



Food and Drug Administration
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January 22, 2016

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

Re: K152741
Trade/Device Name: Mepiseal Soft Silicone Sealant
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 22, 2015
Received: September 23, 2015

Dear Ms. 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" (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)

K152741

Device Name

Mepiseal® Soft Silicone Sealant

Indications for Use (Describe)

Mepiseal is intended to be used on periwound skin in conjunction with a wound dressing to prevent leakage and premature loosening of the dressing. It is designed to fill uneven skin surfaces and mold around wounds in challenging anatomical locations. When used under NPWT dressings, Mepiseal serves as a sealant to help create and maintain a seal, which enables delivery of effective negative pressure wound therapy.

When used under Negative Pressure Wound Therapy (NPWT) dressings to aid in seal formation, Mepiseal is compatible with Avance Dressing Kits that include Avance Film with Safetac Technology and Avance Transparent Film.

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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Traditional 510(k): Mepiseal® Soft Silicone Sealant

510(k) SUMMARY

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

Date Prepared: January 19, 2015

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

Official Correspondent: Megan Bevill
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Trade/Proprietary Names: Mepiseal® Soft Silicone Sealant

Common Name: NPWT Dressing

Regulation Name: Powered Suction Pump

Device Class: Class II

Regulation Number: 21 CFR 878.4780

Product Code: OMP

Predicate Device Name(s): Avance® Foam Dressing Kits (K141847)
SNaP SecuRing, a component of SNaP Wound Care System (K132080)

Reason for 510(k) Submission:

This premarket notification has been prepared to obtain clearance for a line addition to Mölnlycke's Wound Care product offering: the Mepiseal Soft Silicone Sealant.

Description of Device:

The subject device is a soft silicone sealant intended to be used on periwound skin in conjunction with a wound dressing and is designed to fill uneven skin surfaces and mold around wounds in challenging anatomical locations. Mepiseal serves the same function as the soft silicone layer of any wound dressing, to maintain the seal of the dressing around the wound. It is considered an accessory to the wound dressing and can be used under conventional wound dressings and under Negative Pressure Wound Therapy (NPWT) dressings.

Intended Use/Indication for Use:

Mepiseal is intended to be used on periwound skin in conjunction with a wound dressing to prevent leakage and premature loosening of the dressing. It is designed to fill uneven skin surfaces and mold around wounds in challenging anatomical locations. When used under NPWT dressings, Mepiseal serves as a sealant to help create and maintain a seal, which enables delivery of effective negative pressure wound therapy.

When used under NPWT dressings to aid in seal formation, Mepiseal is compatible with the Avance Dressing Kits that include Avance Film with Safetac Technology and Avance Transparent Film.

Technological Characteristics:

Feature	Mepiseal Soft Silicone Sealant	Avance Foam Dressing Kits	SNaP SecuRing
510(k) clearance	Subject of submission	K141847	K132080
Rationale for inclusion	Subject of submission	Primary predicate	Reference device
Manufacturer	Mölnlycke Health Care	Mölnlycke Health Care	Spiracur
Common name	NPWT Dressing	NPWT Dressing Kits	NPWT Dressing Kits
Regulation	21 CFR 878.4780	21 CFR 878.4780	21 CFR 878.4683
Class name	Powered Suction Pump	Powered Suction Pump	Non-powered Suction Pump
Class	II	II	II
Product code	OMP	OMP	OKO
Indication for use/Intended use	<p>Mepiseal is intended to be used on periwound skin in conjunction with a wound dressing to prevent leakage and premature loosening of the dressing. It is designed to fill uneven skin surfaces and mold around wounds in challenging anatomical locations. When used under NPWT dressings, Mepiseal serves as a sealant to help create and maintain a seal, which enables delivery of effective negative pressure wound therapy.</p> <p>When used under NPWT dressings to aid in seal formation, Mepiseal is compatible with the Avance Dressing Kits that include Avance Film with Safetac Technology and Avance Transparent Film.</p> <p>(Mepiseal is part of the Avance NPWT System, with the following indications:)</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>	<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>	<p>The SNaP SecuRing functions to improve the seal of the dressing around the wound.</p> <p>(The SNaP SecuRing is part of the SNaP Wound Care System, with the following indications:)</p> <p>The SNaP Wound Care System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing through the removal of excess exudates, infectious material and tissue debris. The SNaP Wound Care System is indicated for removal of small amounts of exudate from chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, venous or pressure), surgically closed incisions, flaps and grafts.</p>
NPWT system includes device to augment seal	Subject of this submission	No	Yes
Sealant material	Soft silicone	No sealant included	Hydrocolloid
Sealant application method	Supplied in two-component applicator; product is dispensed through mixer in applicator onto periwound skin a covered with dressing	No sealant included	Supplied as soft, moldable ring; manipulated to desired shape with hands, then applied to periwound skin and covered with dressing

Traditional 510(k): Mepiseal® Soft Silicone Sealant

Sealant use situation	Use on difficult to dress/seal wounds, including those with uneven skin surfaces and those in challenging anatomical locations	No sealant included; no current solution for difficult to dress/seal wounds	Use on uneven skin surfaces and challenging body contours
Single use or Reusable	Single Use	Single Use	Single Use
Sterility	Non-sterile, controlled bioburden	Sterile	Unknown

Performance Data:

Bench testing has been performed to demonstrate that Mepiseal is capable of sealing air leaks in the Avance NPWT system and does not otherwise interfere with the system's ability to transport fluid away from the wound. Mepiseal's performance has been evaluated under both soft silicone films and acrylic films (Avance Film with Safetac Technology and Avance Transparent Film) and found to be acceptable.

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.