



August 27, 2025

Infection Elimination Solutions, LLC
% Connie Qiu
Sr. Medical Technology Regulatory Consultant
ProPharma MedTech
1129 20th Street NW
Suite 600
Washington, District of Columbia 20036

Re: K243166
Trade/Device Name: Dermalage
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 28, 2025
Received: July 28, 2025

Dear Connie Qiu:

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,

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

Indications for Use

510(k) Number (if known)

K243166

Device Name

Dermalage

Indications for Use (Describe)

Dermalage for over-the-counter use is intended for cleansing wounds for the removal of foreign material, such as debris and dirt, from dermal wounds.

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 - Dermalage

This 510(k) summary is prepared in accordance with the requirements of 21 CFR §807.92.

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Date of Submission: August 27, 2025

Proprietary Name: Dermalage

Common Name: Dressing, Wound, Drug

Regulatory Class: Unclassified

Regulation: Unclassified

Product Codes: FRO

Predicate Device(s): K103713 Elta Wound Cleanser

Device Description:

Dermalage is a liquid solution intended for cleansing wounds. The solution is applied by spraying directly onto the affected area until wet and then allowed to air dry. When sprayed, Dermalage moves across the wound bed by mechanical action to aid in the removal of foreign objects such as dirt and debris from granulating wounds. The Dermalage solution is provided in a bottle with a manual spray pump configuration.

Dermalage is a combination product that contains water, sodium laureth sulfate, sodium lauryl sulfoacetate, disodium laureth sulfosuccinate, cocamidopropyl betaine, sorbitol, Imidazolidinyl Urea, and sodium hydroxide. Imidazolidinyl Urea acts solely as a preservative to inhibit growth of microorganisms within the product before opening and between uses.

Dermalage is limited to use by a single patient for up to 24 hours.

Indications for Use:

Dermalage for over-the-counter use is intended for cleansing wounds for the removal of foreign material, such as debris and dirt, from dermal wounds.

Technological Characteristics and Substantial Equivalence

The following table provides a comparison of the subject device, Dermalage, to the predicate device, K103713 Elta Wound Cleanser. The table compares the wound wash devices' intended use, indications for use, principle of operation, and technological characteristics including materials and results of performance testing. Based on the shared product code, intended use, preservative, mechanism of action, and similar technological characteristics, the subject device does not raise new questions of safety or effectiveness compared to the predicate device.

Table 1 Comparison of Subject and Predicate Devices

	Subject Device K 243166 Dermalage	Predicate Device K103713 Elta Wound Cleanser (Currently marketed as Skintegrity®)	Comparison
Product Code	FRO	FRO	Same
Regulation	Unclassified	Unclassified	Same
Rx or OTC	OTC	OTC	Same
Indications for Use (OTC)	Dermalage for over-the-counter use is intended for cleansing wounds for the removal of foreign material, such as debris and dirt, from dermal wounds.	Elta Wound Cleanser is intended for the removal of foreign material, such as debris, and dirt, from dermal wounds.	Same
Biocompatibility	Biocompatible, ISO 10993-1	Non cytotoxic Non irritating	Same, both met satisfactory biocompatibility requirements for wound washes. Limited information is publicly available on the predicate device. Additional biocompatibility testing has been conducted on the subject device.
Appearance	Clear, colorless solution	Clear to very slight hazy solution	Same, both are clear solutions.
Mechanism of Action	Mechanical removal of dirt, debris from wounds by the action of fluid moving across	Mechanical removal of dirt, debris from wounds by the action of fluid	Same

	the wound.	moving across the wound.	
Application Method	Spray bottle (2oz, 4oz, 8oz) Topical use	Spray bottle (1oz, 8oz, 16oz) Topical use	Same, both are intended or topical use, applied by spray bottle and offered in multiple sizes.
Characteristics	Aqueous	Aqueous	Same
Density (at 20°C)	1g/ml	1.05	Similar. Differences do not raise new questions of safety and effectiveness.
Materials	Water Sorbitol Sodium laureth sulfate Sodium lauryl sulfoacetate Disodium laureth sulfosuccinate, Cocamidopropyl betaine, Sodium Hydroxide (Germall 115) Imidazolidinyl Urea (preservative)	Water Sorbitol Disodium cocoamphodiacetate Lactic acid Polysorbate 80 Triethanolamine Disodium EDTA Methylparaben Lauryl polyglucose Imidazolidinyl urea (preservative)	The subject and predicate devices are both surfactant-based wound cleansers that share the same preservative Imidazolidinyl urea. Additionally, both contain water and sorbitol. Biocompatibility, shelf-life, antimicrobial effectiveness and final product release testing met all relevant acceptance criteria. Differences in the other materials do not raise new questions of safety and effectiveness.
Buffer	Not buffered	Not buffered	Same
Sterility	Non-sterile	Non-sterile	Same

Discussion of Performance testing

The following performance testing was carried out to demonstrate substantial equivalence to the predicate device.

- Cytotoxicity (ISO 10993-5)
- Maximization (ISO 10993-10)
- Intracutaneous Reactivity (ISO 10993-10)
- Acute Toxicity (ISO 10993-11)
- Pyrogenicity (ISO 10993-11, USP<151>)
- Toxicological risk assessment
- Shelf-Life Testing
- Antimicrobial Effectiveness Testing (USP <51>)

Conclusion

Based on the testing and comparison to the predicate device, Dermalage is as safe and effective as the predicate device, K103713 Elta Wound Cleanser.