August 11, 2026

Urgo Medical North America, LLC
Steven Dowdley
Vice President of Quality Assurance and Regulatory Affairs
100 Lexington St.
Suite 400
Fort Worth, Texas 76102

Re: K253665
Trade/Device Name: Vashe Plus Antimicrobial Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 10, 2026
Received: July 10, 2026

Dear Steven Dowdley:

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
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.*

510(k) Number *(if known)*
K253665

Device Name
Vashe Plus Antimicrobial Solution

Indications for Use *(Describe)*
Under the supervision of healthcare professional, Vashe Plus Antimicrobial Solution is intended for cleansing, irrigating, debridement (slough removal), moistening, 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, first and second degree burns, post-surgical, abrasions, minor irritations of the skin, diabetic foot ulcers, grafted and donor sites, and exit sites (ports).
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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

*"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."*

# K253665

510(k) SUMMARY

The following is a summary of 510(k) safety and performance information in accordance with 21 CFR 807.92.

## I. SUBMITTER

**Submitted by:**
Urgo Medical North America, LLC
100 Lexington Street, Suite 400
Fort Worth, Texas 76102
Phone: (855) 888-8273
Establishment Registration: 3010060216
Owner Operator:10042824
Contact Person: Steven Dowdley, Vice President of Quality and Regulatory Affairs
Date Prepared: August 6, 2026

## II. DEVICE

Name of Device: Vashe Plus Antimicrobial Solution (K253665)
Common or Usual Name: Wound Cleanser.
Classification Name: Solution, Saline Wound Dressing.
Class: Unclassified.
Product Code: FRO
510(k) Review Panel: General & Plastic Surgery

## III. PREDICATE DEVICES

| Predicate Device | 510(k) Number | Clearance Date |
|---|---|---|
| Vashe Wound Solution | K131848 | 03/31/2014 |

## IV. DEVICE DESCRIPTION

Vashe Plus Antimicrobial Solution is a saline-based wound cleanser that contains hypochlorous acid as a preservative that inhibits microbial contamination within the solution while on the shelf. Vashe Plus Antimicrobial Solution creates a moist environment and removes slough and other foreign materials from the wound bed. As a result of the mechanical action of moving across the wound bed, dirt, debris and microorganisms are removed.

## V. INDICATION FOR USE

Under the supervision of healthcare professional, Vashe Plus Antimicrobial Solution is intended for cleansing, irrigating, debridement (slough removal), moistening, 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, first and second degree burns, post-surgical, abrasions, minor irritations of the skin, diabetic foot ulcers, grafted and donor sites, and exit sites (ports). Moistening and lubricating absorbent wound dressings.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

| Comparison Category | Predicate Device - Vashe Wound Solution (K131848) | Subject Device - Vashe Plus Antimicrobial Solution (K253665) |
|---|---|---|
| Device Class Name | Dressing, Wound, Dressing | Dressing, Wound, Dressing |
| Product Code | FRO | FRO |
| Indication for use | 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. | Under the supervision of healthcare professional, Vashe Plus Antimicrobial Solution is intended for cleansing, irrigating, debridement (slough removal), moistening, 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, first and second degree burns, post-surgical, abrasions, minor irritations of the skin, diabetic foot ulcers, grafted and donor sites, and exit sites (ports). Moistening and lubricating absorbent wound dressings. |
| Mode of action | Mechanical cleansing with fluid moving across the wound. Soak the wound to moisten tissue and loosen exudate. | Mechanical cleansing with fluid moving across the wound. Soak the wound to moisten tissue and loosen exudate. |
| Antimicrobial Preservative | Hypochlorous Acid | Hypochlorous Acid |
| Preservative Function | HOCl prevents microbial growth within the solution | HOCl prevents microbial growth within the solution |
| Packaging Bottle | Polyethylene terephthalate (PET) | Polyethylene terephthalate (PET) |
| Volume | 118ml, 250ml, 475ml, 1000ml | 250ml, 475ml, 1000ml |

## VII. NON-CLINICAL DATA

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, 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.

| Specific Test / Standard | Purpose / Methodology | Criteria | Results |
|---|---|---|---|
| Antimicrobial Preservative Effectiveness (USP <51>) | Evaluated the preservative system's ability to inhibit microbial growth. Testing was conducted on 9-month aged samples (representing end-of-shelf-life) and included a simulated 7-day multi-use period with repeated dispensing to mimic worst-case clinical use. | Demonstrated >4.5-log reduction against all five challenge microorganisms (*S. aureus, P. aeruginosa, E. coli, C. albicans, A. brasiliensis*) with no growth of fungi, meeting USP <51> Category 2 criteria. | Pass |

| | | | |
|---|---|---|---|
| Stability Testing | Verified that the solution maintains its active ingredients over its shelf life. Evaluated pH and Available Free Chlorine (AFC) on three lots after 3 months of storage at 25°C and 40°C. | pH and AFC remained within specification, supporting the labeled storage conditions of 5°C to 25°C. | Pass |
| Material Compatibility | Assessed the chemical compatibility of the solution with commonly used vented spike adapter materials (PVC and medical-grade silicone). Measured AFC, pH, and visual integrity after 10 minutes and 4 hours of contact. | pH and AFC values remained within specification, and there was no visual degradation of the tubing. | Pass |
| Cytotoxicity (ISO 10993-5) | Evaluated the potential toxicity of the solution, including solutions conditioned by contact with PVC and silicone tubing materials. | Demonstrated no cytotoxic effect greater than Grade 2. | Pass |
| Sensitization, Irritation, & Acute Systemic Toxicity (ISO 10993-1) | Evaluated the biological response of the device based on its chemical characterization, nature of body contact (breached/compromised surface), and limited contact duration (<24 hours). | Met the criteria for all relevant endpoints to establish adequate biocompatibility. | Pass |
| Material-Mediated Pyrogenicity (MMP) (ISO 10993-11 Annex G) | A risk assessment was conducted in lieu of animal testing to evaluate the pyrogenic potential of the added components (potassium acetate, hydrochloric acid, sodium bicarbonate, and increased hypochlorous acid). | None of the constituents fell into any recognized pyrogenic substance category, demonstrating low material mediated pyrogenicity. | Pass |
| Porcine Wound Healing Study (GLP Compliant) | Assessed the impact of the device on the wound healing process using a full-thickness dermo-epidermic wound model in pigs. Included macroscopic, morphometric, and histopathologic assessments at 9 and 32 days. | The device induced minimal or no tissue reaction. Overall wound healing performance was marked and similar to the control and negative control groups. | Pass |

## VIII. CLINICAL DATA

No clinical data was required to support substantial equivalence.

## IX. CONCLUSION

The conclusion drawn from the nonclinical testing demonstrates that the subject device, the Vashe Plus Antimicrobial Solution, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K131848.