July 21, 2026

Xuzhou Kernel Medical Equipment Co., Ltd.
% Gang Che
Prrc
3.Xuzhou Kernel Medical Equipment Co., Ltd.
Kernel Mansion, Economic Development District
Xuzhou, Jiangsu 221004
China

Re: K261775
Trade/Device Name: Uv Phototherapy (KN-4001A, KN-4001B, KN-4001AB)
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: May 28, 2026
Received: May 29, 2026

Dear Gang Che:

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,

YAN FU -S

Digitally signed by YAN FU -S
Date: 2026.07.21 19:40:28 -04'00'

for Tanisha L. Hithe
Assistant Director
DHT4A: Division of General 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)*
K261775

Device Name
Uv Phototherapy (KN-4001A, KN-4001B, KN-4001AB)

Indications for Use *(Describe)*
The devices are indicated for use to treat diagnosed skin disorders such as, but not limited to, psoriasis, vitiligo, and atopioc dermatitis (eczema) under the direction of a physician. The population may range from pediatric to geriatric.

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

K261775

Date of Summary Preparation: May 29, 2026

Update to current: July 21, 2026

1. Submitter's Identifications

Submitter's Name: Xuzhou Kernel Medical Equipment Co., Ltd.
Address: Kernel Mansion, Economic Development District, Xuzhou City, Jiangsu Province, China
Contact Person: Che Gang
Contact Title: PRRC
Contact E-mail Address: chg@kernelmed.com
Telephone: +86-516-87732208

2. Correspondent’s Identifications

Correspondent’s Name: Guangzhou Junyi Information Technology Co., Ltd.
Address: Room 304, Building A, No. 62 Nanyun 2nd Road, Science Town, Huangpu District, Guangzhou City, Guangdong, 510663, China
Contact Person: Shanfeng Jiang
Contact Title: Regulation Control Manager
Contact E-mail Address: Jiang13620586569@126.com
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3. Name of the Device

Device Classification Name: Ultraviolet lamp for dermatologic disorders
Trade Name: Uv Phototherapy
Model:KN-4001A,KN-4001B,KN-4001AB
Classification Panel: General & Plastic Surgery
Product Code: FTC
Device Classification: Class II
Regulation Number: 21 CFR 878.4630

4. The Predicate Devices

Predicate Devices K230382　3 Series NeoLux　Daavlin Distributing Company

5. Device Description

5.1 Device introduction:

This instrument consists of an irradiator, control circuit, and UV phototherapy software. Suitable for clinical units or under the guidance of doctors, for patients with skin diseases to self

treat vitiligo, psoriasis, and atopic dermatitis (eczema) with ultraviolet radiation. The irradiation device is equipped with multiple light sources. During operation, the light sources in the irradiation device emit ultraviolet light to irradiate the entire body or local area of the patient. The controller controls the ultraviolet light exposure time according to the dose required by the patient. Dermatologists establish a treatment plan based on the condition, determine the treatment site and the working mode of phototherapy, initial treatment dose, course of treatment, and interval time for patients. The device is equipped with a LCD touch screen. When the operator sets the treatment time or required dose through the operation interface on the control panel, the treatment begins and the light bulb will light up, emitting the specified amount of light.

6. Intended Use of Device

The devices are indicated for use to treat diagnosed skin disorders such as, but not limited to, psoriasis, vitiligo, and atopic dermatitis (eczema) under the direction of a physician. The population may range from pediatric to geriatric.

7. Summary of Substantial Equivalence

Table 1 Comparison to Predicate Device for UV Phototherapy

	Proposed Device	**Predicate device**	**Comparison**
510k Number		K230382	------
Product Code	FTC	FTC	Same
Proprietary Name	Uv Phototherapy	3 Series NeoLux	------
Model	KN-4001A, KN-4001B, KN-4001AB	/	------
Manufacturer	Xuzhou Kernel Medical Equipment Co., Ltd.	Daavlin Distributing Company	------
Indications for Use	The devices are indicated for use to treat diagnosed skin disorders such as, but not limited to, psoriasis, vitiligo, and atopic dermatitis (eczema) under the direction of a physician. The population may range from pediatric to geriatric.	The 3 Series Neolux devices are indicated for use to treat diagnosed skin disorders such as, but not limited to, psoriasis, vitiligo, and atopic dermatitis (eczema) under the direction of a physician. The population may range from pediatric to geriatric.	Same
Prescription Required	Yes	Yes	Same
Patient Population	Pediatric to Geriatric	Pediatric to Geriatric	Same
Structure	Whole body all the cabin	Whole body all the cabin	Same
UV radiation spectrum	UVA: spectral range 320nm~400nm, peak wavelength 368nm ± 3nm; UVB: Spectral range 305nm~315nm, peak wavelength 311nm ± 3nm.	Unknown	Similar The UV radiation spectrum of the proposed device is similar to the predicate device, so this definition does not affect the safety and effectiveness.

Patient Contact	There is no direct patient contact with the device during treatment– Areas of skin are exposed to controlled ultraviolet radiation from a distance of roximately 20cm±1cm away.	There is no direct patient contact with the device during treatment– Areas of skin are exposed to controlled ultraviolet radiation from a distance of approximately 9 inches (22.86 cm) away.	Similar The Patient Contact of the proposed device is similar to the predicate device, so this definition does not affect the safety and effectiveness.
Anatomical Sites	Topical skin treatment	Topical skin treatment	Same
Application Environment	Hospital, Clinic, Medical Center, Private Medical Practice, or other Professional Medical environments under the direction of a physician.	Hospital, Clinic, Medical Center, Private Medical Practice, or other Professional Medical environments under the direction of a physician.	Same
Materials	Interior: Assembles components, ballasts,electronics housed in a metal frame with reflective internal surfaces, fluorescent lamps, and protective acrylic.	Interior: Assembles components, ballasts, electronics housed in a metal frame with reflective internal surfaces, fluorescent lamps, and protective acrylic.	Same
Manufacturing Methods	Identical	Identical	Same
Number of Lamps	40	24 - 48	Same
Lamp Spectrums	UV through Visible	UV through Visible	Same
Treatment Area	Full Body	Full Body	Same
Patient Cooling	Fan	Fan	Same
Power Output (mW/cm^2)	2–25 mW/cm^2	5–25mW/cm^2	Similar The Power Output of the proposed device is similar to the predicate device, so this definition does not affect the safety and effectiveness.

Controller	Embedded Software Controller SmartTouch Controller	ClearLink Controller Flex Controller SmartTouch Controller	Similar The Controller of the proposed device is similar to the predicate device, so this definition does not affect the safety and effectiveness.
Reference standards	Comply with IEC 60601-1-2,IEC60601-1,IEC62471,IEC 60601-2-57	Unknown	Unknown
Discussion for Substantially Equivalent (SE)	The proposed device Uv Phototherapy has the same purpose as the predicate device: Product Code, Indications for Use, Prescription Required, Patient Population, Structure ,Anatomical Sites, Application Environment, Materials, Manufacturing Methods, Number of Lamps, Lamp Spectrums, Treatment Area, Patient Cooling,Reference standards, and Label and Labeling. These items can be controlled within the scope of application. There are slight differences between the ,UV radiation spectrum, Patient Contact, Power Output and the controller. These small differences between the proposed devices and predicate devices do not cause new safety and effectiveness problems. According to the non clinical test results, the proposed device is as safe and has good performance as the predicate device. So the proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.		

8.Substantial Equivalence discussion:

The indication for use of the Uv Phototherapy KN-4001A, KN-4001B, KN-4001AB are the same as that for the predicate devices. Most technical specifications of the Uv Phototherapy KN-4001A, KN-4001B, KN-4001AB are either the same or substantially equivalent as compared to the predicate devices. There are no technological differences that raise new or different questions of safety or effectiveness.

9. Non-Clinical Tests Performed:

The following non-clinical testing was provided in this 510(k):

Electrical Safety and Electromagnetic Compatibility Testing –Uv Phototherapy KN-4001A, KN-4001B,KN-4001AB equipment has been tested and meets the following standard requirements of medical equipment:

● IEC 60601-1:2020 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance.

● IEC 60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances - Requirements and tests.

● IEC 60601-2-57:2023 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

Photobiological Safety Testing – The Uv Phototherapy KN-4001A, KN-4001B,KN-4001AB have been tested and comply with IEC 62471:2006, Photobiological safety of lamps and lamp systems, 1st edition.

Software Verification and Validation – System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

In accordance with the FDA Guidance for Content of Premarket Submissions for Device Software Functions (June 2023), the premarket submission documentation level for this device is designated as Basic Documentation Level.

Equipment performance testing and verification– The Uv Phototherapy KN-4001A, KN-4001B,KN-4001AB were subjected to equipment performance testing; The device has passed all the tests mentioned above, and based on these test results, the manufacturer believes that the Uv Phototherapys KN-4001A, KN-4001B,KN-4001AB are essentially equivalent to the device without causing new safety and effectiveness issues.

10. Conclusion:

Based on comparing to predicate device, the proposed device of Uv Phototherapy KN-4001A, KN-4001B,KN-4001AB are determined to be Substantially Equivalent (SE) to the predicate device, in respect of safety and effectiveness.

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