.
Design Features	The Avance Tubing is a single lumen tubing with connectors on each end to facilitate the assembly of the tubing to a dual lumen transfer pad on one end and to the pump's canister on the other end.	The Extension Tubing is a single lumen tubing with connectors on each end to facilitate the assembly of the tubing to a single lumen transfer pad on one end and to the pump's canister on the other end.
Product Offering	Unit item Kitted with Avance canisters	Unit item Kitted with Venturi canisters
Single Use	Y	Y
Sterility	EtO	NS
Subject Avance Y-Connector		
Feature	**Avance Y-Connector**	**Avance Y-Connector S**
510(k) clearance	Subject device	K151872
Manufacturer	Mölnlycke Health Care	Mölnlycke Health Care
Common name	Y-connector for NPWT system	Y-connector for NPWT system
Regulation	21 CFR 878.4780	21 CFR 878.4780
Class name	Powered Suction Pump	Powered Suction Pump
Class	II	II

Product code	OMP	OMP
Functionality within NPWT system	The Avance Y-Connector allows connection of multiple Avance dressings to one pump in order to accommodate large or multiple wounds.	The Avance Y-Connector S connects and allows therapy of multiple wounds simultaneously by using one pump.
Indication for use	The Avance NPWT system, with associated products, are indicated for patients who would benefit from a suction device (negative pressure wound therapy), as it may promote wound healing via the removal of fluids, including irrigation and body fluids, wound exudate and infectious materials. Examples of appropriate wound types include: chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.	The Avance NPWT system, with associated products, are indicated for patients who would benefit from a suction device (negative pressure wound therapy), as it may promote wound healing via the removal of fluids, including irrigation and body fluids, wound exudate and infectious materials. Examples of appropriate wound types include: chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.
Design Features	Dual lumen y-tube with quick connectors on each end to facilitate assembly to canister tubing and dual lumen transfer pads; allows therapy of multiple wounds simultaneously using one pump.	Single lumen tubing with y-connector; ends utilize taper fit connectors to facilitate assembly to canister tubing and single lumen transfer pads; allows therapy of multiple wounds simultaneously using one pump.
Single Use	Y	Y
Sterility	EtO	NS
Subject Avance ViewPad		
Feature	**Avance ViewPad**	**Avance ViewPad, as cleared within the Avance Foam Dressing Kits**
510(k) clearance	Subject device	K141847
Manufacturer	Mölnlycke Health Care	Mölnlycke Health Care
Common name	Dressing kit component for NPWT system	Dressing kit component for NPWT system
Regulation	21 CFR 878.4780	21 CFR 878.4780
Class name	Powered Suction Pump	Powered Suction Pump
Class	II	II
Product code	OMP	OMP
Functionality within NPWT system	Placed on top of the wound cover (film), connected to the wound filler via a hole cut in the wound cover, and then connected to the pump tubing for delivery of NPWT and transport of fluids/exudate away from the wound.	Placed on top of the wound cover (film), connected to the wound filler via a hole cut in the wound cover, and then connected to the pump tubing for delivery of NPWT and transport of fluids/exudate away from the wound.
Indication for use	The Avance NPWT system, with associated products, are indicated for patients who would benefit from a suction device (negative pressure wound therapy), as it may promote wound healing via the removal of fluids, including irrigation and body fluids, wound exudate and infectious materials. Examples of appropriate wound types include: chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.	The Avance NPWT system, with associated products, are indicated for patients who would benefit from a suction device (negative pressure wound therapy), as it may promote wound healing via the removal of fluids, including irrigation and body fluids, wound exudate and infectious materials. Examples of appropriate wound types include: chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.
Design Features	Same design feature as Avance ViewPad (K141847) With modifications to the quick connector and slide clamp.	The Avance ViewPad consists of a body with dual lumen tubing and a quick connector to facilitate connection to the canister tubing. Incorporates a slide clamp to block tubing during dressing changes.
Product Offering	Unit item	Unit item

	Kitted in Avance Foam Dressing Kits	Kitted in Avance Foam Dressing Kits
Single Use	Y	Y
Sterility	EtO	EtO

All technological differences between the subject and predicate devices have been accounted for within the submission through detailed device comparisons, nonclinical testing, and other means. Technological differences have been shown to raise no new issues of safety or effectiveness.

Non-Clinical Testing:
The subject devices have been evaluated in accordance with ISO 10993 and have been shown to be non-cytotoxic, non-sensitizing, and non-irritating. The results meet the ISO 10993 criteria for their intended use.

Bench testing has been performed to demonstrate that the line additions to the Avance NPWT System do not negatively affect the ability of the NPWT system to transport fluid away from the wound, that pressure is delivered in accordance with the pump settings, and that the alarm functionality of the NPWT pump is maintained. The subject Avance Tubing, Avance Y-Connector, and Avance ViewPad performed as intended in the test setups, and all predefined acceptance criteria were met.

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

Conclusion:
The subject devices are substantially equivalent to the predicate and reference devices with respect to design, technological characteristics, intended use, and conformance to standard requirements.