March 11, 2026

Huizhou Foryou Medical Co., Ltd.
Huiqi Huang
R&D Engineer
North Shangxia Rd. Dongjiang Hi-tech Industry Park
Huizhou, Guangdong 516005
China

Re: K252028
Trade/Device Name: LUOFUCON® Wound Gel Extra
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 12, 2026
Received: February 12, 2026

Dear Huiqi Huang:

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), 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 Medical Device File (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,

MUSTAFA A. MAZHER -S

For 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)*
K252028

Device Name

LUOFUCON® Wound Gel Extra

Indications for Use *(Describe)*

Prescription:

LUOFUCON® Wound Gel Extra is indicated for the management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1st and superficial 2nd degree burns, partial and full thickness wounds and surgical incisions.

OTC:

LUOFUCON® Wound Gel Extra is indicated for the management minor cuts, minor lacerations, minor burns (1st degree burns), and abrasions.

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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1. SUBMITTER:

Huizhou Foryou Medical Devices Co., Ltd.

Address: North Shangxia Rd., Dongjiang Hi-tech Industry Park, 516005, Huizhou, Guangdong, China.

Phone: +86-0752-5302185

Contact Person: Huiqi Huang

Date Prepared: February 12th, 2026

2. SUBJECT DEVICE

Device Name: LUOFUCON® Wound Gel Extra

Common Name: Wound Dressing

Classification Name: Dressing, Wound, Drug

Regulatory Class: Unclassified

Product Code: FRO

Review Panel: General & Plastic Surgery

3. PREDICATE DEVICE:

510(k) Number: K163188

Product Name: Next Science Wound Gel (Rx)

Manufacturer: Next Science, LLC

4. DEVICE DESCRIPTION:

LUOFUCON® Wound Gel Extra is a clear, odorless, sterile amorphous hydrogel wound dressing that helps maintain a clean, moist wound environment. LUOFUCON® Wound Gel Extra is applied directly to the wound and then covered

with an appropriate dressing. LUOFUCON® Wound Gel Extra contains high moisture content and can provide moisture to the wound. The use of LUOFUCON® Wound Gel Extra on a wound creates a moist environment that is conducive to healing. LUOFUCON® Wound Gel Extra can facilitate debridement through a moist wound environment. LUOFUCON® Wound Gel Extra provides preservative properties through benzalkonium chloride(BAC) to help inhibit the growth of microorganisms within the gel while in the tube.

LUOFUCON® Wound Gel Extra is supplied in a tube (collapsible, polypropylene tube, sealed on one end and fitted with a screw cap on the other end).

5. INDICATIONS FOR USE:

Prescription:

LUOFUCON® Wound Gel Extra is indicated for the management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1st and superficial 2nd degree burns, partial and full thickness wounds and surgical incisions.

OTC:

LUOFUCON® Wound Gel Extra is indicated for the management minor cuts, minor lacerations, minor burns (1st degree burns), and abrasions.

6. COMPARISON WITH THE PREDICATE DEVICES

LUOFUCON® Wound Gel Extra and the predicate devices consist of different ingredients. However, they have the same intended use, similar designs and performance, and meet the biocompatibility requirements.

The table below compares the subject device to the predicate devices.

Item	Subject Device	Predicate Device
Device Name	LUOFUCON® Wound Gel Extra	Next Science Wound Gel (Rx)
510(k) number	K252028	K163188
Product Code	FRO	FRO

Item	Subject Device	Predicate Device
Classification	Unclassified	Unclassified
Prescription & OTC	Prescription, OTC	Prescription
Composition	Water, hydroxyethyl cellulose, propylene glycol, trisodium citrate, benzalkonium chloride, sodium gluconate, disodium EDTA.	Benzalkonium chloride 0.13%, polyethylene glycol 400, polyethylene glycol 3350, sodium citrate, citric acid and water.
Indications for Use (Prescription)	LUOFUCON® Wound Gel Extra is indicated for the management of ulcers (including diabetic foot and leg ulcers and pressure ulcers), 1st and Superficial 2nd degree burns, partial and full thickness wounds and surgical incisions.	Next Science™ Wound Gel is intended for use in the management of wounds such as Stage I-IV pressure ulcers, partial and full thickness wounds, diabetic foot and leg ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites.
Indications for Use (OTC)	LUOFUCON® Wound Gel Extra is indicated for the management minor cuts, minor lacerations, minor burns (1st degree burns), and abrasions.	N/A
Mechanism	Hydrophilic polymer for maintaining high moisture content.	Hydrophilic polymer for maintaining high moisture content.
Preservative agent	Benzalkonium Chloride	Benzalkonium Chloride
Performance	USP <51> preservative effectiveness testing	USP <51> preservative effectiveness testing
Sterilized	Sterile	Not provided sterile

7. SUBSTANTIAL EQUIVALENCE DISCUSSION

LUOFUCON® Wound Gel Extra has been subjected to ISO 10993 biocompatibility studies to demonstrate the device is as safe as its predicate devices. The performance tests were conducted to demonstrate that the subject device is as

effective as its predicate devices.

Biocompatibility Testing

Based on Table A.1 of ISO 10993-1 and Table A.1 of FDA Guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", the subject device is categorized as a surface device in contact with breached or compromised surface with prolonged duration. The relevant biocompatibility endpoints were conducted tests as required and the results showed that LUOFUCON® Wound Gel Extra meets biocompatibility requirements of the ISO 10993-1 standard and FDA Guidance, and it raised no new safety concerns for biocompatibility to the predicate devices.

Performance Testing

The following performance tests were conducted on subject device in comparison to the predicate devices:

- ●Appearance
- ●Weight
- ●Loss on Drying
- ●Fluid Affinity
- ●pH Value
- ●Preservative Effectiveness
- ●Sterility

Animal Study

A Porcine Wound Healing Study was conducted to evaluate the effect of the subject device on the wound healing process. Under the conditions of the study,

LUOFUCON® Wound Gel Extra did not inhibit normal wound healing and did not trigger adverse biological reactions.

Clinical Studies

No clinical study was conducted.

8. CONCLUSIONS

Based on the comparison analysis, performance tests, biocompatibility tests and animal study provided in this submission, the subject device, LUOFUCON® Wound Gel Extra is demonstrated to be substantially equivalent to the legally marketed predicate device, Next Science Wound Gel (Rx)(K163188). So, the subject device is considered Substantially Equivalent (SE) to the predicate device.