Medela AG
Invia Motion Negative Pressure Wound Therapy System

510(k) Summary

OCT 1 2012

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

DATE: August 30, 2012

SUBMITTER:

Medela AG
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PRIMARY CONTACT PERSON:

Adrienne Lenz, RAC
Member
Pathway Regulatory Consulting, LLC
T 262-290-0023

SECONDARY CONTACT PERSON:

Markus Bütler
Vice President Quality Management and Regulatory Affairs
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):

K080357 Medela Invia Wound Therapy

K083375 Smith and Nephew Renasys Go

K093526 KCI USA, Inc. V.A.C.Via Negative Pressure Wound Therapy System

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DEVICE DESCRIPTION:

The Medela Invia Motion Negative Pressure Wound Therapy (NPWT) System is comprised of the Invia Motion NPWT Pump, canister/tubing set, power supply, carrying case, patient and user instructions, and Invia NPWT kits. The INVIA Motion is also compatible with Avance NPWT kits manufactured by Mölnlyke Healthcare.

Invia Motion NPWT pump is a suction pump for Negative Pressure Wound Therapy with an optical and acoustic status display. Invia Motion NPWT pump is a single patient use pump for continuous or intermittent operation and has a lifetime of 60 days.

Invia Motion NPWT pump is portable and can be operated independent of the electrical Invia Motion power supply due to a rechargeable battery. Acoustic and optical signals are triggered for variances from the set values as well as for faults.

Invia Motion NPWT system is intended for use in a home or other health care facility by medical personnel or trained lay users adhering to the instructions for use. The user may not be hard of hearing or deaf and must have normal visual acuity.

INTENDED USE:

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 (such as diabetic, neuropathic, pressure or venous insufficiency), 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 Invia Wound Therapy system for most features. The indications for use of Invia Motion are the same as KCI's V.A.C Via NPWT System. Invia Motion is similar to the predicate devices in its indications for use, contra-indications and patient population. The user interface is also similar to the predicated devices. The main difference is in the volume of the canister, which is reduced but still sufficient for the expected daily volumes. The smaller size improves mobility. The pump is also intended for a single patient and has a useful life of 60 days, which is sufficient for single patient use.

SUMMARY OF NON-CLINICAL TESTS:

The Invia Motion Negative Pressure Wound Therapy System complies with voluntary standards for electrical safety, electromagnetic compatibility, biocompatibility, sterilization and use in the

home healthcare environment. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Software Validation
- Electrical safety and electromagnetic compatibility testing per IEC 60601-1 and IEC 60601-1-2 standards, respectively
- Testing for use in the home healthcare environment per IEC 60601-1-11
- Biocompatibility testing per ISO 10993-1 standards
- Sterilization validation
- Usability testing was conducted and demonstrated that the production versions of the labeling and device design provided first-time Invia® Motion™ NPWT System end-users with clear, concise instructions and the ability to avoid patterns of preventable use errors or difficulties when operating the device that could result in harms to the product end-users. Fifteen (15) Health Care Professionals (HCP) and 15 patient lay users (LU) were enrolled to participate in the study, which was conducted in the United States with English speakers. Representative product training for their user-population was provided and a training decay time was included prior to the evaluation. All 15 LU end-users (100%) successfully completed their target population use tasks by performing routine maintenance of the device and identifying and troubleshooting device acoustic and optical display signals to maintain safe and effective performance of the device. All close-calls and use-errors observed during the HCP use-scenarios and sub-tasks were resolved during the evaluation and did not affect patient safety.
- Bench Testing demonstrated that the design specifications were met, including device performance and reliability. Comparison of performance of the Invia Motion with its compatible NPWT kits to the predicate device concluded that the Invia Motion is equivalent in maintaining set pressures across the specification range and in removing fluids in simulated wounds.

SUMMARY OF CLINICAL TESTS:

The Invia Motion Negative Pressure Wound Therapy System has not been the subject of clinical testing. A clinical evaluation of published literature has been conducted for Invia Motion.

CONCLUSION:

Medela AG considers the Invia Motion Negative Pressure Wound Therapy System to be as safe, as effective, and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 1 2012

Medela AG
% Pathway Regulatory Consulting, LLC
Ms. Adrienne Lenz, RAC
W324S3649 County Road E
Dousman, Wisconsin 53118

Re: K113678
Trade/Device Name: Invia Motion Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: OMP
Dated: August 30, 2012
Received: September 04, 2012

Dear Ms. 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.

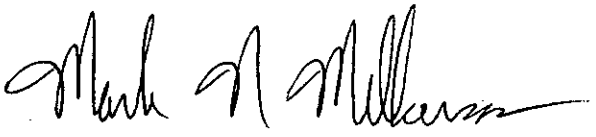
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K113678

Device Name: Invia Motion Negative Pressure Wound Therapy System

Indications for Use:

Invia Motion NPWT System:

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 (such as diabetic, neuropathic, pressure or venous insufficiency), flaps and grafts.

Prescription Use_X___ AND/OR Over-The-Counter Use__

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113678