May 9, 2018

Medela AG
% Adrienne Lenz
Hyman, Phelps, & McNamara, P.C.
700 Thirteenth Street NW Suite 1200
Washington, DC 20005-5929 US

Re: K172145
Trade/Device Name: Invia Foam Dressing Kits With FitPad, 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 Liberty Negative Pressure Wound Therapy System, Invia Gauze Dressing Kits with FitPad
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: April 6, 2018
Received: April 9, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172145

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

Indications for Use *(Describe)*
The Invia Motion 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 Motion 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 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
– 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.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*
K172145

Device Name
Invia Liberty Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
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 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

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)

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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)*
K172145

Device Name
Invia Foam Dressing Kit with FitPad

Indications for Use *(Describe)*
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 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 Foam Dressing Kit with FitPad 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

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)

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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)*
K172145

Device Name
Invia Gauze Dressing Kit with FitPad

Indications for Use *(Describe)*
The Invia Gauze 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 Gauze Dressing Kit with FitPad 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 Gauze Dressing Kit with FitPad 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

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)

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K172145 510(k) Summary

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

DATE: May 8, 2018

SUBMITTER:

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Phone: +41-41-7695151-651
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PRIMARY CONTACT PERSON:

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SECONDARY CONTACT PERSON:

Judith Bernardo
Global RA Director & Team Leader Global RA Healthcare
Medela AG

DEVICE:

TRADE 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 Liberty Negative Pressure Wound Therapy System, Invia Foam Dressing Kit with FitPad, Invia Gauze Dressing Kit with FitPad

510(K) NUMBER: K172145

COMMON/USUAL NAME: Negative Pressure Wound Therapy System

CLASSIFICATION NAMES: 878.4780 Powered Suction Pump

CLASS: CLASS II

PRODUCT CODE: OMP

PREDICATE DEVICE(S):

Invia Motion Negative Pressure Wound Therapy System (all models) (K161128)
Invia Liberty Negative Pressure Wound Therapy System (K142626)
Invia Foam Dressing Kits with FitPad (K170088)
ActiV.A.C. Therapy Unit (K120033)
VA.C Therapy System using Granufoam Dressing (K120033)

DEVICE DESCRIPTION:

The labeling of the Invia Motion Negative Pressure Wound Therapy (NPWT) System, Invia Liberty NPWT System, Invia Foam Dressing Kit with FitPad and Invia Gauze Dressing Kit with FitPad has been modified to expand the indications for use to include closed surgical incisions. When used on closed surgical incisions, the devices are 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.

INVIA MOTION NPWT SYSTEM

The Invia Motion Negative Pressure Wound Therapy system is available in six versions with different run times. The Invia Motion NPWT pump is a suction pump for Negative Pressure Wound Therapy that provides therapy status through a display and acoustic signals. The Invia Motion NPWT pump 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.

The Invia Motion suction 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.

INVIA LIBERTY NPWT SYSTEM

The Invia Liberty NPWT pump is a suction pump for Negative Pressure Wound Therapy that provides therapy status through a display and acoustic signals. The Invia Liberty NPWT pump is a multi-patient use pump which provides continuous or intermittent operation and multiple negative pressure selection options. The Invia Liberty 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.

The Invia Liberty suction 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.

A variety Negative Pressure Wound Therapy Kits are available for use with the Invia Motion and Invia Liberty NPWT Systems, including the Invia Foam Dressing Kits with FitPad.

INVIA FOAM AND GAUZE DRESSING KITS WITH FITPAD

The Invia FitPad Kit Assortment includes Foam Kits in sizes Small, Medium, Large and X-Large as well as Gauze Kits with FitPad in sizes Medium and Large. The Invia Foam and Gauze Dressing Kits with FitPad provide a double lumen suction interface (FitPad) with Quick-connector. The double lumen suction interface allows flushing down to the dressing and detection of blockage along the entire length of tubing, controlling pressure at the wound site and enabling for easy and secure connection between canister tubing and dressing tubing.

INTENDED USE:

INVIA MOTION NPWT SYSTEM

The Invia Motion 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 Motion 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 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
– Closed surgical incisions

INVIA LIBERTY NPWT SYSTEM

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 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

INVIA FOAM DRESSING KITS WITH FITPAD

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 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 Foam Dressing Kit with FitPad 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

INVIA GAUZE DRESSING KITS WITH FITPAD

The Invia Gauze 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 Gauze Dressing Kit with FitPad 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 Gauze Dressing Kit with FitPad 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

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

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

The Invia Motion NPWT System, Invia Liberty NPWT System and Invia Dressing Kits with FitPad use the same fundamental technology as the predicate versions and equivalent technology to the ActiV.A.C. Therapy Unit and Granufoam Dressing (K120033) as shown in Tables 5.1 – 5.4. The Invia Motion NPWT System, Invia Liberty NPWT System and Invia Dressing Kits with FitPad are identical to the predicate versions for all indications except the addition of closed surgical incisions. All indications, including the new indication for closed surgical incisions are the same as those of the ActiV.A.C. Therapy Unit (K120033).

Additional non-significant changes to the hardware, software, labeling and sterile packaging of the Invia Liberty NPWT System were reported.

TABLE 5.1 COMPARISON OF INVIA MOTION TO PREDICATE DEVICE

		Primary Predicate Device	**Secondary Predicate Device**
	Invia Motion	**Invia Motion (K161128)**	**ActiV.A.C. Therapy Unit (K120033)**
Indications for Use	The Invia Motion 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 Motion 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 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 – Closed surgical incisions	The Invia Motion Negative Pressure Wound Therapy (NPWT) system is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy) as it may promote 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	The ActiVAC., InfoVAC., V.AC. ATS, V.AC. Freedom, V.AC. Via, and V.A.C. Simplicity Negative Pressure Wound Therapy Systems are integrated wound management systems for use in acute, extended and home care settings. When used on open wounds, they are intended 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 exudate and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts. When used on closed surgical incisions, they are 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 exudates via the application of negative pressure wound therapy.

		Primary Predicate Device	Secondary Predicate Device
	Invia Motion	**Invia Motion (K161128)**	**ActiV.A.C. Therapy Unit (K120033)**
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	• 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	Do not place foam dressings of the V.A.C. Therapy System directly in contact with exposed blood vessels, anastomotic sites, organs or nerves. • Malignancy in the wound • Untreated osteomyelitis • Non-enteric and unexplored fistulas • Necrotic tissue with eschar present • Sensitivity to silver (V.A.C. GranuFoam Silver Dressing only)
Environment of Use	The Invia Motion NPWT system is intended for use in acute, extended and home care settings.	The Invia Motion NPWT system is intended for use in acute, extended and home care settings.	The ActiVAC., InfoVAC., V.AC. ATS, V.AC. Freedom, V.AC. Via, and V.A.C. Simplicity Negative Pressure Wound Therapy Systems are integrated wound management systems for use in acute, extended and home care settings.

		Primary Predicate Device	Secondary Predicate Device
	Invia Motion	**Invia Motion (K161128)**	**ActiV.A.C. Therapy Unit (K120033)**
User Interface	Four button keypad, LCD Display, Audio indicator, Disposable Canister/Tubing Set 150ml disposable canister with solidifier and double lumen tubing, clamp and Quick-connector,100-240 VAC 50/60 Hz 8W power supply, carrying case, Y-connector, drain adapter	Four button keypad, LCD Display, Audio indicator, Disposable Canister/Tubing Set 150ml disposable canister with solidifier and double lumen tubing, clamp and Quick-connector,100-240 VAC 50/60 Hz 8W power supply, carrying case, Y-connector, drain adapter	Power button and touch screen, Audio indicator, ActiV.A.C. 300ml Canister with Gel (1 disposable canister (sterile fluid path), tubing, clamp and connector), 100-240 VAC 50/60Hz 0.8A power supply, carrying case, Y-connector,
Specifications			
Max. vacuum mmHg/kPa	-175mmHg -23kPa	-175mmHg -23kPa	-200 mmHg
Min. vacuum mmHg/kPa	-40mmHg -5kPa	-40mmHg -5kPa	-25 mmHg
Therapy modes	Continuous & Intermittent	Continuous & Intermittent	Continuous & Intermittent
Runtime	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	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	Not applicable

		Primary Predicate Device	Secondary Predicate Device
	Invia Motion	**Invia Motion (K161128)**	**ActiV.A.C. Therapy Unit (K120033)**
IP-Protection	IP-22	IP-22	IPX0
Type	BF	BF	B
Operating Ambient Temperatures	+5…+40°C	+5…+40°C	+5…+40°C
Operating Ambient Humidity	15…93% R.L.	15…93% R.L.	0…95% R.L.
Canister capacity [ml]	150ml	150ml	300 ml
Weight [kg]	0.47 - 0.48kg	0.47 - 0.48kg	1.08 kg
Dimensions mm	176x97x52mm (with canister)	176x97x52mm (with canister)	19.3 x 15.2 x 6.49 cm

TABLE 5.2 COMPARISON OF INVIA LIBERTY TO PREDICATE DEVICES

		Primary Predicate	**Secondary Predicate**
	Invia Liberty Negative Pressure Wound Therapy System	**Invia Liberty Negative Pressure Wound Therapy System (K142626)**	**ActiV.A.C. Therapy Unit (K120033)**
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 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 Medela® Invia Liberty Negative Pressure Wound Therapy System is indicated to help promote wound healing, through means including drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.	The ActiVAC., InfoVAC., V.AC. ATS, V.AC. Freedom, V.AC. Via, and V.A.C. Simplicity Negative Pressure Wound Therapy Systems are integrated wound management systems for use in acute, extended and home care settings. When used on open wounds, they are intended 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 exudate and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts. When used on closed surgical incisions, they are 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 exudates via the application of negative pressure wound therapy.

		Primary Predicate	Secondary Predicate
	Invia Liberty Negative Pressure Wound Therapy System	**Invia Liberty Negative Pressure Wound Therapy System (K142626)**	**ActiV.A.C. Therapy Unit (K120033)**
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	– Malignancy of the wound – Untreated osteomyelitis – Unmanaged malnutrition – Non-enteric fistula – Unexplored fistula – Necrotic tissue with eschar present – Do not place Invia Wound Therapy dressing over exposed blood vessels or organs – Do not place directly over anastomoses or sutured vessels	Do not place foam dressings of the V.A.C. Therapy System directly in contact with exposed blood vessels, anastomotic sites, organs or nerves. • Malignancy in the wound • Untreated osteomyelitis • Non-enteric and unexplored fistulas • Necrotic tissue with eschar present Sensitivity to silver (V.A.C. GranuFoam Silver Dressing only)
Environment of Use	Acute, extended and home care settings	Home or other health care facility	Acute, extended and home care settings
User Interface	Five button keypad (power and arrow keys to navigate menus), LCD Display, Audio Indicator, Disposable Canister 0.8 l, 0.3 l, Quick-connector double lumen tubing set, Drain Adapter, Y-connector, 100-240 VAC 50/60Hz 20W Mains adapter, Docking station, Carrying Case, Holder with standard rail	Five button keypad (power and arrow keys to navigate menus), LCD Display, Audio Indicator, Disposable Canister 0.8 l, 0.3 l, Quick-connector double lumen tubing set, Drain Adapter, Y-connector, 100-240 VAC 50/60Hz 20W Mains adapter, Docking station, Carrying Case, Holder with standard rail	Power button and touch screen, Audio indicator, ActiV.A.C. 300ml Canister with Gel (1 disposable canister (sterile fluid path), tubing, clamp and connector), 100-240 VAC 50/60Hz 0.8A power supply, carrying case, Y-connector,
Specifications			
Max. vacuum mmHg/kPa	- 200mmHg -27kPa	- 200mmHg -27kPa	-200 mmHg
Min. vacuum mmHg/kPa	- 40mmHg -5.3kPa	- 40mmHg -5.3kPa	-25 mmHg

		Primary Predicate	Secondary Predicate
	Invia Liberty Negative Pressure Wound Therapy System	**Invia Liberty Negative Pressure Wound Therapy System (K142626)**	**ActiV.A.C. Therapy Unit (K120033)**
Therapy modes	Continuous & Intermittent	Continuous & Intermittent	Continuous & Intermittent
IP-Protection	IP-33	IP-33	IPX0
Type	BF	BF	B
Operating Ambient Temperatures	+5…+40°C	+5…+40°C	+5…+40°C
Operating Ambient Humidity	15…93% R.L.	15…93% R.L.	0…95% R.L.
Canister capacity [ml]	300/800ml	300/800ml	300 ml

TABLE 5.3 COMPARISON OF INVIA FOAM DRESSING KIT WITH FITPAD TO PREDICATE DEVICE

		Primary Predicate	**Secondary Predicate**
	Invia Foam Dressing Kits with FitPad	**Invia Foam Dressing Kits with FitPad (K170088)**	**VA.C Therapy System using Granufoam Dressing (K120033)**
Indications for Use	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 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 Foam Dressing Kit with FitPad 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 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 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 Foam Dressing Kit with FitPad is appropriate for use on the following wounds: – 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	The ActiVAC., InfoVAC., V.AC. ATS, V.AC. Freedom, V.AC. Via, and V.A.C. Simplicity Negative Pressure Wound Therapy Systems are integrated wound management systems for use in acute, extended and home care settings. When used on open wounds, they are intended 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 exudate and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts. When used on closed surgical incisions, they are 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 exudates via the application of negative pressure wound therapy.

		Primary Predicate	Secondary Predicate
	Invia Foam Dressing Kits with FitPad	**Invia Foam Dressing Kits with FitPad (K170088)**	**VA.C Therapy System using Granufoam Dressing (K120033)**
Contra-indications	• 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	• 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	Do not place foam dressings of the V.A.C. Therapy System directly in contact with exposed blood vessels, anastomotic sites, organs or nerves. V.A.C. therapy is contraindicated for patients with: - Malignancy in the wound - Untreated osteomyelitis - Non-enteric and unexplored fistulas - Necrotic tissue with eschar present - Sensitivity to silver (V.A.C. GranuFoam Silver Dressing only)
Environment of Use	Acute, extended and home care settings	Acute, extended and home care settings	Hospital and Home
Application for Closed Surgical Incisions	1. Protect peri-incisional skin with transparent film cut into strips. 2. Protect the surgical incision with a nonadherent contact layer (not part of kit) 3. Apply the foam in strips to cover entire incision length 4. Apply transparent film allowing for coverage of the foam strips and 3–5 cm contact with intact skin 5. Cut a small hole in transparent film and Apply suction pad (FitPad) 6. Connect the dressing tubing to the pump tubing and turn on pump	Not applicable	1. Protect peri-incisional skin with V.A.C. Drape, hydrocolloid or other transparent film leaving suture line exposed 2. Protect the surgical incision with a nonadherent contact layer (not part of kit) 3. Apply the foam in strips to cover entire incision length 4. Cut and place V.A.C. Drape allowing for coverage of the foam strips and 3–5 cm contact with intact skin 5. Cut a small hole in drape and apply suction pad (SensaT.R.A.C) 6. Initiate V.A.C. Therapy

		Primary Predicate	Secondary Predicate
	Invia Foam Dressing Kits with FitPad	**Invia Foam Dressing Kits with FitPad (K170088)**	**VA.C Therapy System using Granufoam Dressing (K120033)**
Dressing (to pack the wound)	Charcoal color Foam Pad Uses a reticulated flexible polyether and polyurethane hydrophobic foam material.	Charcoal color Foam Pad Uses a reticulated flexible polyether and polyurethane hydrophobic foam material.	Black foam pad Uses reticulated polyurethane hydrophobic foam material
Transparent Film to seal the wound	Invia Transparent Film Polyurethane transparent film with acrylic adhesive	Invia Transparent Film Polyurethane transparent film with acrylic adhesive	V.A.C.® Drape, with SENSAT.R.A.C.™ Pad with connector
External Suction Interface	Invia FitPad (double lumen tubing with Quick-Connector)	Invia FitPad (double lumen tubing with Quick-Connector)	SENSAT.R.A.C.™ Pad with connector
Specifications			
Foam Dimensions (Length x Width x Thickness)	Small: 10 cm x 8 cm x 3 cm Medium: 19 cm x 12.5 cm x 3 cm Large: 25 cm x 15 cm x 3 cm X-Large: 60 cm x 30 cm x 1.5 cm	Small: 10 cm x 8 cm x 3 cm Medium: 19 cm x 12.5 cm x 3 cm Large: 25 cm x 15 cm x 3 cm X-Large: 60 cm x 30 cm x 1.5 cm	Small: 10 cm x 7.5 cm x 3.2 cm Medium: 18 cm x 12.5 cm x 3.2 cm Large: 25 cm x 15 cm x 3.2 cm X-Large: 60 cm x 30 cm x 1.5 cm
Sealing Film Dimensions (Length x Width)	32 cm x 26 cm	32 cm x 26 cm	30.5 x 26 cm
Operating Ambient Temperature	+5°C…+40°C	+5°C…+40°C	Not specified

		Primary Predicate	Secondary Predicate
	Invia Foam Dressing Kits with FitPad	**Invia Foam Dressing Kits with FitPad (K170088)**	**VA.C Therapy System using Granufoam Dressing (K120033)**
Operating Ambient Pressure	+70 kPa…+106kPa	+70 kPa…+106kPa	Not specified
Storage Ambient Temperature	-20°C…+50°C	-20°C…+50°C	Not specified
Storage Ambient Humidity	15%...93%	15%...93%	Not specified
Sterilization method	Ethylene oxide sterilized	Ethylene oxide sterilized	Irradiation sterilized
Shelf life	2 years	2 years	3 years

TABLE 5.4 COMPARISON OF INVIA GAUZE DRESSING KIT WITH FITPAD TO PREDICATE DEVICE

		Primary Predicate	**Secondary Predicate**
	Invia Gauze Dressing Kits with FitPad	**Invia Gauze Dressing Kits with FitPad (K170088)**	**VA.C Therapy System using Granufoam Dressing (K120033)**
Indications for Use	The Invia Gauze 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 Gauze Dressing Kit with FitPad 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 Gauze Dressing Kit with FitPad 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 Gauze 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 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. Invia Gauze Dressing Kit with FitPad is appropriate for use on the following wounds: – 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	The ActiVAC., InfoVAC., V.AC. ATS, V.AC. Freedom, V.AC. Via, and V.A.C. Simplicity Negative Pressure Wound Therapy Systems are integrated wound management systems for use in acute, extended and home care settings. When used on open wounds, they are intended 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 exudate and infectious material. Open wound types include: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts. When used on closed surgical incisions, they are 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 exudates via the application of negative pressure wound therapy.

		Primary Predicate	Secondary Predicate
	Invia Gauze Dressing Kits with FitPad	**Invia Gauze Dressing Kits with FitPad (K170088)**	**VA.C Therapy System using Granufoam Dressing (K120033)**
Contra-indications	• 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	• 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	Do not place foam dressings of the V.A.C. Therapy System directly in contact with exposed blood vessels, anastomotic sites, organs or nerves. - Malignancy in the wound - Untreated osteomyelitis - Non-enteric and unexplored fistulas - Necrotic tissue with eschar present Sensitivity to silver (V.A.C. GranuFoam Silver Dressing only)
Environment of Use	Acute, extended and home care settings	Acute, extended and home care settings	Healthcare and home care settings
Application for Closed Surgical Incisions	1. Protect peri-incisional skin with transparent film cut into strips. 2. Protect the surgical incision with a nonadherent contact layer (not part of kit) 3. Apply the gauze in strips to cover entire incision length 4. Apply transparent film allowing for coverage of the gauze strips and 3–5 cm contact with intact skin 5. Cut a small hole in transparent film and Apply suction pad (FitPad) 6. Connect the dressing tubing to the pump tubing and turn on pump	Not applicable	1. Protect peri-incisional skin with V.A.C. Drape, hydrocolloid or other transparent film leaving suture line exposed 2. Protect the surgical incision with a nonadherent contact layer (not part of kit) 3. Apply the foam in strips to cover entire incision length 4. Cut and place V.A.C. Drape allowing for coverage of the foam strips and 3–5 cm contact with intact skin 5. Cut a small hole in drape and apply suction pad (SensaT.R.A.C) 6. Initiate V.A.C. Therapy
Dressing (to pack the wound)	Kerlix AMD Gauze	Kerlix AMD Gauze	Black foam pad Uses reticulated polyurethane hydrophobic foam material

		Primary Predicate	Secondary Predicate
	Invia Gauze Dressing Kits with FitPad	**Invia Gauze Dressing Kits with FitPad (K170088)**	**VA.C Therapy System using Granufoam Dressing (K120033)**
Transparent Film to seal the wound	Invia Transparent Film (sterile). Polyurethane transparent film with acrylic adhesive	Invia Transparent Film (sterile). Polyurethane transparent film with acrylic adhesive	V.A.C.® Drape, with SENSAT.R.A.C.™ Pad with connector
External Suction Interface	Invia FitPad (double lumen tubing with Quick-Connector)	Invia FitPad (double lumen tubing with Quick-Connector)	SENSAT.R.A.C.™ Pad with connector
Specifications			
Dressing Dimensions (Length x Width x Thickness)	Medium: 17 cm x 16 cm Large: 370 cm x 11.4 cm	Medium: 17 cm x 16 cm Large: 370 cm x 11.4 cm	Small: 10 cm x 7.5 cm x 3.2 cm Medium: 18 cm x 12.5 cm x 3.2 cm Large: 25 cm x 15 cm x 3.2 cm X-Large: 60 cm x 30 cm x 1.5 cm
Sealing Film Dimensions (Length x Width)	32 cm x 26 cm	32 cm x 26 cm	30.5 x 26 cm
Operating Ambient Temperature	+5°C…+40°C	+5°C…+40°C	Not specified
Operating Ambient Pressure	+70 kPa…+106kPa	+70 kPa…+106kPa	Not specified
Storage Ambient Temperature	-20°C…+50°C	-20°C…+50°C	Not specified

		Primary Predicate	Secondary Predicate
	Invia Gauze Dressing Kits with FitPad	**Invia Gauze Dressing Kits with FitPad (K170088)**	**VA.C Therapy System using Granufoam Dressing (K120033)**
Storage Ambient Humidity	15%...93%	15%...93%	Not specified
Sterilization method	Ethylene oxide sterilized	Ethylene oxide sterilized	Irradiation sterilized
Shelf life	2 years	2 years	3 years

SUMMARY OF NON-CLINICAL TESTS:

The Invia Motion NPWT System, Invia Liberty NPWT System and Invia Dressing Kits with FitPad underwent the following in support of the substantial equivalence determination for the new closed surgical incision indication:

- Potential risks associated with the new closed surgical incision indication were evaluated in accordance with ISO 14971: 2007.
- A usability engineering process, following the recommendations of the FDA guidance document *Applying Human Factors and Usability Engineering to Medical Devices (Feb. 3, 2016),* was used in the development and evaluation of the usability of the devices for treatment of closed surgical incisions. This included a human factors validation test which demonstrated that the design of the system and materials promote safe use and mitigate the possibility for critical, safety-related errors to the extent that is reasonable or possible for the scenarios tested.
- Performance testing was completed to demonstrate that the pressure at the incision is correct using a closed surgical incision 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 on top of the closed surgical incisional wound model. The testing also compared the devices to the predicate ActiV.A.C. Therapy Unit using Granufoam Dressing (K120033) and demonstrated equivalent performance for use on closed surgical incisions.

Additional testing to support non-significant changes to the Invia Liberty NPWT System since its previous clearance included:

- Software verification and validation testing
- Electromagnetic compatibility testing per IEC 60601-1-2: 2014 (4^{th} edition)
- Verification that EO and ECH residuals remain below maximum specified levels in compliance with ISO 10993-7.

Additional testing to support non-significant changes to the Invia Motion NPWT System since its previous clearance included:

- Software verification and validation testing.

SUMMARY OF CLINICAL TESTS:

Clinical testing was not required to demonstrate the substantial equivalence of the Invia Motion NPWT System, Invia Liberty NPWT System, Invia Foam Dressing Kit with FitPad or Invia Gauze Dressing Kit with FitPad to its respective predicate device.

CONCLUSION:

The differences between the Invia Motion NPWT System, Invia Liberty NPWT System, Invia Foam Dressing Kit with FitPad and Invia Gauze Dressing Kit with FitPad and its respective predicate devices 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 described, Medela AG concludes that the Invia Motion NPWT System, Invia Liberty NPWT System, Invia Foam Dressing Kit with FitPad and Invia Gauze Dressing Kit with FitPad are substantially equivalent to the legally marketed predicate devices.