September 20, 2022

Huizhou Foryou Medical Devices CO., Ltd.
Taylor Deng
R&D Assistant Manager
No.1 Shangxia North Road, Dongjiang Hi-tech Industry Park
Huizhou, Guangdong 516000
China

Re: K213598
Trade/Device Name: LUOFUCON Collagen Wound Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: August 5, 2022
Received: August 5, 2022

Dear Taylor Deng:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213598

Device Name
LUOFUCON® Collagen Wound Dressing

Indications for Use *(Describe)*
LUOFUCON® Collagen Wound Dressing is intended for the management of wounds including: full thickness and partial thickness wounds, pressure ulcers, venous ulcers, ulcers caused by mixed vascular etiologies, diabetic ulcers, partial thickness burns, donor sites and other bleeding surface wounds, abrasions, traumatic wounds healing by secondary intention, dehisced surgical incisions.
The dressing can be cut to the exact size of the wound, and can be used in multiple layers.

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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510(k) Summary

This 510(k) Summary information is being submitted in accordance with the requirement of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(K) Number: K213598

1. Submitter:

Huizhou Foryou Medical Devices CO., Ltd.
Address: No.1 Shangxia North Road, Dongjiang Hi-tech Industry Park, Huizhou, Guangdong, China. 516000
Phone: +86-752-5302185
Contact Person：Taylor Deng
Email address: tfdeng@foryougroup.com
Date Prepared：11/05/2021

2. Subject Device:

Common or Usual Name: Collagen Wound Dressing
Trade or Proprietary Name：LUOFUCON® Collagen Wound Dressing
Classification Name: Dressing, Wound, Collagen
Product Code: KGN
Regulatory Class: Unclassified
Review Panel: General & Plastic Surgery

3. Predicate device and reference device:

The subject device has been found to be substantially equivalent to the legally marketed device (the predicate device).

Predicate device:

The Name of Device: Medline Collagen Wound Dressing
510(K) Number: K060456
Submitter: Medline Industries, Inc.
Classification Name: Dressing, Wound, Collagen
Product Code: KGN
Regulatory Class: Unclassified

Review Panel: General & Plastic Surgery

Reference device:

The Name of Device: Coreleader Colla-Pad
Common Name: Collagen Wound Dressing
510(K) Number: K102946
Manufacturer: CORELEADER BIOTECH CO., LTD.
Classification Name: Dressing, Wound, Collagen
Product Code: KGN
Regulatory Class: Unclassified
Review Panel: General & Plastic Surgery

4. Device description:

LUOFUCON® Collagen Wound Dressing is comprised of a porous matrix of cross-linked bovine collagen. LUOFUCON® Collagen Wound Dressing is a sterile, single use, white or off-white, pliable, absorbent and biodegradable wound dressing.

When the wound dressing absorbs wound exudate or sterile water, LUOFUCON® Collagen Wound Dressing transforms into a soft, conformable gel sheet, maintains a moist wound environment, to protect the wound and support natural healing.

LUOFUCON® Collagen Wound Dressing can be used as a primary wound dressing in direct contact with the wound, or be used in combination with other suitable secondary dressings. The dressing can be cut to the exact size of the wound, and can be used in multiple layers.

LUOFUCON® Collagen Wound Dressing is sterilized and sold after sterilization by radiation using conditions validated following ISO 11137-2:2013.

5. Indication for Use:

LUOFUCON® Collagen Wound Dressing is intended for the management of wounds including:

Full thickness and partial thickness wounds

Pressure ulcers

Venous ulcers
Ulcers caused by mixed vascular etiologies
Diabetic ulcers
Partial thickness burns
Donor sites and other bleeding surface wounds
Abrasions
Traumatic wounds healing by secondary intention
Dehisced surgical incisions

6. Comparison to the predicate device:

Table 5-1 summarizes the similarities and differences of the subject device and the predicate device in terms of intended use, indications for use, technological characteristics (e.g. design, material, physical structure, technology method, main process, mode of action), sterilization, and animal-derived materials safety.

Table 5-1 Comparison between the subject device and the predicate device

Item	**Subject device**	**Predicate device**
510(K) number	To Be Determined	K060456
Product Code	KGN	KGN
Device Class	Unclassified	Unclassified
Review Panel	General & Plastic Surgery	General & Plastic Surgery
Prescription	Yes	Yes
Intended use	LUOFUCON® Collagen Wound Dressing is intended for the management of wounds.	Medline Collagen Wound Dressing is indicated for the management of wounds.
Indications for use	Full thickness and partial thickness wounds, Pressure ulcers, Venous ulcers, Ulcers caused by mixed vascular etiologies, Diabetic ulcers, Partial thickness burns, Donor sites and other bleeding surface wounds, Abrasions, Traumatic wounds healing by secondary intention, Dehisced surgical incisions.	Full thickness and partial thickness wounds, Pressure ulcers, Venous ulcers, Ulcers caused by mixed vascular etiologies, Diabetic ulcers, Partial and full thickness burns, Donor sites and other bleeding surface wounds, Abrasions, Traumatic wounds healing by secondary intention, Dehisced surgical incisions.
Material	Bovine collagen	Collagen
Animal Source	Bovine	Bovine
Physical structure	Porous microstructure	Porous microstructure
Biodegradable	Yes	Yes
Technology method	Reconstructed from purified collagen	Reconstructed from purified collagen
Main processes	Freeze-drying and physical	Freeze-drying and

	cross-linking	cross-linking
Mode of action	LUOFUCON® Collagen Wound Dressing absorbs wound exudate or sterile water transforms into a soft, conformable gel sheet, maintains a moist wound environment, to protect the wound and support natural wound healing.	Medline collagen wound dressing is a unique, sterile biomaterial, forms a soft, conformable moist gel sheet and provides a moist microenvironment at the wound surface, promoting natural healing.
Sterilization	Terminally sterilized by radiation, SAL 10^{-6}	Terminally sterilized by radiation
Packaging	Single barrier	Single barrier
Single use	Yes	Yes
Shelf life	2 years	3 years
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1
Inactivation study of Viruses	Performed, more than 6 logs reduction of viruses	Complied

LUOFUCON® Collagen Wound Dressing has the same intended use, similar indications for use, and very similar technological characteristics to the predicate device *Medline Collagen Wound Dressing* (K060456). Both devices are 100% collagen from bovine and are designed as single-layer, sheet form, porous microstructure, Tyvek packaging, single-use, sterile product. They are manufactured by way of freeze-drying, cross-linking, and irradiation sterilization processes. The subject and predicate devices employ the similar mode of action in that both devices contain an absorbent nature that maintains a moist wound environment to support natural wound healing.

The premarket submission of LUOFUCON® Collagen Wound Dressing is compliant with FDA guidance document-Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices).

7. Non-Clinical Data/Information:

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

Sterilization and Shelf-Life

LUOFUCON® Collagen Wound Dressing is sterilized using gamma radiation to a sterility assurance level of 10^{-6}. In addition to application of the VD_{max}^{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 and the result demonstrated that the shelf-life of LUOFUCON® Collagen Wound Dressing is up to 2 years.

Biocompatibility

Based on Table A.1 of ISO 10993-1 and 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 permanent duration, the relevant biocompatibility endpoints were conducted tests or evaluation as required. The results showed that Collagen Wound Dressing 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.

Biocompatibility tests included:

- Cytotoxicity
- Irritation
- Sensitization
- Material-mediated pyrogenicity
- Acute Systemic Toxicity
- Genotoxicity
- Subchronic Toxicity
- Implantation
- Haemolysis

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 its predicate device. 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
- Weight
- Loss on drying
- Porosity
- Tensile strength
- Free swell absorption
- The time of full absorbency
- pH value
- Heavy metal
- Hydroxyproline assay
- Endotoxin content
- Sterility
- Scanning Electron Microscope (SEM)
- Differential Scanning Calorimetry (DSC)
- Fourier Transform Infrared Spectroscopy (FTIR)
- In-Vitro degradation
- Degree of crosslinking
- Trypsin resistance

Animal-Derived Materials Safety Information

Based on utilization of animal derivative materials in LUOFUCON® collagen wound dressing, the relevant requirements of safety is compliant with FDA guidance document-Medical Devices Containing Materials Derived from Animal Sources (Except for In Vitro Diagnostic Devices) and ISO 22442 standards.

8. Conclusions：

LUOFUCON® Collagen Wound Dressing has the same intended use, similar indications for use, and very similar technological characteristics as the predicate device, with differences in production processes, in-vitro degradation time, size, and shelf-life. The technological differences between the two devices raise no new issues of safety or effectiveness and the subject device is substantially equivalent to the legally marketed predicate device.

Based on the data provided as summarized above, it can be concluded that the subject device is substantially equivalent to the predicate device Medline collagen wound dressing (K060456) with regard to intended use, indications for use, technological characteristics, performance tests, animal-derived materials evaluation, and biocompatibility.