March 25, 2026

Letus Corporation
% Mehdi Kazemzadeh-Narbat
Director, Regulatory Affairs
Mcra, LLC
803 7th St. NW, 4th Floor
Washington, District of Columbia 20001

Re: K252023
Trade/Device Name: MiraChlor Antimicrobial Wound Solution
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 20 2026
Received: February 23, 2026

Dear Mehdi Kazemzadeh-Narbat:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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)*
K252023

Device Name
MiraChlorTM Wound Cleanser Solutions

Indications for Use *(Describe)*
Rx:
Under the supervision of a healthcare professional, MiraChlorTM Wound Cleanser Solutions is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material and debris from exudating wounds, acute and chronic dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, partial-thickness wounds, first- and superficial second-degree burns, abrasions of the skin, diabetic foot ulcers, ingrown toe nails, grafted/ donor sites and exit sites. It is also intended for use to moisten and lubricate wound dressings and for use with devices intended to irrigate wounds.

OTC:
MiraChlorTM Wound Cleanser Solutions is intended for OTC use in the management of minor skin abrasions, minor lacerations, minor cuts, and intact skin.

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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510(k) Summary

Device Trade Name: MiraChlor™ Wound Cleanser Solutions

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Date Prepared: March 20, 2026

Classifications: Dressing, Wound, Drug

Class: Unclassified

Product Code: FRO

Primary Predicate: Vashe Wound Therapy Solution (K123072)

Indications For Use:
The MiraChlor™ Wound Cleanser Solutions is indicated for the following:

Rx:

Under the supervision of a healthcare professional, *MiraChlor™ Wound Cleanser Solutions* is intended for the cleansing, irrigation, moistening, debridement and removal of foreign material and debris from exudating wounds, acute and chronic dermal lesions including stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, post-surgical wounds, partial-thickness wounds, first- and superficial second-degree burns, abrasions of the skin, diabetic foot ulcers, ingrown toe nails, grafted/donor sites and exit sites. It is also intended

for use to moisten and lubricate wound dressings and for use with devices intended to irrigate wounds.

OTC:

MiraChlor™ Wound Cleanser Solutions is intended for OTC use in the management of minor skin abrasions, minor lacerations, minor cuts, and intact skin.

Device Description:

MiraChlor™ Wound Cleanser Solutions are saline based wound cleansers that contain hypochlorous acid as a preservative that inhibits microbial contamination within the solution while on the shelf. MiraChlor™ Wound Cleanser Solutions create a moist environment and remove slough and other foreign materials from the wound bed. As a result of mechanical action of solution moving across the wound bed, dirt, and debris, are removed. Moistening and cleansing a wound, such as by using MiraChlor™ Wound Cleanser Solutions.

Predicate Devices:

Primary Predicate: Vashe Wound Therapy Solution (K123072)

Performance Testing Summary:

Biocompatibility Testing The biocompatibility evaluation for the *MiraChlor™ Wound Cleanser Solutions* was conducted in accordance with "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

Bench Testing The following tests were performed to support the performance of *MiraChlor™ Wound Cleanser Solutions*: package integrity, visual inspection, osmolality, pH, Free Available Chlorine (FAC) and Raman Spectroscopy.

USP <51> testing was used to support preservative effectiveness of the product with the compendia organisms: *P. aeruginosa* (ATCC 9027), *E. coli* (ATCC 8739), *S. aureus* (ATCC 6538), *C. albicans* (ATCC 10231), *A. brasiliensis* (ATCC 16404).

USP <61>/<62> testing was used to evaluate bioburden levels to demonstrate controlled microbial levels across manufacturing lots.

Substantial Equivalence:

MiraChlor™ Wound Cleanser Solutions is substantially equivalent in technological characteristics including formulation, design, performance, route of administration, and intended use to the Vashe Wound Therapy Solution (K123072). The subject device and the proposed cleared predicate are topical saline based wound cleansers that contain hypochlorous acid, with similar indications for use.

The antimicrobial hypochlorous as a preservative in the proposed MiraChlor™ Wound Cleanser Solutions and the predicates have been shown to inhibit microbial growth within the product while the product is on the shelf.

Conclusion:
MiraChlor™ Wound Cleanser Solutions and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The data included in this submission demonstrates substantial equivalence to the predicate devices listed above. MiraChlor™ Wound Cleanser Solutions is as safe, as effective, and performs as well as the predicate devices.