DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 4, 2016

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

Re: K161935
Trade/Device Name: Avance Foam Dressing Kit - XL
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: July 13, 2016
Received: July 14, 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)*
K161935

Device Name
Avance Foam Dressing Kit - XL

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 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.

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: July 13, 2016

Applicant:
Mölnlycke Health Care US, LLC
5550 Peachtree Parkway, Suite 500
Norcross, GA 30092
Registration number: 3004763499
Owner/Operator Number: 8030877

Official Correspondent:
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Manager, Regulatory Affairs
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Trade/Proprietary Names: Avance Foam Dressing Kit - XL

Common Name: NPWT Dressing Kit

Regulation Name: Powered Suction Pump

Device Class: Class II

Regulation Number: 21 CFR 878.4780

Product Code: OMP

Predicate Device Information: Avance® Foam Dressing Kits (K141847)

Reason for 510(k) Submission:
This premarket notification has been prepared to obtain clearance for the following line addition to Mölnlycke's Avance Negative Pressure Wound Therapy (NPWT) System: Avance Foam Dressing Kit – XL.

Description of Devices:
The subject of this premarket notification is a line addition to the Avance NPWT System: the Avance Foam Dressing Kit in size XL. Prior to this submission, the product offering consisted of foam dressing kits in sizes small, medium, and large.

The subject Avance Foam Dressing Kit – XL consists of the same components as the Avance Foam Dressing Kits cleared under K141847:

- Avance ViewPad
- Avance Foam (green)
- Avance Transparent Film

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:

Feature	Avance Foam Dressing Kits - XL	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	The Avance Foam Dressing Kit – XL contains all dressing components necessary to administer NPWT using foam as a wound filler material.	The Avance Foam Dressing Kits contain all dressing components necessary to administer NPWT using foam as a wound filler material.
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.
Dressing kit components	• Avance ViewPad (I pc) • Avance Foam, XL (2 pcs) • Avance Transparent Film (6 pcs)	(size L: largest size of comparable K141847 kit) • Avance ViewPad (1 pc) • Avance Foam, L (1 pc) • Avance Transparent Film (2 pc)
Single use or Reusable	Single use	Single use
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 device has been evaluated in accordance with ISO 10993 and has been shown to be biocompatible for the intended use.

Bench testing has been performed to demonstrate that the line addition to the Avance NPWT System does not negatively affect the ability of the NPWT system to transport fluid away from the wound and that pressure is delivered in accordance with the pump settings. The subject Avance Foam Dressing Kit - XL 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.