November 2, 2018

Medela AG
c/o Adrienne Lenz
Senior Medical Device Regulation Expert
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, District of Columbia 20005

Re: K180415
Trade/Device Name: Invia White Foam NPWT
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 28, 2018
Received: October 1, 2018

Dear Adrienne Lenz:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cynthia Chang -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180415

Device Name
Invia White Foam NPWT

Indications for Use *(Describe)*
The Invia White Foam in conjunction with the Invia Foam Dressing Kits with FitPad, the Invia Motion and Invia Liberty Negative Pressure Wound Therapy (NPWT) systems is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy) as it creates an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material.

The Invia White Foam is appropriate for use for the following wounds:
– Acute or sub-acute wounds
– Chronic wounds
– Dehisced wounds
– Pressure ulcers
– Diabetic/neuropathic ulcers
– Venous insufficiency ulcers
– Traumatic wounds
– 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

DATE: November 1, 2018

SUBMITTER:

Medela AG
Lättichstrasse 4b
6341 Baar / Switzerland
Phone +41 (0)41 769 51 51
Fax + 41 (0)41 769 51 00

PRIMARY CONTACT PERSON:

Adrienne R. Lenz
Senior Medical Device Regulation Expert
Hyman, Phelps, & McNamara, P.C.
T 202-737-4292

SECONDARY CONTACT PERSON:

Judith Bernardo
Global RA Director
Medela AG

DEVICE:

TRADE NAME: Invia White Foam NPWT

COMMON/USUAL NAME: Negative Pressure Wound Therapy Dressing Kit

CLASSIFICATION NAMES: 878.4780 Powered Suction Pump

REVIEW PANEL: General and Plastic Surgery

PRODUCT CODE: OMP

PREDICATE DEVICE(S):

K170088 Medela Invia Foam Dressing Kit with FitPad

K142646 Genadyne XLR8 White Foam Dressing Kit

DEVICE DESCRIPTION:

The Invia White Foam is a single packed, sterile, polyvinyl alcohol (PVA) foam intended for use in conjunction with the previously cleared Invia Foam Dressing Kit with FitPad (K170088), Invia Motion (K161128) and Invia Liberty (K142626) negative pressure wound therapy (NPWT) systems. It is a stand-alone wound dressing used as an alternative or as a supplement to the wound dressing in the Invia Foam Dressing Kit with FitPad. The Invia White Foam is available in two sizes (small, large). The Invia White Foam is for use by healthcare professionals in acute, extended and home care settings.

The Invia White Foam NPWT is an open cell, hydrophilic, PVA foam moistened in sterile water. Like other NPWT foams, the Invia White Foam NPWT is an effective wound dressing, allowing a controlled application of sub-atmospheric pressure to the local wound environment to remove wound exudate. The Invia White Foam NPWT allows the passage of fluid through the foam and away from the wound bed. The foam can be used with both constant and intermittent NPWT delivery. It is able to be cut to size to suit a particular wound size.

INTENDED USE:

The Invia White Foam in conjunction with the Invia Foam Dressing Kits with FitPad, the Invia Motion and Invia Liberty Negative Pressure Wound Therapy (NPWT) systems is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy) as it creates an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material.

The Invia White Foam is appropriate for use for the following wounds:
– Acute or sub-acute wounds
– Chronic wounds
– Dehisced wounds
– Pressure ulcers
– Diabetic/neuropathic ulcers
– Venous insufficiency ulcers
– Traumatic wounds
– Partial thickness burns
– Flaps and grafts

TECHNOLOGY:

The proposed Invia White Foam NPWT has similar indications for use and uses the same fundamental technology as the legally marketed predicate devices to which substantial equivalency is claimed, the Invia Foam Dressing Kit with FitPad (K170088) and Genadyne XLR8 White Foam Dressing Kit (K142646).

	Subject Device	**Predicate 1**	**Predicate 2**
	Invia White Foam NPWT	**Invia Foam Dressing Kit with FitPad (K170088)**	**Genadyne XLR8 White Foam Dressing Kit (K142646)**
Picture			
Manufact./Name	Medela AG	Medela AG	Genadyne Biotechnologies Incorporated
510(k) Number	-	K170088	K142646
Product code	OMP	OMP	OMP
Indications for Use	The Invia White Foam in conjunction with the Invia Foam Dressing Kits with FitPad, the Invia Motion and Invia Liberty Negative Pressure Wound Therapy (NPWT) systems is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy) as it creates an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. The Invia White Foam is appropriate for use for the following wounds: • Acute or sub-acute wounds • Chronic wounds • Dehisced wounds • Pressure ulcers • Diabetic/neuropathic ulcers • Venous insufficiency ulcers • Traumatic wounds • Partial thickness burns • Flaps and grafts	The Invia Foam Dressing Kit with FitPad in conjunction with the Invia Motion and Invia Liberty Negative Pressure Wound Therapy (NPWT) systems is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy) as it creates an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. The Invia Foam Dressing Kit with FitPad is appropriate for use for the following wounds: • Acute or sub-acute wounds • Chronic wounds • Dehisced wounds • Pressure ulcers • Diabetic/neuropathic ulcers • Venous insufficiency ulcers • Traumatic wounds • Partial thickness burns • Flaps and grafts	Genadyne XLR8 White Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4-XLR8 Wound Vacuum System (K090638) to deliver negative pressure wound therapy to the wound. Genadyne A4-XLR8 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris. XLR8 White Foam Dressing is appropriate for use on the following wounds: • Pressure ulcers • Diabetic/Neuropathic Ulcers • Venous insufficiency Ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds • Skin flap and grafts

	Subject Device	Predicate 1	Predicate 2
	Invia White Foam NPWT	**Invia Foam Dressing Kit with FitPad (K170088)**	**Genadyne XLR8 White Foam Dressing Kit (K142646)**
Contraindications	• Necrotic tissue with eschar present • Untreated osteomyelitis • Non-enteric and unexplored fistulas • Malignancy in wound (with exception of palliative care to enhance quality of life) • Exposed vasculature • Exposed nerves • Exposed anastomotic site of blood vessels or bypasses • Exposed organs	• Necrotic tissue with eschar present • Untreated osteomyelitis • Non-enteric and unexplored fistulas • Malignancy in wound (with exception of palliative care to enhance quality of life) • Exposed vasculature • Exposed nerves • Exposed anastomotic site of blood vessels or bypasses • Exposed organs	Unknown
Environment of Use	acute, extended and home care settings	acute, extended and home care settings	Hospital, long term care and home settings
User	healthcare professional only	healthcare professional only	healthcare professional only
Therapy modes	Constant and intermittent use	Constant and intermittent use	Constant and intermittent use
Dimensions	Small 10 cm x 7.5 cm x 1cm Large 15 cm x 10 cm x 1 cm	Small 10 cm x 8 cm x 3 cm Medium 19 cm x 12.5 cm x 3 cm Large 25 cm x 15 cm x 3 cm X Large 60 cm x 30 cm x 1.5 cm	Small 10 cm x 7.5 cm x 1cm Medium 15 cm x 10 cm x 1 cm Large 20 cm x 15 cm x 1 cm
Operating Ambient Temperatures	+5 - +40 °C	+5 - +40 °C	Unknown
Operating Ambient Humidity	15 - 93%	15 - 93%	Unknown
Operating Pressure	70 - 106 kPa	70 - 106 kPa	Unknown
Storage Ambient Temperatures	-20 - +50°C	-20 - +50°C	Unknown
Storage Ambient Humidity	15 - 93%	15 - 93%	Unknown
Storage Pressure	70 - 106 kPa	70 - 106 kPa	Unknown
Packaging Type	Aluminium foil packed moistened with sterile water	Tyvec/Foil pouch packed dry	Aluminium foil packed moistened with sterile water
Sterile	Yes	Yes	Yes
Sterilization Method	Gamma radiation	Ethylene oxide	Gamma radiation
Vacuum therapy range	-40 - -200mmHg	-40 - -200mmHg	-40 - -230mmHg
Principles of operation	Open cell foam, hydrophilic, pore size 900 - 1200 microns, stronger tensile strength than PU foam	Open cell foam, hydrophobic, pore size 600-800 microns	Hydrophilic, stronger tensile strength than PU foam
Foam Material	Polyvinyl alcohol foam	Polyurethane foam	Polyvinyl alcohol foam

	Subject Device	Predicate 1	Predicate 2
	Invia White Foam NPWT	**Invia Foam Dressing Kit with FitPad (K170088)**	**Genadyne XLR8 White Foam Dressing Kit (K142646)**
Features	White, Open cell foam, softer than PU foam, decreased in-growth of granulation, , high tensile strength >150 kPa than PU foam,	Charcoal black, open cell foam	White, Open cell foam, softer than PU foam, decreased in-growth of granulation, , high tensile strength >150 kPa than PU foam,

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

SUMMARY OF NON-CLINICAL TESTS:

The following data were provided in support of the substantial equivalence determination:

- Risk Analysis.
- Sterilization information is provided according to the 2016 guidance document *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile.* The Invia White Foam NPWT is gamma sterilized and has been shown to have a shelf life of 2-years
- Biocompatibility evaluation and testing was completed according to the FDA guidance "Use of International Standard ISO- 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." All tests passed demonstrating the biocompatibility of the Invia White Foam for its intended use.
- A Usability Engineering Report was prepared following FDA's 2016 guidance document *Applying Human Factors and Usability Engineering to Medical Devices*. It concludes that the Invia White Foam NPWT, used in conjunction with the previously cleared Invia Foam Dressing Kits with FitPad components (K170088) has been found to be safe and effective for the intended users, uses and use environments.
- The Invia White Foam was tested to verify its functionality and performance in conjunction with the Invia Foam Dressing Kit with FitPad, the Invia Liberty, and the Invia Motion pumps at the minimal and maximal pressure settings using a wound model. Various worst case scenarios and experimental setting combinations were applied to validate the system performance. The Invia Liberty and the Invia Motion pumps both showed a constant vacuum value within the wound model, with efficient liquid removal discharged through the external suction interface and draining into the canister. In addition, the notification information functionality was found to be in accordance with pump specifications.
- The Invia White Foam was tested to demonstrate equivalent performance to the predicate Genadyne PVA White Foam (K142646). Testing of the Invia White Foam NPWT in conjunction with the Invia Foam Dressing Kit with FitPad, the Invia Liberty and the Invia Motion pumps in comparison to the Genadyne XLR8

pump together with Genadyne's White Polyvinyl Alcohol (PVA) Foam across the specified pressure settings using a wound model was performed. The test results confirm equivalent vacuum performance and suction of fluid in the wound model throughout the entire duration of test when applying the worst case conditions.

SUMMARY OF CLINICAL TESTS:

Clinical testing was not required to demonstrate the substantial equivalence of the Invia White Foam NPWT to its predicate devices.

CONCLUSION:

Medela AG considers the Invia White Foam NPWT to be substantially equivalent to the predicate devices.