February 2, 2026

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

Re: K251582
Trade/Device Name: Redermax Antibacterial Wound Matrix
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 28, 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 13484 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 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 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)*

K251582

Device Name

Redermax Antibacterial Wound Matrix

Indications for Use *(Describe)*

Redermax Antibacterial Wound Matrix is intended for the management of wounds.
Redermax Antibacterial Wound Matrix is indicated for the management of:
• Partial and full thickness wounds
• Pressure ulcers
• Venous ulcers
• Diabetic ulcers
• Chronic vascular ulcers
• Tunneled/undermined wounds
• Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence)
• Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)
• Draining wounds.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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) #: K251582

510(k) Summary

Prepared on: 2026-01-02

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 13017720592
Applicant Contact	Dr. Sean Chen
Applicant Contact Email	sean.chen@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	Redermax Antibacterial Wound Matrix
Common Name	Antibacterial Wound Matrix
Classification Name	Pre-Amendment
Regulation Number	Unclassified
Product Code(s)	FRO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate#	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K051647	PuraPly® Antimicrobial Wound Matrix	FRO

Device Description Summary

21 CFR 807.92(a)(4)

Redermax Antibacterial Wound Matrix is a sterile, single-use device intended for use in the management of wounds. Redermax is a soft, white, conformable, non-friable, absorbable, three-dimensional matrix that provides an environment for the body's healing process to occur. Redermax is supplied dry in sheet form. The device consists of composite fibers made from biocompatible and biodegradable materials. With a defined rate of absorption, the matrix provides a physical structure for wound healing before complete degradation through hydrolysis. Redermax is a porous matrix composed of poly(lactic-glycolic acid) (PLGA), polydioxanone (PDO), Poloxamer 188, and poly (hexamethylene biguanide) hydrochloride (PHMB), and based on in vitro testing, the PHMB effectively reduces the growth of bacteria within the Redermax Wound Matrix for a period of up to 7 days. The device does not contain any human or animal materials or tissue.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Redermax Antibacterial Wound Matrix is intended for the management of wounds.
Redermax Antibacterial Wound Matrix is indicated for the management of:

- Partial and full thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunneled/undermined wounds
- Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)
- Draining wounds.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Redermax Antibacterial Wound Matrix is intended for the management of wounds. PuraPly® Antimicrobial Wound Matrix is intended for the management of wounds. Based on in vitro testing, the PHMB effectively reduces the growth of bacteria within the Redermax Wound Matrix for a period of up to 7 days. No clinical studies have been conducted, and no clinical benefit has been demonstrated related to the role of this antibacterial. Both Redermax and PuraPly® are intended for the management of wounds. While PuraPly® is also designed to reduce bacterial penetration through the device, Redermax features a perforated structure and therefore does not claim to prevent trans-device bacterial penetration.

This difference in functionality is acknowledged and does not constitute a new intended use under 21 CFR 807.100(b)(2), as Redermax remains intended for external wound management, rather than acting as a full impermeable barrier.

Technological Comparison

21 CFR 807.92(a)(6)

The Redermax™ Antibacterial Wound Matrix was compared with the primary predicate, PuraPly® Antimicrobial Wound Matrix (K051647), to evaluate technological characteristics relevant to safety and performance. Both devices are absorbable wound matrices intended for the management of partial-and full-thickness wounds, including pressure ulcers, venous ulcers, diabetic ulcers, surgical wounds, trauma wounds, tunneled/undermined wounds, and draining wounds, and share the same overall intended use.

Device form, appearance, and handling characteristics are comparable among the subject and predicate devices. Redermax is supplied as a sterile, white, flat sheet that is soft, pliable, trimmable, and capable of adhering to the wound bed, consistent with the handling characteristics of the predicate device. None of the devices require a specific orientation during application.

Material composition and structural design differ among the devices but serve the same functional purpose. Redermax is composed of electrospun composite fibers of PLGA and PDO with Poloxamer 188 and PHMB, and the primary predicate consists of an animal-derived collagen matrix coated with PHMB. Both devices utilize biodegradable, biocompatible materials forming absorbable matrices to support wound management.

Resorbability and degradation profiles are comparable. Redermax demonstrates substantial resorption by Day 14 and complete degradation within approximately 28 days, consistent with the degradation behavior reported for the predicate device. The purpose of biodegradability for devices is to avoid removal from the wound bed and reduce the risk of secondary injury.

Antimicrobial characteristics are comparable between the subject device and the primary predicate device. Redermax incorporates PHMB at 2.5 wt%, while the primary predicate contains PHMB at a lower concentration. In both PHMB-containing devices, PHMB functions as a device protectant to resist bacterial colonization within the matrix. Despite the difference in PHMB concentration, PHMB is released in a controlled manner concurrent with matrix degradation, with complete release occurring within approximately one month, consistent with the primary predicate. This difference does not alter the intended antimicrobial function and does not raise different questions of safety or effectiveness.

Mechanical performance, absorbency, and safety-related characteristics are comparable. Redermax demonstrates tensile breaking strength greater than 4.1 N, absorbency within the range of predicate performance, acceptable heavy metal content per ISO 10993-18, sterility assurance via irradiation, and confirmed biocompatibility.

Packaging, sterilization, and clinical use practices are comparable. Redermax is supplied sterile via E-beam sterilization in a double sterile barrier system, consistent with predicate devices. Differences in fixation methods and re-application practices reflect labeling and clinical use differences and do not alter the fundamental technological characteristics of the devices.

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

Redermax was subjected to a number of tests to assess its performance and biocompatibility. These include:

- Physical and Chemical Properties: Thickness, absorbency, pH, and composition
- Antibacterial Performance: Using a modified AATCC 100 test on six bacterial species, Redermax consistently demonstrated ≥4-log reductions throughout the shelf life
- In Vitro Degradation: Redermax achieved complete mass loss (~90-100%) within 28 days, comparable to the predicate
- 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 15 months was confirmed via accelerated aging (258 days at 40 °C) and real-time data (8 months and 15 months)
- Sterilization: E-beam sterilization validated per ISO 11137-2, ensuring a SAL of 10^-6

Not Applicable.

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