July 26, 2022

Medela AG
Mike McAndrew
Director of Quality and Regulatory Americas
Lattichstrasse 4b
Baar, 6340
Switzerland

Re: K214112
Trade/Device Name: Invia Ease Negative Pressure Wound Therapy (NPWT) System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: June 15, 2022
Received: June 21, 2022

Dear Mike McAndrew:

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 Morabito, Ph.D.
Assistant Director
DHT4B: Division of 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K214112

Device Name
Invia Ease NPWT system

Indications for Use *(Describe)*
The Invia Ease Negative Pressure Wound Therapy (NPWT) system 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 exudates and infectious material. When used on closed surgical incisions, the Invia Ease NPWT System 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 (NPWT).

The Invia Ease NPWT system is intended for use in acute, extended and home care settings.

The Invia Ease NPWT system is appropriate for the following indications:
- Acute or subacute 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.

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Medela AG
Invia Ease NPWT system
Traditional 510(k)

510(k) Summary Information (K214112)

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

Date Summary Prepared:	July 12, 2022
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:	Mike McAndrew In representation of Medela AG Head of Quality and Regulatory Americas at Medela LLC Phone: +1 815 578 2376 Email: Mike.McAndrew@medela.com
Device Information	Trade/Device Name: Invia Ease NPWT System Regulation Name: Powered Suction Pump Regulation Number: 21 CFR§878.4780 Common Name: Negative Pressure Wound Therapy Pump and Accessories Device Classification Name: 878.4780 Powered Suction Pump Product Code: OMP Regulatory Class: II Review Panel: General & Plastic Surgery
Predicate Device Information	K172145 Manufacturer: Medela AG Device Name: Invia Liberty NPWT system The predicate device has not been subject to a design-related recall.

Device Description

The Invia Ease Negative Pressure Wound Therapy (NPWT) System is a suction pump designed to help promote wound healing through Negative Pressure Wound Therapy (NPWT). The Invia Ease pump is reusable and portable pump intended to be used in acute, extended and home care settings.

The Invia Ease pump provides adjustable negative pressure with constant and intermittent therapy modes. Invia Ease NPWT System comprises the Invia Ease pump and the following accessories: Invia Ease canisters with integrated tubing, Invia Ease carrying case, Invia Ease handle, Invia Ease IV pole/ bed holder, and Invia Ease charger US.

The Invia Ease user interface includes two tactile buttons: an on/off button on the side of the pump and a mute button on the top of the pump. The pump is also equipped with a large touchscreen display on top of the pump, a status indicator bar on the front-side of the pump, which wraps around the side of the pump, as well as a charging port below the on/off button. Optical status of the pump is provided on the touchscreen and acoustic notifications are also used.

The pump is used with 300 ml, 500 ml and 1000 ml canisters that include a release button and canister tubing with Quick-Connector. The pump is compatible with Invia dressings (NPWT dressings from Medela AG) that interface via the Quick-Connector.

Invia Ease NPWT system is intended to be used in conjunction with the Invia dressings only.

Indications for Use

The Invia Ease Negative Pressure Wound Therapy (NPWT) System 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 exudates and infectious material.

When used on closed surgical incisions, the Invia Ease NPWT System 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 (NPWT).

The Invia Ease NPWT System is intended for use in acute, extended and home care settings.

The Invia Ease NPWT System is appropriate for the following indications:

- Acute or subacute 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

The Invia Ease Negative Pressure Wound Therapy (NPWT) System is a modified version of the Invia Liberty NPWT System, which was most recently cleared in K172145.

The Invia Ease NPWT pump has the same intended use, similar indications for use, and has equivalent fundamental technology as the legally marketed predicate device to which substantial equivalency is claimed.

Both Invia Ease NPWT System and Invia Liberty use an equivalent suction aggregate to create the necessary vacuum in the same manner and provide same therapy modes: continuous and intermittent.

Characteristic	Invia Liberty NPWT System (Predicate Device K172145)	Invia Ease NPWT System (Subject Device K214112)	Comment
Product code	OMP	OMP	Same
Indications for Use	The Invia Liberty Negative Pressure Wound Therapy (NPWT) system 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 Liberty NPWT system 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 Ease Negative Pressure Wound Therapy (NPWT) system 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 exudates and infectious material. When used on closed surgical incisions, the Invia Ease NPWT system 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.	Equivalent. The use environment is added, but it is already included in the Instructions for Use of the predicate device

Characteristic	Invia Liberty NPWT System (Predicate Device K172145)	Invia Ease NPWT System (Subject Device K214112)	Comment
	The Invia Liberty NPWT system is appropriate for use for the following indications: - Acute or subacute wounds - Chronic wounds - Dehisced wounds - Pressure ulcers - Diabetic/Neuropathic ulcers - Venous insufficiency ulcers - Traumatic wounds - Partial thickness burns - Flaps and grafts - Closed surgical incisions	The Invia Ease NPWT system is intended for use in acute, extended and home care settings. The Invia Ease NPWT System is appropriate for the following indications: - Acute or subacute wounds - Chronic wounds - Dehisced wounds - Pressure ulcers - Diabetic/Neuropathic ulcers - Venous insufficiency ulcers - Traumatic wounds - Partial thickness burns - Flaps and grafts - Closed surgical incisions	
Contra-indications	- 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	- Necrotic tissue with eschar present - Untreated osteomyelitis - Non-enteric and unexplored fistulas - Malignancy in the 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	Similar
Intended Use	Negative Pressure Wound Therapy	Negative Pressure Wound Therapy	Same
Patient population	Adult - multiple patient	Adult - multiple patient	Same
Environment of Use	Acute, extended and home care settings	Acute, extended and home care settings	Same
Weight	1.0 kg	1.1 kg	Similar
Dimensions (l x w x h)	170 x 90 x 150 (without canister) 290 x 95 x 235 mm (with 300 ml canister)	175 x 90 x 125mm (without canister) 203 x 90 x125 (with 300 ml canister)	Similar

Characteristic	Invia Liberty NPWT System (Predicate Device K172145)	Invia Ease NPWT System (Subject Device K214112)	Comment
Standard safety device	Bacteria and overflow protection filter	Bacteria and overflow protection filter	Same
Useful Life	4000 hours	2000 hours	Similar. Both devices provide sufficient life for clinical use.
Software	Embedded	Embedded	Same
IP Protection class	IP33	IP22	Similar. Both devices provide adequate protection from ingress of dust or water.
Protection type	BF	BF	Same
Operating ambient temperatures	+5 °C to +40°C	+5°C to +40°C	Same
Operating ambient humidity	15…93% RH	15 to 90% RH (non-condensing)	Similar. Both devices meet IEC 60601 standards
Canister capacity	300 ml 800 ml	300 ml 500 ml 1000 ml	Similar. Both devices offer multiple canister sizes to meet market needs.
User Control	Five button keypad (power and arrow keys to navigate menus)	Mute button, On/Off Button and touch screen	Similar. Both devices provide user controls for similar functions.
Visual indicator	LCD display	LED Light indicator status	Similar

Characteristic	Invia Liberty NPWT System (Predicate Device K172145)	Invia Ease NPWT System (Subject Device K214112)	Comment
Audio indicator	Low battery Tube flushing Loss of negative pressure	"Low priority" alarms: – Battery low – Temperature high – No canister detected – Pump in wrong position "Medium priority" alarms: – Pause reminder – Battery empty – Internal temperature exceeded – High leakage – Blockage – Canister full – Defective charger – Pump error	Similar. The subject device's approach to audio indicators uses more modern technology and meets IEC 60601-1-8 alarm standard for Low and Medium priority alarms.
Max. vacuum	-200 mmHg / -27 KPa	-200 mmHg / -27 KPa	Same
Min. vacuum	-40 mmHg / -5.3 KPa	-40 mmHg / -5.3 KPa	Same
Vacuum regulation type	Electric vacuum regulator controlled by Software	Electric vacuum regulator controlled by Software	Same
Vacuum gauge type	Electric vacuum sensor, digital dial	Electric vacuum sensor, digital dial	Same
Therapy modes	Continuous & intermittent	Continuous & intermittent	Same
Air Flushing	Adaptive air flush when a sensory threshold is reached.	Adaptive air flush when a sensory threshold is reached	Same
Blockage Detection	An acoustic signal will sound and a blockage symbol will appear on the display when the Invia Liberty NPWT pump detects a blockage in tubing.	An acoustic signal will sound and a blockage symbol will appear on the touch screen.	Same
Power Source – Direct Plug-in	Switching Power Supply • Input: 100-240VAC, 50/60Hz, 0.8A max. • Output: 12VDC, 2A (Max) • Off the Shelf plug connection to pump	Switching Power Supply • Input: 100-240VAC, 50/60Hz, 0.8A max. • Output: 12VDC, 2A (Max) • Custom magnetic connection to pump	Similar

Characteristic	Invia Liberty NPWT System (Predicate Device K172145)	Invia Ease NPWT System (Subject Device K214112)	Comment
Power Source – Internal Battery	Rechargeable Li-Ion battery (2 cells) 7.4VDC – 2500mAh	Rechargeable Li-Ion battery (4 cells) 7.2VDC – 5000mAh	Similar
Electrical Safety	Meets IEC 60601-1 Standard	Meets IEC 60601-1 Standard	Same
Electromagnetic Compatibility	Meets IEC 6060-1-2 Standard	Meets IEC 6060-1-2 Standard	Same
Electrical Insulation Class	Class II (double insulated)	Class II (double insulated)	Same
Compatible Dressings	Invia Foam Dressing Kit with FitPad - s/m/l/xl (3 pcs) (087.6221/22/23/24) - s/m/l (15 pcs) (087.6225/26/27) Invia Gauze Dressing Kit with FitPad - med/large (3 pcs) (087.7170/71) - med (15 pcs) (087.7172) Invia FitPad (sterile) (087.0028) Invia Transparent Film (087.0030) Invia Abdominal Dressing Kit (087.6250) Invia Silverlon NPWT Antimicrobial Wound Contact Dressing, - 10 x 12 cm (US) (087.7001) - 12 x 20 cm (US) (087.7002) Invia White Foam NPWT, PVA foam dressing - small (087.6303) - large (087.6304)	Invia Foam Dressing Kit with FitPad - s/m/l/xl (3 pcs) (087.6221/22/23/24) - s/m/l (15 pcs) (087.6225/26/27) Invia Gauze Dressing Kit with FitPad - med/large (3 pcs) (087.7170/71) - med (15 pcs) (087.7172) Invia FitPad (sterile) (087.0028) Invia Transparent Film (087.0030) Invia Abdominal Dressing Kit (087.6250) Invia Silverlon NPWT Antimicrobial Wound Contact Dressing, - 10 x 12 cm (US) (087.7001) - 12 x 20 cm (US) (087.7002) Invia White Foam NPWT, PVA foam dressing - small (087.6303) - large (087.6304)	Same

Summary of Non-Clinical Tests

The Invia Ease NPWT System complies with voluntary standards for sterilization, biocompatibility, electrical safety, electromagnetic compatibility, use in acute, extended and home care settings 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.
- Testing in accordance with the following standards and regulations:
    - ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, Medical Electrical Equipment - Part 1: General requirements for Basic Safety and Essential Performance.
    - IEC 60601-1-6; 2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
    - IEC 60601-1-8: 2020 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
    - IEC 60601-11:2015, Medical Electrical Equipment - Part 1-11: General requirements for Basic Safety and Essential Performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
    - IEC 60601-1-2:2014 (Edition 4.0), Medical electrical equipment - Part 1-2: General requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests.
    - AIM Standard 7351731 Rev. 2.00 2017-02-23, Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard
    - ANSI IEEE C63.27-2017, American National Standard for Evaluation of Wireless Coexistence
    - IEC 62133-2 Edition 1.0 2017-02, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
    - ISO 10079-1 Third Edition 2015-11-01, Medical suction equipment - Part 1: Electrically powered suction equipment [Including: Amendment 1 (2018)]
    - FCC, 47 C.F.R. Part 15 Subparts B and C
- Sterilization and shelf-life information in accordance with the FDA Guidance document *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile*.
- A biocompatibility evaluation was completed according to the 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"* and draft guidance document *Select Updates for Biocompatibility of Certain Devices in Contact with Intact Skin*.

The subject device was evaluated for cytotoxicity, intracutaneous reactivity, skin sensitization:

Component	Biocompatibility Test	ISO Standard
Canister	Cytotoxicity	ISO 10993-5
	Intracutaneous reactivity	ISO 10993-10
	Sensitization	ISO 10993-10
Tubing	Cytotoxicity	ISO 10993-5
	Intracutaneous reactivity	ISO 10993-10
	Sensitization	ISO 10993-10

- The software/firmware verification and validation were provided in accordance with the FDA Guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*. The software for the subject devices was considered as a "Moderate" level of concern, since prior to mitigations of hazards, failure of the software could lead to minor injury, such as pain. Additionally, a cybersecurity evaluation was performed according to the FDA Guidance document *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*.
- The usability testing was conducted to validate the use in acute, extended and home care settings in accordance with the recommendations of the FDA guidance document *Applying Human Factors and Usability Engineering to Medical Devices*
- Bench testing was conducted to check that specifications were met under conditions of Intermittent as well as Constant therapy modes with power supplied from both the internal battery and external AC/DC power adaptor and with each compatible dressing kit.

List of bench testing performed
Performance Test of Invia Ease with all Medela AG cleared dressing kits
Vacuum Performance Test (with leak)
Noise Test
Pump Endurance Test
Pump Tightness Test
IP Protection - IP22 Test
Filter Test
Battery Run time Test
Display Stability Test
Transport Validation Invia Ease Pump & Accessories

Summary of Clinical Tests

Clinical testing was not needed to support substantial equivalence.

Conclusions

The tests demonstrate that the subject device is substantially equivalent to the legally marketed predicate device in terms of safety and effectiveness.