August 14, 2026

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

Re: K261646
Trade/Device Name: Redermax® Antibacterial Wound Matrix
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 18, 2026
Received: May 18, 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.

510(k) Number *(if known)*
K261646

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, partial-thickness 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.

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Submitter's Information:

Manufacturer: Beijing Kreate Medical Co., Ltd.

Address: C306, West Ring South Road #18, E-town, Beijing, China.

Official Correspondent: Christopher Swanson

Regulatory Affairs Consultant

(310) 869-1441

cswanson@scientifichorizonsconsulting.com

Device Information:

Device Name:	Redermax Antibacterial Wound Matrix
Common Name:	Antibacterial Wound Matrix
Classification	Unclassified
Product Code:	FRO
Predicate Device:	K251582, Redermax Antibacterial Wound Matrix

Device Description

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. Based on structural characterization, in vitro cell-interaction observations, and in vivo histological findings, the matrix has a highly porous fibrous structure. The device provides a porous, absorbable matrix that supports cellular infiltration during wound healing. 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 Antibacterial Wound Matrix for a period of up to 7 days. The device does not contain any human or animal materials or tissue.

Indications for Use

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, partial-thickness burns, and skin tears)
• Draining wounds.

Technological Characteristics

Redermax® Antibacterial Wound Matrix remains substantially equivalent to the legally marketed predicate device, Redermax Antibacterial Wound Matrix (K251582). The subject device has the same design, material composition, PHMB concentration, chemical composition, principle of operation, manufacturing process, sterilization method, packaging configuration, and wound-management indication as K251582. The differences are limited to labeling updates supported by new evidence.

The subject device is a modification of the predicate device (K251582) limited to updated product labeling. Four labeling updates are included: (1) in the IFU Device Description section, addition of a matrix description stating that it has a highly porous fibrous structure, and that the device provides a matrix for cellular infiltration; (2) removal of the single-application restriction and addition of re-application instructions, permitting healthcare practitioners to reapply a new, sterile Redermax matrix every 7-14 days over a previously absorbed application when wound conditions require continued management.

The matrix-related device description is supported by structural characterization, in vitro cell-interaction observations, and in vivo histology. The repeat-application language is supported by a repeat-use porcine wound study using a marketed PHMB comparator and by the updated Biological Evaluation Report. The data demonstrate that the proposed labeling updates do not raise new or different questions of safety or effectiveness and support substantial equivalence to K251582.

Non-Clinical Testing

The subject device maintains the same materials, design, manufacturing process, and mechanism of action as that of the previously cleared Redermax Antibacterial Wound Matrix. The proposed change is limited to the labeling. Since there is no material change to the existing device, testing results from previous submission (K251582) were leveraged to support this submission. These include (except the Animal Testing):

• 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

• Animal Testing: A full-thickness skin defect model in Bama minipigs showed comparable healing rates to the comparator 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

New bench characterization and cell study results support the device description updates.

New animal study and biological evaluation were conducted to address the related local safety and performance questions with repeated application and further support tissue integration function of the device.

Clinical Testing

No clinical testing was conducted, referenced, or relied upon in support of this submission.

Comparison to Predicate Device

Redermax® Antibacterial Wound Matrix is substantially equivalent to K251582. The subject device is the same as the predicate device with respect to design, material composition, PHMB concentration, principle of operation, manufacturing process, sterilization method, packaging configuration, and indications for use. This 510(k) consists of focused labeling updates to the device description, repeat-application instructions, and precautionary language. These updates are supported by the new repeat-application animal study, updated biological evaluation, structural/cellular characterization.

Substantial Equivalence

Device Characteristics	Subject Device Redermax® N/A	Primary Predicate Device Redermax Antibacterial Wound Matrix K251582
Applicant	Beijing Kreate Medical Co., Ltd.	Beijing Kreate Medical Co., Ltd.
Indication	Redermax® 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, partial-thickness burns, and skin tears) ● Draining wounds.	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.
Appearance	White flat sheet	White flat sheet
Ingredient	Device is formed by composite fibers electrospun from poly(lactic-glycolic acid) (PLGA), polydioxanone (PDO), Poloxamer 188, and poly(hexamethylene biguanide) hydrochloride (PHMB).	Device is formed by composite fibers electrospun from poly(lactic-glycolic acid) (PLGA), polydioxanone (PDO), Poloxamer 188, and poly(hexamethylene biguanide) hydrochloride

Device Characteristics	Subject Device Redermax® N/A	Primary Predicate Device Redermax Antibacterial Wound Matrix K251582
		(PHMB).
Packaging	Double sterile pack.	Double sterile pack.
Handling characteristics	Soft, pliable, and can be trimmed and can adhere to the wound bed easily.	Soft, pliable, and can be trimmed and can adhere to the wound bed easily.
Degradation/Resorption profile	Underwent complete degradation within 28 days *in vitro*. Substantially resorbed in Day 14 and complete resorption in Day 28 in Animal study	Underwent complete degradation within 28 days *in vitro*. Substantially resorbed in Day 14 and complete resorption in Day 28 in Animal study
PHMB concentration and release profile	PHMB Concentration: 2.5 wt% of the total wound matrix The in vitro release of PHMB from a 12.5 cm^2 Redermax sample was 0.80 mg.	PHMB Concentration: 2.5 wt% of the total wound matrix The in vitro release of PHMB from a 12.5 cm^2 Redermax sample was 0.80 mg.
Method of application		Apply a non-adherent dressing followed by secondary dressings, as appropriate, for the type and

Device Characteristics	Subject Device Redermax® N/A	Primary Predicate Device Redermax Antibacterial Wound Matrix K251582
	Apply a non-adherent dressing followed by secondary dressings, as appropriate, for the type and stage of wound. The optimal secondary dressing is determined by wound location, size, depth and physician or provider.	stage of wound. The optimal secondary dressing is determined by wound location, size, depth and physician or provider.
Re-application practice	If the wound is free of infection and necrosis, but not fully epithelialized, reapply a newly prepared Redermax Antibacterial Wound Matrix over the previously absorbed/degraded application. The device may remain in place till fully resorbed. If necessary, reapply Redermax Antibacterial Wound Matrix every 7-14 days, or based on wound status and matrix degradation/absorption, following the appropriate preparation and application steps.	Redermax Antibacterial Wound Matrix is intended for single application only. Do not reapply after the initial matrix has been absorbed.
Tensile breaking strength/stiffness	Greater than 4.1 N	Greater than 4.1 N
Surgical Application Restrictions	Device does not have requirement for specific orientation	Device does not have requirement for specific orientation
Size	1.4 cm disc [0.55 in.] 2.5 cm × 2.5 cm [1 in.× 1in.]	1.4 cm disc [0.55 in.] 2.5 cm × 2.5 cm [1 in.× 1in.]

Device Characteristics	Subject Device Redermax® N/A	Primary Predicate Device Redermax Antibacterial Wound Matrix K251582
	5 cm × 5 cm [2 in.× 2 in.] 5 cm × 7.5 cm [2 in.× 3in.]	5 cm × 5 cm [2 in.× 2 in.] 5 cm × 7.5 cm [2 in.× 3in.]
Sterilization	Sterile (E-beam)	Sterile (E-beam)
Sterility	Sterile	Sterile
Biocompatibility	Biocompatible	Biocompatible
Resorbable	Yes	Yes

Substantially Equivalent Conclusion

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 with new labeling updates does not raise new safety concern, and is substantially equivalent to the cited predicate device.