April 16, 2026

Beijing Kreate Medical Co., Ltd.
% Christopher Swanson
Regulatory Affairs Consultant
Scientific Horizons Consulting, LLC
5270 California Ave.
Suite 300
Irvine, California 92617

Re: K260020
Trade/Device Name: Redermo Wound Matrix
Regulatory Class: Unclassified
Product Code: QSZ
Dated: December 30, 2025
Received: January 5, 2026

Dear Christopher Swanson:

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.*

Submission Number *(if known)*

K260020

Device Name

Redermo Wound Matrix

Indications *for* Use *(Describe)*

The product is intended for use in the management of wounds, including: Partial and full thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wound (e.g., donor site/grafts, post-laser surgery, post Mohs surgery, podiatric wounds, dehisced wounds), trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds.

Type of Use *(Select one* or *both, as applicable)*

[X] 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) #: K260020

510(k) Summary

Prepared on: 2026-04-14

Contact Details

21CFR 807.92(a)(1)

Applicant Name	Beijing Kreate Medical Co., Ltd.
Applicant Address	C306, West Ring South Road #18, E-town Beijing 100023 China
Applicant Contact Telephone	+86-15910462412
Applicant Contact	Mr. Gary Gao
Applicant Contact Email	gaoxiangfei@kreatemed.cn
Correspondent Name	Scientific Horizons Consulting LLC
Correspondent Address	5270 California Ave Suite 300 Irvine CA 92617 United States
Correspondent Contact Telephone	(310) 869-1441
Correspondent Contact	Mr. Christopher Swanson
Correspondent Contact Email	cswanson@scientifichorizonsconsulting.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Redermo Wound Matrix
Common Name	Wound Matrix
Classification Name	Unclassified
Regulation Number	878.4490
Product Code(s)	QSZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate#	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K170300	Restrata Wound Matrix	QSZ

Device Description Summary

21 CFR807.92(a)(4)

The Redermo Wound Matrix is a sterile, single use device intended for the management of wounds. The device is a soft, white, conformable, non-friable, absorbable, three-dimensional matrix that provides an environment for the body's healing process to occur. The device is composed of composite fibers made from biocompatible and biodegradable materials. The matrix has a fibrous structure with high porosity, which is structurally similar to native extracellular matrix. The matrix provides a scaffold for cellular infiltration, vascularization, and tissue formation, as demonstrated by in vivo testing. Redermo Wound Matrix is formed by composite fibers made from poly(p-dioxanone) (PDO), poly (lactic-co-glycolic acid) (PLGA) and Poloxamer 188 (P 188). The device does not contain any human or animal materials or tissue.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The product is intended for use in the management of wounds, including: Partial and full thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wound (e.g., donor site/grafts, post-laser surgery, post Mohs surgery, podiatric wounds, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The device has the same indication as the predicate device. Both Redermo and Restrata are intended for use in the management of wounds, including: Partial and full thickness wounds, pressure sores/ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wound (e.g., donor site/grafts, post-laser surgery, post Mohs surgery, podiatric wounds, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds.

Technological Comparison

21 CFR 807.92(a)(6)

The Redermo Wound Matrix shares the same technological characteristics as the predicate device (Restrata). The device is composed of poly(lactic-co-glycolic) acid and polydiaxonone (PDO), same types of polymer materials used in the predicate device (Restrata). Both devices are fabricated using the same electrospinning process technology. Redermo is made of composite fibers overlaying on each other. These fibers form a porous matrix structure. Following application on the wound bed, the fibers will gradually degrade as the new tissue form in their place. The subject device has less than 1% poloxamer 188, which is to increase the wettability of the device and has no other function. Poloxamer 188 has been widely used in other wound dressing products such as the device (Curaline Polyurethane Foam Dressing, K121361). It has a long and safe history and has been used in various wound products.

Both devices are provided sterile using E-beam sterilization and utilize double sterile barrier packaging systems. The subject device packaged a desiccant inside to control moisture and extend shelf life, which does not introduce different questions of safety or effectiveness. The handling characteristics are comparable, as both devices are soft, pliable, trimmable, and capable of adhering to the wound bed. The purpose of biodegradability and resorption is identical for both devices, eliminating the need for removal and avoiding secondary injury. In vitro and in vivo studies demonstrate complete degradation and resorption of the subject device within approximately 28 days. The subject device is equivalent or identical to the predicates in key safety and performance metrics, including sterility, biocompatibility, heavy metal safety (ISO 10993-18).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Redermo was subjected to a number of tests to assess its performance and biocompatibility. These include:
- Physical and Chemical Properties: Thickness, absorbency, pH, and composition
- In Vitro Degradation: Redermo achieved complete mass loss (~90–100%) within 28 days
- Animal Testing: A full-thickness skin defect model in Bama minipigs showed comparable healing rates to the predicate without adverse tissue reaction
- Biocompatibility: ISO 10993-based testing demonstrated an acceptable safety profile and addressed all long term endpoints
- Shelf-life and Packaging: Stability up to 2 years was confirmed via accelerated aging (183 days at 45 °C) and real-time data (24 months)
- Sterilization: E-beam sterilization validated per ISO 11137-2, ensuring a SAL of 10^-6

Not Applicable

Based on the information provided within this 510(k) submission, including the non-clinical testing performed, it is concluded that the proposed Redermo Wound Matrix is safe, effective, and substantially equivalent to the predicate device listed.