K122132
page 1 of 3

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 17 2013

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

Date Prepared:	December 18, 2012
Applicant:	Mölnlycke Health Care US, LLC 5550 Peachtree Parkway, Suite 500 Norcross, GA 30092 Registration number: 3004763499 Owner/Operator Number: 9067000
Official Correspondent:	Angela L. Bunn, RAC Director, Regulatory Affairs of the Americas Tel: 678-250-7930 Fax: 678-250-7981 e-mail: **angela.bunn@molnlycke.com**
Trade/Proprietary Name:	Avance® Foam Dressing Kits
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):	RENASYS™ Foam NPWT Dressing Kits with Suction Pad

Description of Device:

Mölnlycke Health Care has developed a Negative Pressure Wound Therapy System in conjunction with Medela AG, which consists of the Avance® NPWT Pump (which is the Medela INVIA Liberty pump cleared under K080357) and the Avance® Foam Dressing Kits (subject of this submission). The Invia Liberty pump will be private labeled with the Avance® NPWT Pump branding. This pump is compatible with the Avance® Foam Dressing Kits described in the below Table.

Product Code	Product Description
662151	Avance® Foam Dressing Kit incl Transparent Film, Transfer Pad – Small
662251	Avance® Foam Dressing Kit incl Transparent Film, Transfer Pad – Medium
662351	Avance® Foam Dressing Kit incl Transparent Film, Transfer Pad – Large
662000	Avance® Transparent Film
664151	Avance® Foam Dressing Kit incl Film with Safetac®, Transfer Pad – Small
664251	Avance® Foam Dressing Kit incl Film with Safetac®, Transfer Pad – Medium
664351	Avance® Foam Dressing Kit incl Film with Safetac®, Transfer Pad – Large
664000	Avance® Film with Safetac® Technology

The Avance® Foam Dressing Kit is a negative pressure wound therapy device intended to provide negative pressure to the wound bed and thereby transport exudates from the wound.

The Avance® Foam Dressing Kit is a combination of different components developed and arranged to meet the needs of the clinical for specific size and types of wounds.

The Avance® Foam Dressing Kit is appropriate for use on the following wounds:

- Traumatic
- Surgical (sterna/abdominal/extremity)
- Chronic wounds including pressure ulcers, diabetic foot ulcers and venous leg ulcers
- Partial-thickness burns
- Dehisced wounds
- Flaps and grafts

The Avance® Foam Dressing Kits will be contraindicated for the following treatment areas:

- Direct positioning of NPWT over exposed organs, large veins and arteries, tendons or nerves
- Malignant wounds
- Untreated osteomyelitis
- Non-enteric or unexplored fistulas
- Undebrided wounds with necrotic tissue and eschar present

Intended Use/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 exudates and infectious materials. Examples of appropriate wound types include: chronic, acute, traumatic, sub-acute and dehisced, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.

Performance Data:

The vacuum level values measured in the wound model are within the chosen levels and shows a constant and uniform behavior.

The fluid was efficiently transported from the wound model without lockage or problems.

The system was tested over the time period of 73 hours without any problems or errors.

Clinical Testing:

No clinical data was required.

Conclusion:

Based on the information presented in this submission, it can be concluded that the Avance® Foam Dressing Kits are equivalent to the RENASYS™ Foam NPWT Dressing Kits with Suction Pad (K110647) predicate with respect to intended use, materials, design, and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

Janaury 17, 2013

Re: K122132
Trade/Device Name: Avance® Foam Dressing Kits
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 15, 2012
Received: December 4, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K122132

Device Name: Avance® Foam Dressing Kits

Indications 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 exudates and infectious materials. Examples of appropriate wound types include: chronic, acute, traumatic, sub-acute and dehisced, ulcers (such as pressure or diabetic), partial-thickness burns, flaps and grafts.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang

(Division Sign-Off)

Division of Surgical Devices

510(k) Number _____