DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

October 7, 2015

Medela AG
% E.J. Smith
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K151261
Trade/Device Name: Invia Foam Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Power suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: September 10, 2015
Received: September 11, 2015

Dear Mr. Smith:

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" (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 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 on last page.

510(k) Number *(if known)*
K151261

Device Name
Invia Foam Dressing Kit

Indications for Use *(Describe)*
The Invia Foam Dressing Kit is intended to be used in conjunction with the Invia Motion and Invia Liberty NPWT Systems to deliver negative pressure wound therapy to the wound. The Invia Foam Dressing Kit is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by removal of excess exudates, infectious material and tissue debris..

Invia Foam Dressing Kit is appropriate for use on the following wounds:
- Pressure Ulcers
- Diabetic/Neuropathic Ulcers
- Venous Insufficiency Ulcers
- Traumatic Wounds
- Post-operative and Dehisced Surgical Wounds
- Skin 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

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

SUBMITTER

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PRIMARY CONTACT PERSON

Orlando Antunes
Vice President Regulatory Affairs

Date Prepared: October 6, 2015

DEVICE NAME

Trade Name:	Invia Foam Dressing Kit
Common/Usual Name:	Foam Dressing
Classification Name:	Negative Pressure Wound Therapy Powered Suction Pump and Accessories
Regulation Number:	21 CFR 878.4780
Product Code:	OMP
Device Class:	Class II
Review Panel:	General & Plastic Surgery

PREDICATE DEVICE

Manufacturer	Brand Name	510(k) Number
Kevo Medical Supplies	Kevo NPWT - αHemo30 Foam Dressing Kit	K113199

DEVICE DESCRIPTION

The Invia Foam Dressing Kit consists of a Foam Pad, a Connection Tube including a Ported Pad and Thin Film Drapes (1-3 pieces depending on the Kit size). The Foam Pad is manufactured using a reticulated flexible polyester and polyurethane hydrophobic foam material. The single-use dressing is housed in a Tyvek/Mylar Pouch which is sterilized using EtO, Ethylene Oxide.

Catalog Number	Description	Size
087.6111	Invia Foam Dressing Kit 100mm x 80mm x 30mm	Small
087.6112	Invia Foam Dressing Kit 125mm x 190mm x 30mm	Medium
087.6113	Invia Foam Dressing Kit 150mm 250mm x 30mm	Large

DEVICE INTENDED USE

The Invia Foam Dressing Kit is intended to be used in conjunction with the Invia Motion and Invia Liberty NPWT Systems to deliver negative pressure wound therapy to the wound. The Invia Foam Dressing Kit is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by removal of excess exudates, infectious material and tissue debris.

Invia Foam Dressing Kit is appropriate for use on the following wounds:

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DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Discussion of Technological Characteristics

The Invia Foam Dressing Kit and the predicate device (Kevo NPWT - αHemo30 Foam Dressing Kit (K113199) have the identical indications for use, both use a reticulated flexible polyether based polyurethane foam dressing material, are hydrophobic, are provided sterile, offer small, medium and large sizes of the exact same dimensions, and are used for negative pressure wound therapy.

Non-Clinical Performance Data

The following non-clinical tests were conducted:

- ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
- ASTM F756-08 Standard Practice for Assessment of Hemolytic Properties of Materials
- USP 37-NF:32 <85> Bacterial Endotoxins Tests
- USP 37-NF: 32 <71> Sterility Tests
- ISO 10993-7 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals
- ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO 11737-1 Sterilization of Medical Devices – Microbiological Methods – Part 1: Determination of the Population of Microorganisms
- ISO 11737-2 Sterilization of Medical Devices – Microbiological Methods – Part 2: Tests for Sterility Performed in the Definition, Validation and Maintenance of a Sterilization Process

Comparative Bench Test

A reference and comparison study was performed to support substantial equivalence of the Invia Foam Dressing Kit's using the Genadyne A4 XLR8 Wound Vacuum System and comparing the results to those of the Medela Invia Liberty and Medela Invia Motion NPWT Suction Pumps.

Testing was performed on the 3 NPWT Suctions Pumps in the constant and intermittent modes using pressure setting ranges of -60 - -200mmHg over a 73 hours period. Medela also conducted Pressure Distribution and Alarm Functionally tests. According to the comparative performance testing the Genadyne XLR8 NPWT Suction Pump and the Medela Invia Liberty and Medela Invia Motion NPWT Suction Pumps provided almost identical performance and functionality when used in conjunction with the Invia Foam Dressing Kit and demonstrated substantial equivalence.

CLINICAL STUDY

No clinical study was conducted.

CONCLUSION

Using the Invia Foam Dressing Kit in conjunction with the Medela Invia Liberty and Medela Invia Motion NPWT Pumps versus the Genadyne A4 XLR8 NPWT Pump produced similar safety and effectiveness results as a negative pressure wound therapy device. The Invia Foam Dressing Kit has the identical intended use, fundamental scientific technology, components, sterilization method, sterile packaging and production processes found in the predicate kit and is substantially equivalent to the legally marketed predicate device.