DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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November 17, 2016

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

Re: K161939
Trade/Device Name: Avance Abdominal Dressing Kit
Regulation Number: 21 CFR 878.3300
Regulation Name: Mesh, Surgical, Non-Absorbable, Large Abdominal
Regulatory Class: Class II
Product Codes: OXJ, OMP
Dated: October 14, 2016
Received: October 17, 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,

Jennifer R. Stevenson -A

FDA

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)*
K161939

Device Name
Avance Abdominal Dressing Kit

Indications for Use *(Describe)*
The Avance Foam Abdominal Dressing Kit is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries may be required. Its intended use is with patients who have open abdominal wounds with exposed viscera and organs, and including but not limited to patients with abdominal compartment syndrome. It is intended for use in acute hospital settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre. The dressing kit is intended for use together with the Avance Max NPWT pump and its accessories.

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

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

Date Prepared: November 16, 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 Abdominal Dressing Kit

Common Name: NPWT Dressing Kit

Regulation Name: Surgical Mesh

Device Class: Class II

Regulation Number: 21 CFR 878.3300

Product Code: OXJ, OMP

Predicate Device Information: Avance Abdominal Dressing Kit (K130852)
Reference 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 Abdominal Dressing Kit.

Description of Device:
The subject device consists of the components necessary to dress an open abdominal wound for NPWT. Kit components include: Avance ViewPad, Avance Abdominal Foam, Avance Transparent Film, and Avance Organ Contact Layer.

Indication for Use:
The Avance Foam Abdominal Dressing Kit is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries may be required. Its intended use is with patients who have open abdominal wounds with exposed viscera and organs, and including but not limited to patients with abdominal compartment syndrome. It is intended for use in acute hospital settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre. The dressing kit is intended for use together with the Avance Max NPWT pump and its accessories.

Technological Characteristics:

Feature	Avance Abdominal Dressing Kit	Avance Abdominal Dressing Kit
510(k) clearance	Subject device	K130852
Manufacturer	Mölnlycke Health Care	Mölnlycke Health Care
Common name	NPWT Dressing Kit	NPWT Dressing Kit
Regulation	21 CFR 878.3300	21 CFR 878.3300
Class name	Mesh, Surgical, Non-Absorbable, Large Abdominal Wall Defects	Mesh, Surgical, Non-Absorbable, Large Abdominal Wall Defects
Class	II	II
Product code	OXJ, OMP	OXJ, OMP
Functionality within NPWT system	The Avance Abdominal Dressing Kit contains all components necessary to dress an abdominal wound in preparation for administering NPWT.	The Avance Abdominal Dressing Kit contains all components necessary to dress an abdominal wound in preparation for administering NPWT.
Indication for use	The Avance Foam Abdominal Dressing Kit is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries may be required. Its intended use is with patients who have open abdominal wounds with exposed viscera and organs, and including but not limited to patients with abdominal compartment syndrome. It is intended for use in acute hospital settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre. The dressing kit is intended for use together with the Avance Max NPWT pump and its accessories.	The Avance Foam Abdominal Dressing Kit is indicated for temporary bridging of abdominal wall openings where primary closure is not possible and/or repeat abdominal entries may be required. Its intended use is with patients who have open abdominal wounds with exposed viscera and organs, and including but not limited to patients with abdominal compartment syndrome.
Dressing kit components	• Avance ViewPad (1 pc) • Avance Abdominal Foam (2 pcs) • Avance Transparent Film (4 pcs) • Avance Organ Contact Layer (1 pc)	• Avance Transfer Pad (I pc) • Avance Abdominal Foam (2 pcs) • Avance Film with Safetac technology (4 pcs) • Avance Organ Contact Layer (1 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 10993-1 and have been shown to meet the criteria for their 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. The subject Avance Abdominal Dressing Kit performed as intended in the test setup, and all predefined acceptance criteria were met.

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

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