July 7, 2023

Medela AG
% Adrienne Lenz
Principal Medical Device Regulatory Expert
Hyman, Phelps, & McNamara
700 Thirteenth Street, N.W.
Washington, District of Columbia 20005

Re: K223388
Trade/Device Name: Invia® Integrated Dressing
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: June 6, 2023
Received: June 6, 2023

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Julie A. Morabito -S

Julie A. Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223388

Device Name
Invia ® Integrated Dressing

Indications for Use *(Describe)*

The Invia® Integrated Dressing in conjunction with the Invia NPWT Systems is indicated for patients who would benefit from a suction device (NPWT) as when used on open wounds 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.
When used on closed surgical incisions, the Invia Integrated Dressing is also intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of Negative Pressure Wound Therapy.

The Invia Integrated Dressing is appropriate for use for the following indications:

- 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
- Closed surgical incisions

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 Information

In accordance with 21 C.F.R. §807.92(a) the following summary of information is provided:

Date Summary Prepared:	July 7, 2023
Submitter/Applicant:	Medela AG Lättichstrasse 4b CH 6340 Baar Switzerland Phone: +41 41 562 51 51 Fax: +41 41 562 51 00
Primary Contact Person:	Adrienne Lenz Principal Medical Device Regulatory Expert Hyman, Phelps & McNamara P.C. Phone: (202) 737-4292 Email: ALenz@hpm.com
Device Information	Trade/Device Name: Invia® Integrated Dressing Regulation Name: Powered suction pump Regulation Number: 21 C.F.R. § 878.4780 Common Name: Negative Pressure Wound Therapy System Device Classification Name: Powered suction pump Product Code: OMP Regulatory Class: II Review Panel: General & Plastic Surgery
Predicate Device Information	Invia Foam Dressing Kits With FitPad K172145 Manufacturer: Medela AG
Reference Device Information	PICO 7 Single Use Negative Pressure Wound Therapy System K202157 Manufacturer: Smith & Nephew Medical Limited

Device Description

The Invia Integrated Dressing is a sterile NPWT dressing, consisting of: a pad area designed to evenly distribute the negative pressure and to draw off the exudate, a perforated silicone adhesive wound contact layer to provide a gentle but secure adhesion to the skin, and a double lumen tubing with Quick-connector to connect the dressing to the Invia NPWT pumps.

The Invia Integrated Dressing is available in three different sizes as shown below.

Table 5-1: Invia Integrated Dressing covered by this 510(k)

Description	Invia® Integrated Dressing		
REF (model number)	101035697	101035698	101035699
Pad area size	10cm x 10cm	10cm x 15cm	10cm x 25cm
Dressing Size	18cm x 18cm	18cm x 23cm	18cm x 33cm

The Invia Integrated Dressing is designed to be compatible with the Invia Negative Pressure Wound Therapy Systems (Invia® Liberty NPWT suction pump, cleared via K142626 and K172145) and Invia® Motion (cleared via K161128 and K172145) and Invia® Ease suction pumps (K214112).

For wounds greater than 0.5 cm in depth, it is likely that a wound filler needs to be used with the Invia Integrated Dressing to ensure adequate treatment of all the wound surfaces. The Invia Integrated Dressing can be used with the wound filler accessory, Invia Black Foam NPWT. The Invia Black Foam NPWT is available in one size as shown below.

Table 5-2: Invia Black Foam NPWT model covered by this 510(k)

Description	Invia® Black Foam NPWT
REF (model number)	101035701
Foam pad size	10 x 8 x 3 cm

Indications for Use

The Invia Integrated Dressing in conjunction with the Invia NPWT Systems is indicated for patients who would benefit from a suction device (NPWT) as when used on open wounds 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.
When used on closed surgical incisions, the Invia Integrated Dressing is also intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of Negative Pressure Wound Therapy.

The Invia Integrated Dressing is appropriate for use for the following indications:

- 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
- Closed surgical incisions

Comparison of Technological Characteristics

Invia® Integrated Dressing has same intended use, same indications for use, and has equivalent fundamental technology as the legally marketed predicate device to which substantial equivalency is claimed.

Characteristics	Subject Device Invia Integrated Dressing	Predicate Device Invia Foam Dressing Kit with FitPad (K172145)	Reference Device PICO 7 (K202157)
Product code	OMP	OMP	OMP
Intended Use	Dressing for Negative Pressure Wound Therapy	Dressing for Negative Pressure Wound Therapy	Dressing for negative pressure wound therapy.
Indication for use	The Invia Integrated Dressing in conjunction with the Invia NPWT Systems is indicated for patients who would benefit from a suction device (NPWT) as when used on open wounds 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. When used on closed surgical incisions, the Invia Integrated Dressing is also intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by	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 when used on open wounds 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. When used on closed surgical incisions, the Invia Foam Dressing Kit with FitPad is also intended to manage the environment of surgical incisions that	PICO 7 is indicated for patients who would benefit from a suction device (NPWT) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. Appropriate wound types include: - Chronic - Acute - Traumatic - Subacute and dehisced wounds - Partial-thickness burns - Ulcers (such as diabetic or pressure) - Flaps and grafts - Closed Surgical incisions PICO 7 Single Use Negative Pressure Wound Therapy System is suitable for use

Characteristics	Subject Device Invia Integrated Dressing	Predicate Device Invia Foam Dressing Kit with FitPad (K172145)	Reference Device PICO 7 (K202157)
	maintaining a closed environment and removing exudate via the application of Negative Pressure Wound Therapy. The Invia Integrated Dressing is appropriate for use for the following indications: - 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 - Closed surgical incisions	continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudates via the application of Negative Pressure Wound Therapy. The Invia Foam Dressing Kit with FitPad is appropriate for use for the following indications: - 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 - Closed surgical incisions	both in a hospital and homecare setting.
Contraindications	The Invia Integrated Dressing has the following 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	The Invia Foam Dressing Kit with FitPad has the following contraindications: - Necrotic tissue with eschar present - Untreated osteomyelitis - Non-enteric and unexplored fistulas - Malignancy in the wound - Exposed vasculature - Exposed nerves - Exposed anastomotic site of blood vessels or bypasses - Exposed organs	Pico 7 is contraindicated for: - Patients with malignancy in the wound bed or margins of the wound (except in palliative care to enhance quality of life). - Previously confirmed and untreated osteomyelitis. - Non-enteric und unexplored fistulas. - Necrotic tissue with eschar present. - Exposed arteries, veins, nerves or organs. - Exposed anastomic sites. PICO 7 should not be used for the purpose of: - Emergency airway aspiration

Characteristics	Subject Device Invia Integrated Dressing	Predicate Device Invia Foam Dressing Kit with FitPad (K172145)	Reference Device PICO 7 (K202157)
			- Pleural, mediastinal or chest tube drainage Surgical suction
Patient population	Adults	Adults	Adults
Use environment	Hospital and home	Hospital and home	Hospital and home
Model number	▪ Art.No 101035697 ▪ Art.No 101035698 ▪ Art.No 101035699	▪ Art.No. 087.6221(3 pcs) ▪ Art.No 087.6222(3 pcs) ▪ Art.No 087.6223(3 pcs) ▪ Art.No 087.6224(3 pcs) ▪ Art.No 087.6225(15 pcs) ▪ Art.No 087.6226(15 pcs) ▪ Art.No 087.6227(15 pcs)	▪ Art.no 66802007
Dimensions specifications (Length x Width)	▪ Small: 18cm x 18cm ▪ Medium: 18cm x 23cm ▪ Large: 18cm x 33cm	▪ Small: 10cm x 8cm ▪ Medium: 19cm x 12.5cm ▪ Large: 25cm x 15cm ▪ X-Large: 60cm x 30cm	▪ 10cm x 20 cm ▪ 10 cm x 30 cm ▪ 10 cm x 40 cm ▪ 15 cm x 15 cm ▪ 15 cm x 20 cm ▪ 15 cm x 30 cm ▪ 20 cm x 20 cm ▪ 25 cm x 25 cm
Sterility	Ethylene oxide sterilized	Ethylene oxide sterilized	Ethylene oxide sterilized
Exudate handling	Canister	Canister	Dressing
Therapeutic pressure	▪ -40mmHg to -200mmHg with Invia Liberty ▪ -40mmHg to -175mmHg with Invia Motion ▪ -40mmHg to -200mmHg with Invia Ease	▪ -40mmHg to -200mmHg with Invia Liberty ▪ -40mmHg to -175mmHg with Invia Motion ▪ -40mmHg to -200mmHg with Invia Ease	▪ -80mmHg (nominal)
Mode of operation	Constant	Constant Intermittent	Constant
Maximum Dressing change interval of the dressing	Up to 7 days (if without wound filler)	Up to 3 days	Up to 7 days (if without wound filler)
Maximum Dressing change interval when using dressing with foam	Up to 3 days	Up to 3 days	Up to 3 days

Characteristics	Subject Device Invia Integrated Dressing	Predicate Device Invia Foam Dressing Kit with FitPad (K172145)	Reference Device PICO 7 (K202157)
Wound filler	Invia Black Foam NPWT	Invia Foam Dressing Kit with FitPad	Smith&Nephew Inc. Foam or gauze wound fillers.
Wound filler Sterilization method	Ethylene oxide sterilized	Ethylene oxide sterilized	Ethylene oxide sterilized
Compatibility with other wound filler included in the kits	▪ Invia Foam Dressing Kit with FitPad (K172145) ▪ Invia White Foam (K180415) ▪ Invia Gauze Dressing Kit (K172145)	▪ Black foam included in the Invia Foam Dressing Kit with FitPad (K172145) ▪ White foam include in Invia White Foam (K180415) ▪ Gauze included in Invia Gauze Dressing Kit (K172145)	Smith&Nephew Inc. ▪ Foam dressing filler (REF 60801021) ▪ Gauze dressing filler (66801020)

Summary of Non-Clinical Tests

The Invia® Integrated Dressing and Invia® Black Foam NPWT wound filler comply with voluntary standards for sterilization, biocompatibility and usability. The following performance data are provided in support of the substantial equivalence determination:

- Risk analysis in accordance with ISO 14971:2019, Medical Devices – Application of Risk Management to Medical Devices.
- Sterilization information in accordance with the FDA's Guidance document entitled "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile." (January 2016).
- A biocompatibility evaluation was completed according to the FDA's Guidance document entitled "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"" (Sept. 2020). The Invia Integrated Dressing and the Invia Black Foam NPWT were categorized as having prolonged contact with breached or compromised surfaces. The following biological endpoints were evaluated based on this categorization: Cytotoxicity, Sensitization, Irritation or Intracutaneous reactivity, Systemic toxicity (acute), Pyrogenicity, and Subchronic toxicity (subacute toxicity).
- A summative human factors study was performed for the Invia Integrated Dressing following the FDA Guidance document "Applying Human Factors and Usability Engineering to Medical Devices" dated February 03, 2016. Overall, the objectives of the study were met, which demonstrated that the product can be used safely and effectively by lay users without patterns of preventable use errors that may cause harm to the user.
- Bench testing was conducted to check that specifications were met and to demonstrate performance equivalence to the predicate Invia® Foam Dressing Kit with FitPad. Verification and validation tests have been executed for the Invia® Integrated Dressing in combination with all Medela Invia NPWT Systems: Invia® Liberty, Invia® Motion and Invia® Ease. Additionally, the subject device has been tested in combination with the following wound fillers: Invia® Black Foam NPWT, the black foam wound fillers included in the Invia® Foam Dressing Kit with FitPad, the Invia® White Foam, and the gauze wound filler included in the Invia® Gauze Dressing Kit.
- Animal Testing was conducted to demonstrate that the subject device can be left in place over the wound for up to 7 days, before proceeding with the dressing change, without any adverse local tissue reactions, macroscopically or histopathologically. This study was conducted in compliance with the OECD Principles of Good Laboratory Practice (as revised in 1997), which are in conformity with other international GLP regulations (21 CFR Part 58).

Summary of Clinical Tests

Clinical testing was not required to support substantial equivalence.

Conclusions

The differences between the Invia® Integrated Dressing and its predicate device, Invia Foam Dressing Kits With FitPad, do not introduce a new intended use and do not raise different questions of safety and effectiveness. Verification and validation testing demonstrated that no adverse effects have been introduced by these differences and that the devices perform as intended.

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