August 18, 2026

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

Re: K254256
Trade/Device Name: LUOFUCON® Wound Matrix
Regulatory Class: Unclassified
Product Code: QSZ
Dated: July 15, 2026
Received: July 15, 2026

Dear Ni Zhan:

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)*
K254256

Device Name
LUOFUCON® Wound Matrix

Indications for Use *(Describe)*
LUOFUCON® Wound Matrix is indicated to cover and protect a wound.
LUOFUCON® Wound Matrix is intended for the management of: partial and full-thickness wounds, partial thickness burns, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, skin tears), draining wounds.
LUOFUCON® Wound Matrix is intended for adults except for those who are allergic to poly(lactic-co-glycolic acid) or polyethylene glycol.

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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"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."

510(k) SUMMARY

(as required by 21 CFR 807.920)

1. Submitter

Huizhou Foryou Medical Devices Co., Ltd.
Address: No.1 North Shangxia Rd. Dongjiang Hi-tech Industry Park,
516005, Huizhou, PEOPLE'S REPUBLIC OF CHINA
Phone: +86-752-5302091
Contact Person: Ni Zhan
Email address: nzhan@foryoumedical.com
Date Prepared: August 4, 2026

2. Subject Device

The Name of Device: Wound Matrix
Common or Usual Name: Wound Matrix
Trade or Proprietary Name：LUOFUCON® Wound Matrix
Classification Name: Absorbable Synthetic Wound Dressing
Product Code: QSZ
Regulatory Class: Unclassified

3. Predicate Device

The Name of Device: Restrata™ Wound Matrix
Trade name: Restrata™ Wound Matrix
510(K) Number: K170300
Submitter: Acera Surgical, Inc.
Classification Name: Absorbable Synthetic Wound Dressing
Product Code: QSZ
Regulatory Class: Unclassified
Review Panel: General & Plastic Surgery

4. Device Description

LUOFUCON® Wound Matrix is a sterile, single-use device intended for use in local management of wounds. LUOFUCON® Wound Matrix is a single-layer, soft, white and degradable matrix that serves to protect a wound.

LUOFUCON® Wound Matrix is made from 2 types of synthetic biocompatible polymers, poly(lactic-co-glycolic acid (PLGA) and polyethylene glycol (PEG), and was designed to include a fibrous structure with high porosity, similar to native extracellular matrix. The device is a porous matrix with the permission of the cell ingression and soft tissue formation in the defect space/wound bed. The device does not contain any human or animal materials or tissues, drugs , nanomaterials and active ingredients.

5. Indication for Use

LUOFUCON® Wound Matrix is indicated to cover and protect a wound.

The LUOFUCON®Wound Matrix is intended for the management of:

- partial and full-thickness wounds
- pressure ulcers
- venous ulcers
- diabetic ulcers
- chronic vascular ulcers
- surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
- trauma wounds (abrasions, lacerations, skin tears)
- partial thickness burns
- draining wounds.

LUOFUCON® Wound Matrix is intended for adults except for those who are allergic to poly(lactic-co-glycolic acid) or polyethylene glycol.

6. Substantially Equivalent (SE)

The subject device has been found to be substantially equivalent to the legally marketed predicate/reference devices.

A table comparing the subject and predicate/reference devices is presented as below:

Characteristic	LUOFUCON® Wound Matrix (Subject Device)	Restrata™ Wound Matrix (Predicate Device)	Comparison
510 (k)	K254256	K170300	N/A
Product Code	QSZ	QSZ	Equivalent to predicate device
Device Class	Unclassified	Unclassified	Equivalent to predicate device
Intended use	LUOFUCON® Wound Matrix is intended for use in the management of wounds,	Restrata is intended for use in the management of wounds	Equivalent to predicate device
Indications for Use	including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, skin tears), partial thickness burns, draining wounds.	including: Partial and full thickness wounds, pressure sores/ ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/ undermined wounds, surgical wounds (e.g., donor site / grafts, post-laser surgery, post-Moh's surgery, podiatric wounds, dehisced wounds), trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds.	Equivalent to predicate device

Characteristic	LUOFUCON® Wound Matrix (Subject Device)	Restrata™ Wound Matrix (Predicate Device)	Comparison
Mode of Action	Protect a wound and facilitate a moist environment for natural healing to occur by forming a physical barrier over the wound bed and providing a scaffold for cellular infiltration and vascularization.	Protect a wound and facilitate a moist environment for natural healing to occur by forming a physical barrier over the wound bed and providing a scaffold for cellular infiltration and vascularization.	Equivalent to predicate device
Material Composition	Synthetic dual polymer matrix comprised of poly (lactic- co - glycolide) and polyethylene glycol (PLGA/PEG)	Synthetic dual polymer matrix comprised of polyglactin and polydioxanone fibers (PGLA/PDO)	PLGA is equivalent to predicate device, PEG is equivalent to reference device
Size	3.0 cm × 3.0 cm 5.0 cm × 5.0 cm 7.0 cm × 7.0 cm 10.0 cm × 10.0 cm 12.5 cm × 17.5 cm	2.5 cm × 2.5 cm (1”×1”) 2.5 cm × 7.5 cm (1”×3”) 5.0 cm × 5.0 cm (2”×2”) 7.5 cm × 7.5 cm (3”×3”) 10.0 cm × 12.5 cm (4”×5”) 12.5 cm × 17.5 cm (5”×7”)	Equivalent to predicate device
Form	Single-layer sheet	Single-layer sheet	Equivalent to predicate device
Surgical Application Restrictions	Device does not have requirement for specific orientation	Device does not have requirement for specific orientation	Equivalent to predicate device
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Equivalent
Endotoxin	<20 EU/Device	<20 EU/Device	Equivalent to predicate device
Single use	Yes	Yes	Equivalent
Sterilization	Sterile, irradiation	Sterile, irradiation	Equivalent to predicate device
Biocompatibility	Biocompatible	Biocompatible	Equivalent

The LUOFUCON® Wound Matrix has the same intended use, indications for use, and similar technological characteristics to the predicate device.

The subject device and the predicate device are both sterile, single-use wound dressings indicated for wound management. Both devices are supplied as single-layer sheet-form matrices and are composed of biocompatible, resorbable polymeric materials. The subject device is manufactured from poly(lactic-co-glycolic acid) (PLGA) and polyethylene glycol (PEG) fibers, whereas the predicate device is manufactured from poly(glycolide-co-lactide) (PGLA) and polydioxanone (PDO) polymers. The subject device and the predicate device use the same mode of action. Both are porous, non-woven matrices designed to protect the wound by forming a physical barrier over the wound bed while

maintaining a moist environment. In addition, both devices provide an extracellular matrix (ECM)-like scaffold that facilitates cellular infiltration and vascularization. Although the polymer compositions differ, the subject device has the same intended use and incorporates the same fundamental technological characteristics as the predicate device, including device configuration, and mode of action.

7. Non-Clinical Data/Information

The following non-clinical data and performance data were provided to demonstrate the safety and performance of the subject device for its intended use and to support a determination of substantial equivalence.

7.1 Sterilization and Shelf-Life

The LUOFUCON® Wound Matrix was sterilized using E-beam radiation to a sterility assurance level of 10^{-6}. In addition to application of the VDmax[25] methodology, the method of radiation sterilization was established and validated per ISO 11137-1/-2.

Per FDA guidance on shelf life, a real-time aging test was conducted to demonstrate the shelf-life of LUOFUCON® Wound Matrix.

7.2 Biocompatibility

Based on Table A.1 of ISO 10993-1/Table A.1 of "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 surface device for breached or compromised surface with long-term duration, the relevant biocompatibility endpoints were conducted tests or evaluation as required. The results showed that LUOFUCON® Wound Matrix meets biocompatibility requirements of the ISO 10993-1 standard and FDA Guidance. The subject device raised no new safety concerns for biocompatibility to the predicate device.

The following biocompatibility tests were conducted:

- Cytotoxicity
- Irritation
- Sensitization
- Material-mediated Pyrogenicity
- Genotoxicity
- Implantation
- Acute Systemic Toxicity
- Subchronic Systemic Toxicity
- Chemical Characterization and Toxicological Risk Assessment
- Chronic Systemic Toxicity
- Carcinogenicity

7.3 Performance Test-Bench

A series of bench tests were conducted which included an evaluation of physical, chemical, and biological properties. Parts of bench test were used to compare the subject device against to the predicate device. The results of the testing confirm that the subject device meets all product

performance requirements for the intended use and demonstrates substantial equivalence to the predicate device.

The following performance tests were conducted on subject devices:

- Appearance
- Thickness
- Morphology
- Tensile strength
- Sterility
- Endotoxin

8. Conclusion

Based on the data provided in this 510(K) submission as summarized above, it can be concluded that the subject device is substantially equivalent to the predicate device concerning intended use, indications for use, technological characteristics, performance data as shown in a series of performance tests and biocompatibility studies. The technological differences between the two devices do not raise different questions of safety or effectiveness.