May 4, 2026

Bechtel Medical, Inc.
Rebecca Monaghan
Director, Regulatory/Quality
174 Bechtel Rd.
Collegeville, Pennsylvania 19426

Re: K254019
Trade/Device Name: Wound Geni™ NPWT System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: December 15, 2025
Received: December 15, 2025

Dear Rebecca Monaghan:

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 (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Plastic and
Reconstructive Surgery Devices
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Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254019

Device Name
Wound Geni™ NPWT System

Indications for Use *(Describe)*
The Wound Geni™ NPWT System is indicated for patients who would benefit from a suction device (NPWT). It creates an environment that allows wound management 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 Wound Geni™ 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 Wound Geni™ NPWT System can only be used with Pensar WoundPro Foam Dressing Kits (K150960).
The Wound Geni™ 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510K Summary

Date Prepared:	Apr 27, 2026
Applicant:	Bechtel Medical Inc
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Primary Contact Person:	Rebecca Monaghan
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Subject Device Name:	Wound Geni™ NPWT System
Trade Name:	Wound Geni™
Regulation Name:	Negative Pressure Wound Therapy Powered Suction Pump
Review Panel	General & Plastic Surgery
Product Code	OMP
Regulation Number	878.4780
Regulatory Class:	Class II
Predicate Device:	Medela AG: Invia Liberty Negative Pressure Wound Therapy System (K172145) (Pump and canister only)

Device Description:
The Wound Geni™ Negative Pressure Wound Therapy (NPWT) System is an AC / battery powered, software-controlled negative-pressure therapy system consisting of a control unit with electric motor-driven diaphragm vacuum pump, power adapter, rechargeable lithium-ion battery and carry case. Accessory devices include non-sterile, disposable collection containers. The Wound Geni™ NPWT System delivers negative pressure wound therapy at pressure settings between -75 and -150 mmHg and can be operated via mains power supply or rechargeable battery. The Wound Geni™ NPWT System creates an environment that promotes wound healing by approximating wound edges, reducing edema, increasing perfusion, encouraging granulation tissue formation, and removing excess fluids and infectious materials from the wound bed.

The software/firmware operates as a stand-alone system without USB connectivity or internet capability.

The Wound Geni™ NPWT System is not compatible with the MR environment and should not enter the MR environment. The Wound Geni™ NPWT System can only be used with Pensar WoundPro Foam Dressing Kits (K150960).

The following components are included in this 510(k) submission:
• Wound Geni™ NPWT System
• Wound Geni™ Collection Container (300ml)
• Wound Geni™ Collection Container (500 ml)

Indications For Use:
The Wound Geni™ NPWT System is indicated for patients who would benefit from a suction device (NPWT). It creates an environment that allows wound management 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 Wound Geni™ 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 Wound Geni™ NPWT System can only be used with Pensar WoundPro Foam Dressing Kits (K150960).
The Wound Geni™ 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

Comparison Table of the Wound Geni™ NPWT System to Predicate Devices

Feature	Proposed Device	Primary Predicate Device
Device Name	Wound Geni™ NPWT System	Invia Liberty Negative Pressure Wound Therapy System
Components included in this submission	NPWT Pump and Canisters	Invia Liberty Pump and Canisters
Applicant	Bechtel Medical, Inc.	Medela AG
510(k) No.	K254019	K172145
Regulation Name	Powered Suction Pump	Powered Suction Pump
Regulation Number	21 CFR 878.4780	21 CFR 878.4780
Classification	Class II	Class II
Product Code	OMP	OMP
Indications for Use	The Wound Geni™ NPWT System is indicated for patients who would benefit from a suction device. It creates an environment that allows wound management 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 Wound Geni™ 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 Wound Geni™ NPWT System can only be used with Pensar WoundPro Foam Dressing Kits (K150960). The Wound Geni™ 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	The Invia Liberty Negative Pressure Wound Therapy (NPWT) system is indicated for patients who would benefit from a suction device (NPWT) 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 the following indications: • Acute or subacute wounds • Chronic wounds • Dehisced wounds • Pressure Ulcers • Diabetic, Neuropathic ulcers • Venous Insufficiency Ulcers • Traumatic wounds • Partial-thickness burns

Feature	Proposed Device	Primary Predicate Device
	• Traumatic wounds • Partial-thickness burns • Flaps and grafts • Closed surgical incisions	• Flaps and grafts • Closed surgical incisions
Contraindications	The Wound Geni™ NPWT System is contraindicated in the presence of: • 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	The Invia Liberty NPWT system is contraindicated in the presence of: • 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
Use Environment	Healthcare facility and home use environment	Healthcare facility and home use environment
Operating Principles	The Wound Geni™ NPWT System creates an environment that promotes wound healing by approximating wound edges, reducing edema, increasing perfusion, encouraging granulation tissue formation and removing excess fluids and infectious materials from the wound. The healthcare professional will place an NPWT dressing on the wound and connect the tubing and set therapy parameters on the NPWT vacuum pump per physician orders. Two modes of therapy are available on the device; continuous or intermittent. The exudate fluid drains into the collection canister via tubing connected to the wound dressing. The user-friendly controls and device display shows therapy status, a leak gauge to indicate the quality of therapy being delivered, and information regarding alarm faults. Acoustic alarms and optical signals are triggered for variances from the set values as well as for faults.	The Invia Liberty NPWT System 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 pump is a suction pump for Negative Pressure Wound Therapy that provides therapy status through a display and acoustic signals. Acoustic and optical signals are triggered for variances from the set values as well as for faults. The Invia Liberty NPWT pump provides continuous or intermittent operation and multiple negative pressure selection options.

Feature	Proposed Device	Primary Predicate Device
	The Wound Geni™ NPWT System will continue to cycle per instructions set by the healthcare professional, until the user pauses the therapy and will continue once the uses restarts therapy. The Wound Geni™ control unit is operable while connected to the electrical AC/DC power supply or, while portable, by the removable rechargeable lithium-ion battery. The battery is recharged while the pump is in use and connected to the electrical power supply.	The Invia Liberty NPWT pump is portable and can be operated using a rechargeable lithium-ion battery. 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.
Patient Population	Adult	Adult
Operating Modes	Continuous/Intermittent	Continuous/Intermittent
Power Source	Electrical power supply/rechargeable battery	Electrical power supply/rechargeable battery
Pressure Range	-75 to -150 mmHg (-10 to -20 kPa)	-60 to -200 mmHg (-8 to -27 kPa)
Canister	300, 500 ml	300, 800 ml

Testing Summary
Testing was completed with the Pensar WoundPro Foam Dressing Kit (K150960) where needed.

Electrical Safety and Electromagnetic Compatibility (EMC)
- IEC 60601-1:2005 + A1:2012 – Medical Electrical Equipment – General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014 – Electromagnetic Compatibility Requirements

Human Factors / Usability
Human factors and usability engineering activities were performed in accordance with FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices" to ensure the device can be used safely and effectively by the healthcare professionals in clinical settings and by trained patients under supervision in home use environment.

Performance Testing
Bench performance testing was conducted to verify and validate that the device meets specifications for pressure accuracy and stability, wound fluid removal and handling, leakage, alarm functionality, and overall system performance under simulated use conditions.

Software Verification and Validation
The software was developed and tested in accordance with IEC 62304 and FDA software guidance documents. Verification and validation testing confirmed that software functions as intended.

Conclusion
The results of non-clinical testing demonstrate the subject device is as safe and as effective as and substantially equivalent to the predicate device.