



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 2, 2015

Molnlycke Health Care, US LLC
Ms. Angela Bunn
Director, Regulatory Affairs for the Americas
5550 Peachtree Parkway, Suite 500
Norcross, Georgia 30092

Re: K151872
Trade/Device Name: Avance[®] Connector S
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 18, 2015
Received: September 21, 2015

Dear Ms. Bunn:

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" (21CFR 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 yours,

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

Indications for Use

510(k) Number (if known)
K151872

Device Name
Avance Y-Connector S

Indications for Use (Describe)

Avance Y-connector S is intended for use in the Avance Negative Pressure Wound Therapy (NPWT) system, to connect and allow therapy of multiple wounds simultaneously by using one pump. 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.

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.

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510(k) SUMMARY OF SAFETY AND EFFICACY

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

Date Prepared: October 26, 2015

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Trade/Proprietary Name: Avance[®] Y Connector S

Common Name: NPWT Dressing Kits

Classification Name: Powered Suction Pump

Device Class: Class II

Regulation Number: 21 CFR 878.4780

Product Code: OMP

Predicate Device Name(s): K141847 - Avance[®] Foam Dressing Kit
K142626 - Invia Liberty System with Y-Connector

Description of Device:

The subject of this submission is the Avance[®] Y-Connector S, which is an accessory to the Avance[®] Negative Pressure Wound Therapy (NPWT) System. It allows connection of multiple dressing kits to one pump in order to accommodate large or multiple wounds. We have classified this device as Class II as it is directly indicated for use with an NPWT Pump which falls under that classification, and the Avance[®] Y-Connector S forms an integral part of the overall system when multiple wound sites require therapy.

The Avance[®] Y-connector S is a polyurethane/polypropylene based single lumen Y-connector. It is designed to function with existing Avance[®] NPWT pumps and dressing kits by connecting the Avance[®] Canister Tubing to two single lumen transfer pads which

are applied to the Avance[®] Foam dressings. Use of the Avance[®] Y-Connector S allows therapy and transportation of exudate from more than one wound simultaneously using one pump. A maximum of two Avance[®] Y-Connector S devices may be used to connect three wounds to one pump.

Intended Use/Indication for Use:

The Avance[®] Y-connector S is intended for use in the Avance[®] Negative Pressure Wound Therapy (NPWT) system, to connect and allow therapy of multiple wounds simultaneously using one pump. 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.

Predicate Device Comparison Table

Predicate Device Comparison			
Feature	Avance® Y-Connector S	Invia Liberty NPWT System with Y connector	Avance® Foam Dressing Kits with ViewPad
510(k) Clearance	Subject of Submission	K142626	K141847
Manufacturer	Mölnlycke Health Care	Medela	Mölnlycke Health Care
Common Name	NPWT Dressing Kits	NPWT Dressing Kits	NPWT Dressing Kits
Classification #	21 CFR 878.4780	21 CFR 878.4780	21 CFR 878.4780
Class Name	Powered Suction Pump	Powered Suction Pump	Powered Suction Pump
Class	II	II	II
Product Code	OMP	OMP	OMP
Indication For Use/Intended Use	<p>Avance® Y-connector S is intended for use in the Avance® Negative Pressure Wound Therapy (NPWT) system, to connect and allow therapy of multiple wounds simultaneously by using one pump.</p> <p>Avance® Y-connector S does not change the intended use of indications for use of the Avance® NPWT System, as stated in K141847.</p>	<p>The Invia Liberty® 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 exudates 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.</p>	<p>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 exudates 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.</p>
Product Feature			
Y Connector	Y connector used to connect more than one dressing kit to a pump	Y connector used to connect more than one dressing kit to a pump	N/A
Tubing	Same tubing as ViewPad; used to connect to the tubing of the Avance® Canister	N/A	ViewPad tubing used to connect to the tubing of the Avance Canister
Single Use	Yes	Yes	Yes
Non-sterile	Yes	Not known	N/A (no Y Connector component)
Biocompatibility	Components meet applicable requirements of ISO 10993-5 and ISO 10993-10	Components meet applicable requirements of ISO 10993-5 and ISO 10993-10	Components meet applicable requirements of ISO 10993

Summary of Performance Testing

The Avance® Y-Connector S has been evaluated for biocompatibility and for performance within the Avance® NPWT System. The results are as follows.

Test Data Summary: Avance® Y-Connector S		
Test	Standard/Test/FDA Guidance	Results Summary
Biocompatibility :		
Cytotoxicity	ISO 10993-5	Under the conditions of the study, the components are not cytotoxic.
Primary Skin Irritation	ISO 10993-10	Under the conditions of the study, the components are not irritants.
ISO Closed Patch Sensitization	ISO 10993-10	Under the conditions of the study, the components are not sensitizers.
Performance :		
NPWT Functionality	Internal Mölnlycke test method for fluid transport in NPWT	The fluid handling properties of the Avance® NPWT System are sufficient to accommodate the exudate flow rate from large exuding wounds. The test setup included the use of the Avance® Y-Connector S to connect multiple wound models.

Clinical Testing:

No clinical data was required.

Conclusion:

Based on the information presented in this submission, it can be concluded that the Avance® Y-Connector S is substantially equivalent to the predicate device identified with respect to intended use, design and technological characteristics.