July 22, 2025

P.G.F. Industry Solutions GmbH
% Leonard Stewart
Regulatory Affairs Manager
Molnlycke Health Care US, LLC
5445 Triangle Parkway
Suite 400
Peachtree Corners, Georgia 30092

Re: K243415
Trade/Device Name: Granudacyn® Wound Irrigation Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 17, 2025
Received: June 17, 2025

Dear Leonard Stewart:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Mustafa A. Mazher -S

For Yu-Chieh Chiu, PhD
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and 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.

Submission Number *(if known)*

K243415

Device Name

Granudacyn® Wound Wash Solution

Indications for Use *(Describe)*

Under the supervision of healthcare professionals, Granudacyn Wound Wash Solution is intended for cleansing, irrigating, moistening, debridement and removal of foreign material including microorganisms and debris from exudating and/ or dirty wounds, acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted and donor sites, and exit sites. It is also intended for moistening and lubricating absorbent wound dressings.

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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510(k) SUMMARY

This 510(k) summary information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Date Prepared: July 21, 2025

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Phone Number: 678-451-6072
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Trade/Proprietary Names: Granudacyn® Wound Wash Solution

Device Class: Unclassified

Unclassified Reason: Pre-Amendment

Product Code: FRO

Predicate Device Name: Vashe® Wound Solution (K131848)
Reference Device Name: Microdacyn® Wound Care Solution (K233399)

Device Description:

Granudacyn® Wound Wash Solution is composed of water (H2O), hypochlorous acid (HOCl), sodium hypochlorite (NaOCl) and sodium chloride (NaCl). Pure water and pure sodium chloride are subjected to an electrolysis process to create the final solution.

Intended Use/Indication for Use:

Under the supervision of healthcare professionals, Granudacyn Wound Wash Solution is intended for cleansing, irrigating, moistening, debridement and removal of foreign material including microorganisms and debris from exudating and/ or dirty wounds, acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted and donor sites, and exit sites. It is also intended for moistening and lubricating absorbent wound dressings.

Technological Characteristics:

Feature	Granudacyn Wound Wash Solution	Vashe Wound Solution	Substantial Equivalence Comments
510(k) clearance	K243415	K131848	NA
Rationale for inclusion	Subject of submission	Predicate device	NA
Manufacturer	P.G.F. Industry Solutions GmbH	Urgo Medical North America, LLC	NA
Device class name	Dressing, Wound, Drug	Dressing, Wound, Drug	Same classification as predicate
Class	Unclassified	Unclassified	Same classification as predicate
Product code	FRO	FRO	Same product code as predicate
Indication for use/Intended use	Under the supervision of healthcare professionals, Granudacyn Wound Solution is intended for cleansing, irrigating, moistening, debridement and removal of foreign material including microorganisms and debris from exudating and/ or dirty wounds, acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted and donor sites, and exit sites. It is also intended for moistening and lubricating absorbent wound dressings.	Under the supervision of healthcare professionals, Vashe Wound Solution is intended for cleansing, irrigating, moistening, debridement and removal of foreign material including microorganisms and debris from exudating and / or dirty wounds, acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, first and second degree burns, abrasions, minor irritations of the skin, diabetic foot ulcers, ingrown toe nails, grafted and donor sites, and exit sites. It is also intended for moistening and lubricating absorbent wound dressings.	Same

Feature	Granudacyn Wound Wash Solution	Vashe Wound Solution	Substantial Equivalence Comments
Composition	Water, sodium chloride Hypochlorous Acid, Sodium Hypochlorite	Vashe(K131848):Water, sodium chloride Hypochlorous Acid	The difference between the predicate and the subject device does not impact substantial equivalence and is supported by Antimicrobial Effectiveness (USP<51>)testing
Use environment	Healthcare facilities and homecare setting	Healthcare facilities and homecare setting	Same
Use Case	Single patient, multi-use	Single patient, multi-use	Same
Mechanism(s) of Action	mechanical removal of wound debris	mechanical removal of wound debris	Same
Antimicrobial Preservative	Preservative: Hypochlorous acid, Sodium Hypochlorite	Vashe(K131848) Preservative: Hypochlorous acid	The difference between the predicate and the subject device does not impact substantial equivalence and is supported by Antimicrobial Effectiveness (USP<51>)testing
Volume	250ml, 500ml,1000ml	118ml, 250ml, 473ml	Difference does not impact substantial equivalence
Application Method	Squeeze bottle, spray nozzle, instillation bottle offered	Squeeze bottle, spray nozzle, instillation bottle offered	Same
Shelf Life	28 months	24 months	Difference does not impact substantial equivalence and is supported by stability studies
Sterility	Non-Sterile	Non-Sterile	Same
Biocompatibility	Biocompatible, Per ISO 10993-1	Biocompatible, Per ISO 10993-1	Same
Antimicrobial Effectiveness	Effective preservative for stated shelf life per, USP<51>	Effective preservative for stated shelf life per, USP<51>	Same
Clinical Data Summary – Subject Device			
Clinical Testing	Clinical data is not required.		

Non-Clinical Testing:

Testing was conducted to demonstrate the safety and the effectiveness of the subject device as well as the substantial equivalence to the predicate device:

- Biocompatibility – the subject device has been evaluated in accordance with ISO 10993-1 and has been shown to meet the criteria for the relevant endpoints, based on the chemical characterization, nature of body contact, and contact duration.
- Preservative Effectiveness – the subject device has been evaluated in accordance with USP <51> for preservative effectiveness and met the criteria aligned with its intended use.

Clinical Data :

No clinical data was required to support substantial equivalence.

Conclusion:

Substantial equivalence was demonstrated through a comparison of intended use, technological characteristics as well as performance and safety. Granudacyn Wound Wash is at least as safe and effective, and performs as well at the predicate device, Vashe Wound Solution.