February 1, 2019

Medela AG
% 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: K182191
Trade/Device Name: Invia Abdominal Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP, FTL
Dated: January 3, 2019
Received: January 3, 2019

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,

Kimberly Ferlin -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)*

K182191

Device Name

Invia Abdominal Dressing Kit

Indications for Use *(Describe)*

The Invia 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 Invia Liberty NPWT System.

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 - K182191

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

DATE: January 31, 2019

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 Lenz, RAC
Senior Medical Device Regulation Expert
Hyman, Phelps & McNamara, P.C.
T (202)737-4292

SECONDARY CONTACT PERSON:

Judith Bernardo
Global RA Director & Team Leader Global RA Healthcare
Medela AG

DEVICE:

TRADE NAME: Invia Abdominal Dressing Kit

COMMON/USUAL NAME: Negative Pressure Wound Therapy Dressing Kit, Mesh, Surgical, Polymeric

CLASSIFICATION NAMES: 878.4780 Powered Suction Pump, 878.3300 Surgical mesh

PRODUCT CODE: OMP, FTL

PREDICATE DEVICE(S):

K130852 Mölnlycke Avance Foam Abdominal Dressing Kit
K170088 Invia FitPad Dressing Kit (Reference Device)
K142626 Invia Liberty Negative Pressure Wound Therapy System (Reference Device)

DEVICE DESCRIPTION:

The Invia Abdominal Dressing Kit consists of an Organ Contact Layer (OCL), two foam pads, four transparent films and a suction interface (Invia FitPad).

- The OCL is an oval polyurethane film with fenestrations intended to protect the abdominal content and enable fluid drainage from the abdomen.
- The foam pad is an oval hydrophobic polyurethane foam with open cell structure intended to be placed over the OCL in order to distribute the negative pressure across the wound surface and allow passage of fluids and exudates through to the negative pressure system.
- The transparent film is a thin transparent polyurethane film with acrylic adhesive intended to fixate the wound filler and seal tight to the skin.
- The Invia FitPad is intended to distribute negative pressure to the wound and transport exudates from the abdominal cavity to the canister of the Invia Liberty Negative Pressure Wound Therapy (NPWT) pump.

The components of the Invia Abdominal Dressing Kit are packaged sterile and are for single use only.

INTENDED USE:

The Invia 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 Invia Liberty NPWT System.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

The Invia Abdominal Dressing Kit is substantially equivalent to the Mölnlycke Abdominal Dressing Kit (K130852), which has equivalent indications for use, intended use and technological characteristics. Additionally, the film, foam and FitPad components used within the Medela Invia Abdominal Dressing kit are identical to those cleared for use in NPWT in 510(k) K170088 Invia Foam Dressing Kit with FitPad. Reference is also given to the Invia Liberty NPWT System (K142626) as the compatible pump used with the Invia Abdominal Dressing Kit.

The table below summarizes the key differences between the Invia Abdominal Dressing Kit and the predicate device.

	Predicate Device **Mölnlycke Avance Foam Abdominal Dressing Kit (K130852)**	**Invia Abdominal Dressing Kit**
Indications 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 NPWT pump and its accessories.	The Invia 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 Invia Liberty NPWT System.
Contra-indications	• Direct positioning NPWT (foam or gauze dressings) over exposed organs, large veins and arteries, anastomotic sites, tendons or nerves • Malignancy in wounds • Untreated osteomyelitis • Non-enteric or unexplored fistulas • Undebrided wound with necrotic tissue and eschar present	• Direct positioning of NPWT foam over exposed organs, large veins and arteries, anastomotic sites, tendons or nerves (unless suitably covered with the Organ Contact Layer) • Necrotic tissue with eschar present • Untreated osteomyelitis • Non-enteric and unexplored fistulas • Malignancy in wound
Intended Use	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 NPWT pump and its accessories.	The intended use of the Invia Abdominal Dressing Kit together with Invia Liberty NPWT system is to manage patients with 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 by a trained physician.

	Predicate Device **Mölnlycke Avance Foam Abdominal Dressing Kit (K130852)**	**Invia Abdominal Dressing Kit**
Environment of Use	It is intended for use in acute hospital settings (trauma, gneral and plastic surgery wards) and should ideally be applied in the operating theatre.	It is intended for use in acute hospital settings (trauma, general and plastic surgery wards) and should ideally be applied in the operating theatre by a trained physician.
Compatible NPWT System	Avance NPWT Pump (K142626, K080357) Suction capacity 5l/min Max. Vacuum -200 mmHg/-27kPa Min. Vacuum -60 mmHg/-5.3kPa	Invia Liberty Negative Pressure Wound Therapy System (K142626, K080357) Suction capacity 5l/min Max. Vacuum -200 mmHg/-27 kPa Min. Vacuum -40 mmHg/-5.3 kPa
Recommended Abdominal Wound Pressure Setting	-120 mmHg	-125 mmHg
Recommended Abdominal Wound Pump Setting	Constant Mode	Constant Mode
Dressing (to pack the wound)	Green Foam Pad Uses a reticulated flexible polyurethane hydrophobic foam material	Charcoal Foam Pad Uses a reticulated flexible polyether and polyurethane hydrophobic foam material.
Transparent Film (to seal the wound)	Avance® Film with Safetac technology Polyurethane film coated with a soft silicone adhesive	Invia Transparent Film Vancive MED-9531S (Avery Dennison) Polyurethane transparent film with acrylic adhesive
External suction interface (ESI)	Avance Transfer Pad (single lumen) Tubing material: PVC Tape: Acrylic adhesive	Invia FitPad (double lumen tubing with Quick-Connector) Tubing material: PVC, RO 1007 K20131 70 S Body material: PVC, RO 1011 K20108 65 S Double Adhesive Tape: Avery MED 1832

	Predicate Device **Mölnlycke Avance Foam Abdominal Dressing Kit (K130852)**	**Invia Abdominal Dressing Kit**
Organ contact layer (OCL to protect the abdominal content and enable fluid drainage from the abdomen)	Soft / flexible 60 micron PUR film Oval 600x800 mm 5 mm fenestrations in square pattern	Soft / flexible 60 micron PUR film Oval 600x800 mm 5 mm fenestrations in square pattern
Packaging	Single Use Dressing Kit is packed sterile. Components are wrapped in repellent nonwoven wrap and packed in transparent unit pouch.	Single Use Dressing Kit is double pouched packed sterile in a Tyvec/Foil pouch
Foam Dimensions (l x w x h)	38 cm × 25 cm × 2 cm (oval)	38 cm x 25 cm x 2 cm (oval)
Sterilization method	Ethylene oxide sterilized	Ethylene oxide sterilized
Shelf life	Not available	2 years

SUMMARY OF NON-CLINICAL TESTS:

The following were completed in support of the substantial equivalence determination:

- Risk Analysis developed in accordance with ISO 14971: 2007.
- A usability process, following the recommendations of the FDA guidance document *Applying Human Factors and Usability Engineering to Medical Devices* (Feb. 3, 2016), was used in the development and evaluation of the usability of the Invia Abdominal Wound Dressing.
    - Three usability experts conducted the heuristic evaluations of the dressing kit and dressing kit IFU.
    - A use-related risk analysis of the dressing kit was also developed.
    - Human factors validation testing of Invia Abdominal Dressing Kit included 15 surgeons with experience operating on open abdomens, representing the expected end users of this product. Participants completed validation sessions that included training representative of that provided in actual use followed by a decay period of one hour before completing usability testing scenarios related to realistic product use. Results of the validation study were successful, with very low error rates observed for the performance scenarios.

- Performance testing demonstrated the functionality of the Invia Abdominal Dressing Kit in combination with the separately cleared compatible NPWT pump as compared to the cleared predicate abdominal dressing kit with its compatible NPWT pump. Testing was completed to demonstrate that the pressure at the wound is within 10% of the setpoint using a wound model, simulated wound exudates, and multiple pressure sensors within the wound model. Testing further demonstrated effective removal of simulated wound exudate from the wound model. Multiple vacuum settings over 30 minutes and 73 hours were used to demonstrate both short and long term performance in pressure stability and removal of simulated wound exudate. Tests were also performed for a short period of time to verify the leakage and blockage notification functionality is in accordance with the description in the Invia Liberty Pump Instructions for use. Comparison to the predicate Mölnlycke Avance Abdominal Dressing Kit (K130852) with its compatible pump was made to demonstrate equivalent performance with NaCl exudate removal over 30 minutes. Results demonstrated that both the Invia Abdominal Dressing Kit and the Avance Foam Abdominal Dressing Kit maintained constant vacuum values within the wound model, with efficient liquid being discharged through the interface and draining into the pump canister at their intended settings. The data demonstrate adequate vacuum performance of the Abdominal Dressing Kit and substantial equivalence to the predicate Mölnlycke Avance Abdominal Dressing Kit (K130852).
- The ethylene oxide sterilization process was validated according to ISO 11135-1:2007 including Annex A (Biological Indicators) and B (Overkill Approach). A sub-lethal cycle (biological indicators, bacteriostatic and fungistasis, product sterility and bioburden), half cycle (biological indicator) and routine cycles (EO and ECH residuals) were performed to establish that an SAL of at least 10^{-6} is provided by the cycle and that EO residuals meet the limits in ANSI/AAMI/ISO 10993-7.
- The sealed Tyvek packaging underwent environmental conditioning, transit simulation and integrity testing, which include visual inspection per ASTM F1886, bubble leak integrity testing per ASTM F2096 and peel strength testing per ASTM F88.
- Accelerated aging tests were performed to support this 2-year shelf life via methods published in FDA recognized standard ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- The Foam, Transparent Film and Suction Port (FitPad) in their final finished form are identical to the Foam, Transparent Film and Suction Port (FitPad) cleared in K170088. Due to the extended use of the foam and film, the following biocompatibility endpoint was evaluated in addition to those recommended for an external communicating device in prolonged contact with tissue/bone/dentin according to the 2016 FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* : Hemocompatibility. Biocompatibility Testing was also performed for the OCL according to the Good Laboratory Practice requirements and biocompatibility evaluation endpoints for an implant device in prolonged contact with tissue/ bone as listed in the aforementioned 2016 FDA biocompatibility guidance document. The following additional biocompatibility endpoint was also assessed for the OCL: Hemocompatibility.

SUMMARY OF CLINICAL TESTS:

Clinical testing was not required to demonstrate the substantial equivalence of the Invia Abdominal Dressing Kit to its predicate device.

CONCLUSION:

The differences between the Invia Abdominal Dressing Kit and its predicate device do not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended.

From the results of nonclinical testing described, Medela AG concludes that the Invia Abdominal Dressing Kit is substantially equivalent to the legally marketed predicate device.