DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 1, 2016

Medela Ag
% Adrienne Lenz
Member
Pathway Regulatory Consulting, LLC
W324s3649 County Road E
Dousman, Wisconsin 53118

Re: K161128
Trade/Device Name: Invia Motion-endure Negative Pressure Wound Therapy System, Invia Motion-7-120 Days Negative Pressure Wound Therapy System, Invia Motion Canister/tubing Set 0.151, Invia Motion Carrying Case, Power Supply
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: October 26, 2016
Received: October 31, 2016

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. 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" (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 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161128

Device Name
Invia Motion Negative Pressure Wound Therapy System
Invia Motion - Endure, Invia Motion – 120 days, Invia Motion – 60 days, Invia Motion – 30 days, Invia Motion – 15 days, Invia Motion – 7 days, Invia Motion Canister/ Tubing Set 0.15l, Invia Motion Carrying Case, Charger

Indications for Use *(Describe)*
The Invia Motion Negative Pressure Wound Therapy (NPWT) system is indicated for patients who would benefit from a suction device (NPWT) 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 Motion 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

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

K161128

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

DATE: October 26, 2016

SUBMITTER:

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Vice President Quality Assurance
Medela AG

DEVICE:

TRADE NAME: Invia Motion

COMMON/USUAL NAME: Negative Pressure Wound Therapy System

CLASSIFICATION NAMES: 878.4780 Powered Suction Pump

PRODUCT CODE: OMP

PREDICATE DEVICE(S):

K113678 Invia Motion Negative Pressure Wound Therapy System
K141926 Invia Endure Negative Pressure Wound Therapy System

DEVICE DESCRIPTION:

The Invia Motion Negative Pressure Wound Therapy (NPWT) system is available in six versions with different run times:

- 7 Days
- 15 Days
- 30 Days
- 60 Days
- 120 Days
- Endure: lasts for one patients entire therapy, max. 3 years

The Invia Motion Negative Pressure Wound Therapy system is comprised of the Invia Motion pump, Invia Motion Canister/Tubing Set 0.15l, Invia Motion Power Supply and Invia Motion Carrying Case. Additionally, several separately cleared accessories and kits are compatible with the Invia Motion NPWT System.

The Invia Motion pump is an AC/DC powered, maintenance-free aspirator for Negative Pressure Wound Therapy which incorporates a DC-motor with membrane aggregate power actuation in its housing. A user friendly MMI (man machine interface) facilitates use and information handling. The Invia Motion NPWT pump provides treatment status through a display and acoustic signals. It is a single patient use pump which provides continuous or intermittent operation and multiple negative pressure selection options. The Invia Motion NPWT pump is portable and can be operated using a rechargeable battery. Acoustic and optical signals are triggered for variances from the set values as well as for faults.

INTENDED USE:

The Invia Motion Negative Pressure Wound Therapy (NPWT) system is indicated for patients who would benefit from a suction device (NPWT) 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 Motion 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

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

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

The Invia Motion Negative Pressure Wound Therapy System uses the same fundamental technology as the predicate pumps for most features. With the exception of minor wording changes to align the indications for use with other Medela NPWT products, the indications for use and the indicated wound types are the same as those of the predicate devices. These changes do not alter the intended use of the device.

The main differences between the Invia Motion NPWT System and the predicate devices are:

- New Invia Motion Canister/Tubing Set 0.15l with double lumen tubing, optimized tubing dimensions with no narrow points at the connector and quick connector coupling. The smaller lumen (air flush tubing) flushes air to remove exudate from the larger lumen. Larger lumen (suction tubing) removes the fluid from the wound into the canister. The quick connector ensures that the connection is easy to connect / disconnect and tight.
- An improved flush function through the entire tubing from the canister down to the wound which allows pressure measured at the pump to correspond to pressure at the wound site and blockage detection
- Visual and acoustic notifications if the pump detects blockage in the tubing from the canister to the wound dressing, and
- A battery compartment door so the battery can be disposed of separately

The table below summarizes the key differences between the Invia Motion NPWT System and the predicate devices.

	Invia Endure (K141926)	Invia Motion (K113678)	Invia Motion
Indications for Use	The portable Medela Invia Endure Negative Pressure Wound Therapy (NPWT) system is indicated to create 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. It is intended for the use in hospitals, clinics, Long Term Care (LTC) and Home Care (HC) settings on adult patients with chronic, acute, subacute, traumatic, dehisced wounds, partial-thickness burns, ulcers (such as diabetic, neuropathic, pressure or venous insufficiency), flaps and grafts.	The portable Medela® Invia Motion negative pressure wound therapy (NPWT) system is indicated to create 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. It is intended for the use in hospitals, clinics, Long Term Care (LTC) and Home Care (HC) settings on adult patients with chronic, acute, subacute, traumatic, dehisced wounds, partial-thickness burns, ulcers (diabetic, neuropathic, pressure or venous insufficiency), flaps and grafts.	The Invia Motion Negative Pressure Wound Therapy (NPWT) system is indicated for patients who would benefit from a suction device (NPWT) 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 Motion 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

	Invia Endure (K141926)	Invia Motion (K113678)	Invia Motion
Contra-indications	• Malignancy in the wound • Untreated osteomyelitis • Non-enteric and unexplored fistulas • Necrotic tissue with eschar present • Exposed vasculature • Exposed nerves • Exposed anastomotic site of blood vessels or bypasses • Exposed organs	• Malignancy in the wound • Untreated osteomyelitis • Non-enteric and unexplored fistulas • Necrotic tissue with eschar present • 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 • Exposed vasculature • Exposed nerves • Exposed anastomotic site of blood vessels or bypasses • Exposed organs
Patient Population	Adults – single patient	Adults – single patient	Adults – single patient
Useful Life	3 years	60 days	Up to 3 years with different run times available
Environment of Use	Hospitals, Clinics, Long Term Care (LTC) and Home Care (HC) settings	Hospitals, Clinics, Long Term Care (LTC) and Home Care (HC) settings	Hospitals, Clinics, Long Term Care (LTC) and Home Care (HC) settings
User Control	Four button keypad (on/off, pressure setting, constant/intermittent mode, Mute acoustic signal / Info used pump time)	Four button keypad (on/off, pressure setting, constant/intermittent mode, Mute acoustic signal / Info used pump time)	Four button keypad (on/off, pressure setting, constant/intermittent mode, Mute acoustic signal / Info used pump time)
Audio Indicator	Information signals as Leakage, Canister full, Battery low, Battery discharged, internal fault, end of Lifetime	Information signals as Leakage, Canister full, Battery low, Battery discharged, internal fault, end of Lifetime	Information signals as Leakage, Canister full, Blockage, Battery low, Battery discharged, Battery missing, Internal fault, end of Lifetime

	Invia Endure (K141926)	**Invia Motion (K113678)**	**Invia Motion**
Canister/ Tubing Set	Disposable Canister/Tubing Set 0.15l with single lumen tubing directly connected to the canister. To connect the tubing connector to the wound drain tubing there is a cone connector that fits to the wound drain tubing.	Disposable Canister/Tubing Set 0.15l with single lumen tubing directly connected to the canister. To connect the tubing connector to the wound drain tubing there is a cone connector that fits to the wound drain tubing.	Disposable Canister/Tubing Set 0.15l with double lumen tubing is directly connected to the canister. The pump tubing and dressing tubing are connected via the Quick Connect.
Power Supply	100-240 Vac 50/60Hz 8W	100-240 Vac 50/60Hz 8W	100-240 Vac 50/60Hz 8W
Carrying Case	Case with shoulder or belt strap	Case with shoulder or belt strap	Case with shoulder or belt strap
Y-Connector	Single lumen Y-connector	Single lumen Y-connector	Double lumen Y-connector with quick connector
Drain Adapter	Not applicable	Not applicable	Drain adapter with quick connector
Suction capacity liters/min	1 l/min	1 l/min	1 l/min
Max. vacuum mmHg/kPa	-175mmHg -23kPa	-175mmHg -23kPa	-175mmHg -23kPa
Min. vacuum mmHg/kPa	-60mmHg -8kPa	-60mmHg -8kPa	-40mmHg -5kPa
Vacuum Regulation type	Electric vacuum regulator	Electric vacuum regulator	Electric vacuum regulator
Vacuum Gauge type	Electric vacuum sensor	Electric vacuum sensor	Electric vacuum sensor
Therapy modes	Continuous & Intermittent	Continuous & Intermittent	Continuous & Intermittent
Air Flush	Not applicable	Not applicable	Adaptive air flush when a sensory threshold is reached.

	Invia Endure (K141926)	Invia Motion (K113678)	Invia Motion
Blockage Detection	Not applicable	Not applicable	An acoustic signal will sound and a blockage symbol will appear on the display when the Invia Motion NPWT pump detects a blockage in tubing.
Runtime	Not applicable	60 days	Invia Motion – Endure, not applicable Other runtimes as stated in model name: Invia Motion – 120 Days Invia Motion – 60 Days Invia Motion – 30 Days Invia Motion – 15 Days Invia Motion – 7 Days
Battery type	NiMH	NiMH	NiMH
IP-Protection	IP-22	IP-22	IP-22
Type	BF	BF	BF
Operating Ambient Temperatures	+5…+40°C	+5…+40°C	+5…+40°C
Operating Ambient Humidity	15…93% R.L.	15…93% R.L.	15…93% R.L.
Canister capacity [ml]	150ml	150ml	150ml
Weight [kg]	0.45kg	0.45kg	0.47 - 0.48kg
Dimensions mm	173x96x51mm (0.15l canister)	173x96x51mm (0.15l canister)	176x97x52mm (0.15l canister)
Standard Safety device	Bacteria / overflow / protection filter	Bacteria / overflow / protection filter	Bacteria / overflow / protection filter

	Invia Endure (K141926)	Invia Motion (K113678)	Invia Motion
NPWT Kits	Multiple available and sold separately	Multiple available and sold separately	Multiple available and sold separately
510(k) clearance for NPWT Kits	K113678 for Invia kits K122132 for Avance kits	K113678 for Invia kits K122132 for Avance kits	K113678 for Invia gauze kits K151261 Invia Foam Dressing Kit with ESI

SUMMARY OF NON-CLINICAL TESTS:

The Invia Motion NPWT System complies with voluntary standards for electrical safety, electromagnetic compatibility, and use in the home healthcare environment. The following were completed in support of the substantial equivalence determination:

- Risk Analysis developed in accordance with ISO 14971: 2007.
- Software verification and validation testing.
- Electrical safety and electromagnetic compatibility testing per IEC 60601-1:2005 (3rd Edition) with US deviations per AAMI/ANSI ES60601-1:2005 standard and IEC 60601-1-2: 2014 (4th edition) standards, respectively
- Safety testing for use in the home per IEC 60601-1-11: 2015 (2nd edition) standard
- Usability was evaluated according to IEC 60601-1-6: 2013 (3rd Edition) and IEC 62366: 2015. A usability validation study was conducted to demonstrate the user can correctly and safely use the Invia Motion NPWT system.
- Performance testing was completed to demonstrate that the pressure at the wound is correct using a wound model and simulated wound exudates. These tests demonstrated a steady rise of the negative pressure at test onset to the set vacuum level, a uniform and constant level throughout the test period, that the vacuum level corresponds to the selected set vacuum level of the pump, and that the volume of fluid dispensed to the wound model corresponded to the volume of fluid removed from the wound model and collected into the pump canister. Constant fluid removal was observed with no evidence of fluid accumulation in the wound model seen.
- Tests to validate the proper functioning of the leakage notifications were performed using a wound model and simulated wound exudates. The test results confirm the blockage and leakage notification signals behave correctly.

- Bench Testing verified a motor-runtime of 3000h, which corresponds to a 3-year lifetime. Confirmation of the limited runtime for models other than the Endure was performed as part of the software testing.
- The sterilization process for the Invia Motion canister/tubing was validated according to ISO 11135-1:2007 including Annex A (Biological Indicators) and B (Overkill Approach). Validation was carried out by the following cycles
    - Product Profile (pre-conditioning room, sterilizer chamber, de-gas cell) included in the Half Cycle
    - Sub-lethal Cycle (Biological Indicators, Product Sterility and Bio Burden)
    - Half cycle (Biological Indicators and Bacteriostasis & Fungistasis)
    - Routine Cycles (Residuals EO and ECH)
- Accelerated aging tests were performed to support this 5-year shelf life of the canister/tubing set via methods published in FDA recognized standard ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- Biocompatibility Testing was performed according to ISO 10993-1: 2009 at NAMSA, an accredited testing laboratory. The studies have been conducted according to the Good Laboratory Practice (GLP) requirements. The Canister/Tubing set was tested according to the following conditions according to FDA guidance from May 1, 1995 and ISO 10993-1: 2009:
    - Cytotoxicity 10993-5: 2009
    - Sensitization 10993-10: 2010
    - Irritation or intracutaneous reactivity 10993-10: 2010
    - Systemic toxicity (acute) 10993-11: 2006

SUMMARY OF CLINICAL TESTS:

Clinical testing was not required to demonstrate the substantial equivalence of the Invia Motion Negative Pressure Wound Therapy System to its predicate device.

CONCLUSION:

The differences between the Invia Motion Negative Pressure Wound Therapy System and its predicate devices 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 Motion Negative Pressure Wound Therapy System is substantially equivalent to the legally marketed predicate devices.