November 19, 2025

Huizhou Foryou Medical Devices Co., Ltd.
Guosheng Tan
R&D Engineer
North Shangxia Rd. Dongjiang Hi-Tech Industry Park
Huizhou, Guangdong 516005
China

Re: K250642
Trade/Device Name: LUOFUCON® Skin and Wound Cleanser (Spray, Mist, Squeeze, Bottle.)
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 27, 2025
Received: October 27, 2025

Dear Guosheng Tan:

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.
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)*
K250642

Device Name

LUOFUCON® Skin and Wound Cleanser (Spray, Mist, Squeeze, Bottle.)

Indications for Use *(Describe)*

Prescription Use:
LUOFUCON® Skin and Wound cleanser is intended for cleaning wounds and for moistening and lubricating absorbent wound dressings for ulcers, burns, post-surgical wounds and abrasions.

OTC Use:
LUOFUCON® Skin and Wound cleanser is intended for cleaning wounds and moistening absorbent wound dressings for the management of minor cuts, abrasions, lacerations and minor bums.

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

K250642

This 510(k) Summary information is being submitted in accordance with Title 21, CFR Section 807.92.

I. SUBMITTER

Huizhou Foryou Medical Devices Co., Ltd.

Address :	North Shangxia Rd. Dongjiang Hi-tech Industry Park, 516005, Huizhou, PEOPLE'S REPUBLIC OF CHINA
Phone:	+86-0752-5302185
Contact Person:	Guosheng Tan
Date Prepared:	March 4, 2025

II. SUBJECT DEVICE

Trade/Proprietary Names:	LUOFUCON® Skin and Wound Cleanser
Common Name:	Wound Cleanser
Classification Name:	Dressing, Wound, Drug
Regulatory Class:	Unclassified
Product Code:	FRO
510(K) Review Panel:	General & Plastic Surgery

III. PREDICATE DEVICE

Primary Predicated Device :

510(k) Number:	K161623
Device Name:	Prontosan® wound irrigation solution
Manufacturer:	Braun Medical Inc.

Secondary Predicated Device :

510(k) Number:	K110744
Device Name:	Prontosan® wound irrigation solution
Manufacturer:	B. Braun Medical Inc.

IV. DEVICE DESCRIPTION

LUOFUCON® Skin and Wound Cleanser is a clear, colorless solution with a mild odor. It helps in the mechanical removal of debris and foreign materials from the skin, wounds, or application sites. This product contains 0.1% w/w polyhexamethylene

biguanide (PHMB) as a preservative, which helps inhibit the growth of microorganisms in the solution.

LUOFUCON® Skin and Wound Cleanser is available in various packaging forms, such as Spray, Mist, Squeeze, and Bottle models. They can be suited for different clinical situations.

V. INDICATIONS FOR USE

Prescription Use:

LUOFUCON® Skin and Wound Cleanser is intended for cleaning wounds and for moistening and lubricating absorbent wound dressings for ulcers, burns, post-surgical wounds and abrasions.

OTC Use:

LUOFUCON® Skin and Wound Cleanser is intended for cleaning wounds and moistening absorbent wound dressings for the management of minor cuts, abrasions, lacerations and minor bums.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

LUOFUCON® Skin and Wound Cleanser compared with the predicate devices in terms of technological characteristics. The following table shows their similarities and differences.

Item	Subject Device	Primary Predicate Device (K161623)	Secondary Predicate Device (K110744)	Comparison
Regulatory Class	Unclassified	Unclassified	Unclassified	Same
Product Code	FRO	FRO	FRO	Same
Intended Use	**Prescription use:** LUOFUCON® Skin and Wound Cleanser is intended for cleaning wounds and for moistening and lubricating absorbent wound dressings for ulcers, burns,	**Prescription use:** Prontosan® Wound Irrigation Solution is intended for cleaning wounds and for moistening and lubricating absorbent wound dressings for ulcers, burns,	**OTC use:** Prontosan® Wound Irrigation Solution for over-the-counter use, is intended for cleaning wounds and moisteningd absorbent wound dressings for the	Same

Item	Subject Device	Primary Predicate Device (K161623)	Secondary Predicate Device (K110744)	Comparison
	post-surgical wounds and abrasions. **OTC use:** LUOFUCON® Skin and Wound Cleanser is intended for cleaning wounds and moistening absorbent wound dressings for the management of minor cuts, abrasions, lacerations and minor bums.	post-surgical wounds and abrasions.	management of minor cuts, abrasions, lacerations and minor burns.	
Where Used	Prescription/OTC	Prescription	OTC	Same
Delivery System	Aqueous solution	Aqueous solution	Aqueous solution	Same
Mechanism of Action	Dirt debris and foreign material are mechanically removed by the action of the fluid moving across the skin or wound.	Dirt debris and foreign material are mechanically removed by the action of the fluid moving across the skin or wound.	Dirt debris and foreign material are mechanically removed by the action of the fluid moving across the skin or wound.	Same
Composition	Purified water, Sodium chloride, Allantoin, Poloxamer, Cocamidopropyl Hydroxysultaine, Disodium EDTA, 0.1%w/w Polyhexamethylene biguanide(PHMB), Polyethylene glycol 200.	Purified Water, 0.1% Undecylenamidopropyl Betaine,0.1% Polyaminopropyl Biguanide (Polyhexanide [PHMB]).	Purified Water, 0.1% Undecylenamidopropyl Betaine,0.1% Polyaminopropyl Biguanide (Polyhexanide [PHMB]).	Both the Subject Device and the Predicate Device use PHMB at the same concentration as a preservative and betaine-based surfactants as a cleaning agent. Differences in the other materials do not raise new questions of safety and effectiveness.

Item	Subject Device	Primary Predicate Device (K161623)	Secondary Predicate Device (K110744)	Comparison
Antimicrobial Preservative	Polyhexamethylene biguanide (PHMB)	Polyhexamethylene biguanide (PHMB)	Polyhexamethylene biguanide (PHMB)	Same
Sterile claim	Non-sterile	Sterilized using aseptic processing techniques	Sterilized using aseptic processing techniques	Both the Subject Device and the Predicate Device have the same microbial limits Requirements. Differences do not raise new questions of safety and effectiveness.
Packaging formats	Polyethylene bottles with various packaging structure types, such as spray type, mist type , squeeze type and bottle type.	Polyethylene bottles with various packaging structure types, such as ampoule type and squeeze type.	Polyethylene bottles with various packaging structure types, such as ampoule type and squeeze type.	Same packaging materials: all can safely deliver the liquid to the application site. Difference does not impact substantial Equivalence.
Intended use-life	Solution may be used for up to 28 days.	Solution may be used for up to 28 days.	Solution may be used for up to 28 days.	Same
Use	Multiple use within a single patient	Multiple use within a single patient	Multiple use within a single patient	Same

VII. PERFORMANCE DATA

The following performance data were provided to support the determination of substantial equivalence.

Performance testing

Performance testing was conducted to verify that the subject device met all design specifications and was Substantially Equivalent (SE) to the predicate devices.

Test Method	Purpose	Acceptance	Results
Internal Method	Osmotic Pressure Test	250-310 mOsmol/kg.	304 mOsmol/kg
Internal Method	Surface Tension Test	20-40mN/m	33.5 mN/m
USP <791>	pH Value Test	4.0-6.0	4.85
Internal Method	PHMB Content Test	0.10±0.02%	0.1032%

Test Method	Purpose	Acceptance	Results
USP <51>	Antimicrobial Preservative Effectiveness Test	For bacteria：Not Less Than 2.0 log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days. For yeast and molds：No increase from the initial calculated count at 14 and 28 days.Test Results.	Pass
USP <61>	Microbial Limit Test	Total aerobic bacteria ≤100CFU/mL; total mold and yeast ≤10CFU/mL. Coliforms, Staphylococcus aureus and Pseudomonas aeruginosa shall not be detected.	Pass

Biocompatibility testing

Based on the FDA Guidance Document titled 'Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process', and a series of ISO 10993 standards, the subject device is categorized as surface devices for breached or compromised surface with limited duration. The relevant standards for biocompatibility testing of the subject device are presented as follows.

Test Method	Purpose	Acceptance	Results
ISO 10993-5:2019	Cytotoxicity	The cellular activity of the 100% concentration extract of the test sample was greater than 70%	Under conditions of the study, device extract is cytotoxic.
ISO 10993-23:2021	Irritation	No abnormal reaction or death was observed in either of the two extracts	Under the conditions of the study, device is not an irritant. / Pass
ISO 10993-10:2021	Sensitization	The difference between the mean score of the test sample and the mean score of the solvent control is 0 and no more than1.0	Under the conditions of the study, device is not a sensitizer. / Pass
ISO 10993-11:2017	Acute Systemic Toxicity	No abnormal reaction or death was observed	Under the conditions of the study, device did not show acute systemic toxicity in vivo. /pass
ISO 10993-6:2016	Implantation	No or minimal irritation (or reactivity)	Test sample is considered to have minimal or no response compared to the implanted market control sample.
USP <151>	Material-Mediated Pyrogenicity	Non-pyrogenic	Under the conditions of the study, non-pyrogenic

Animal Study

A porcine wound healing study was carried out to assess the impact of the subject device on the wound healing process. Under the study conditions, LUOFUCON® Skin and Wound Cleanser had no effect on normal wound healing.

Clinical Study

No clinical studies were conducted for the subject device.

VIII. CONCLUSIONS

Based on a comparison of the intended use and technological characteristics of the subject device with those of the predicate devices, the subject device, LUOFUCON® Skin and Wound Cleanser, is as safe, as effective, and performs as well as the legally marketed predicate devices, Prontosan® wound irrigation solution (K161623, K110744).