February 6, 2025

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

Re: K242977
Trade/Device Name: 308nm Excimer Phototherapy Device (CN-308E, KN-4003B3, KN-4003B4, KN-5000C KN-5000D, KN-5000H, KN-5000K)
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: Class II
Product Code: FTC
Dated: September 26, 2024
Received: September 26, 2024

Dear Che Gang:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.02.06 22:17:17 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Office of Product Evaluation and Quality
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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)*
K242977

Device Name
308nm Excimer Phototherapy Device (CN-308E, KN-4003B3, KN-4003B4, KN-5000C KN-5000D, KN-5000H, KN-5000K)

Indications for Use *(Describe)*
308nm Excimer Phototherapy Device is intended to be used for the treatment of psoriasis and vitiligo. It is to be used on intact skin only.

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.

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K242977 - 510(k) Summary

Date of Summary Preparation: January 15 2025

1. Submitter's Identifications

Submitter's Name: Xuzhou Kernel Medical Equipment Co., Ltd.
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2. Correspondent's Identifications

Correspondent's Name: Guangzhou Junyi Information Technology Co., Ltd.
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Contact Title: Regulation Control Manager
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3. Name of the Device

Device Classification Name: Light, Ultraviolet, Dermatological
Trade Name: 308nm Excimer Phototherapy Device
Model: CN-308E, KN-4003B3, KN-4003B4, KN-5000C,KN-5000D, KN-5000H, KN-5000K
Classification Panel: General & Plastic Surgery
Product Code: FTC
Device Classification: Class II
Regulation Number: 21 CFR 878.4630

4. The Predicate Devices

Predicate Devices K200971 308nm Excimer System Xuzhou Kernel Medical Equipment Co., Ltd.

5. Device Description

5.1 Device introduction:

Ultraviolet phototherapy originated in the 1920s. Due to the development of science and technology, the technology of artificial light source has developed rapidly. UVB therapy, as a representative, has become one of the effective methods to treat various skin diseases in developed

countries such as Europe and America.

6. Intended Use of Device

308nm Excimer Phototherapy Device is intended to be used for the treatment of psoriasis and vitiligo. It is to be used on intact skin only.

7. Summary of Substantial Equivalence

Table 1 Comparison to Predicate Device for 308nm Excimer Phototherapy Device

	Proposed Device	**Predicate device**	**Comparison**
510k Number		K200971	------
Product Code	FTC	FTC	Same
Proprietary Name	308nm Excimer Phototherapy Device	308nm Excimer System	------
Model	CN-308E, KN-4003B3, KN-4003B4, KN-5000C,KN-5000D, KN-5000H, KN-5000K	KN-5000C KN-5000D	------
Manufacturer	Xuzhou Kernel Medical Equipment Co., Ltd.	Xuzhou Kernel Medical Equipment Co., Ltd.	------
Indications for Use	308nm Excimer Phototherapy Device is intended to be used for the treatment of psoriasis and vitiligo. It is to be used on intact skin only.	The 308nm Excimer System is intended to be used for the treatment of psoriasis and vitiligo. It is to be used on intact skin only.	Same
Prescription Required	Yes	Yes	Same
Mode of Operation	Non-continuous operation	Non-continuous operation	Same
Wavelength	308 nm ±2nm	308 nm ±2nm	Same
Irradiation mode	Handheld irradiation	Handheld irradiation	Same
Cooling of light source	Air cooling	Air cooling	Same
Treatment Area	CN-308E:30cm²±10%; KN-4003B3,KN-4003B4: 8cm²±10%; KN-5000C,KN-5000D: 20cm²±10%,	20cm²±10%	Similar The treatment area of the proposed device is similar to the predicates K200971. The proposed device has

	KN-5000H, KN-5000K: 12 cm²±10%		passed safety testing. This difference will not improve the safety and effectiveness of the proposed equipment.
Max. UV Irradiation Intensity	10-70 mW/cm²	50 mW/cm²	Similar The Max. UV Irradiation Intensity of the proposed device is similar to the predicate device K200971, so this definition does not affect the safety and effectiveness.
Treatment Time	0~120s	0~120s	Same
Maximum dose	5000mJ/cm²	5 J/cm²（5000mJ/cm²）	Same
Power supply	AC 100-240V 50/60Hz Input Power: KN-5000C: 160VA KN-5000D: 200VA CN-308E:120VA KN-5000H/KN-4003B3:40VA KN-5000K:70VA KN-4003B4：50VA	AC100-240V, 50/60Hz Input Power: KN-5000C: 160VA KN-5000D: 200VA	Similar The “ Power supply” is a little different from the predicate devices, but they all comply with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-83 requirements. So the differences will not raise any safety or effectiveness issue.
MED Dose Determinati on	Manual MED test (KN-5000H is not applicable)	Manual MED test	Same
Display	Touch LCD screen	8 inches touch LCD screen	Same
Security Type	Classification by type of anti-electric shock: Class II; Classification according to the degree of anti-electric shock: Type BF.	Classification by type of anti-electric shock: Class I; Classification according to the degree of anti-electric shock: Type B.	Similar The anti-electric shock type of household medical devices is BF. This product comply with IEC

			60601-1 requirements. The security type does not affect the safety and effectiveness.
Patient Leakage Current	Complied with IEC 60601-1 and IEC 60601-1-11，IEC 60601-2-83	Complied with IEC 60601-1 and IEC 60601-2-57	Similar The Patient Leakage Current of the proposed device is similar to the predicates K200971 . The proposed device has passed safety testing. This difference will not improve the safety and effectiveness of the proposed equipment.
Operating Environment	Temperature： 5～35℃ Relative humidity：≤85% Atmospheric pressure:： 700hPa～1060hPa	Temperature： 5～35℃ Relative humidity：≤85% Atmospheric pressure:： 700hPa～1060hPa	Same
Environmental for transportation and storage	Ambient temperature:-40 ~ 55 ℃ Relative humidity: ≤90% Atmospheric pressure:500 ~ 1060hpa	Ambient temperature:-40 ~ 55 ℃ Relative humidity: ≤90% Atmospheric pressure:500 ~ 1060hpa	Same
Electrical Safety/ Performance	Comply with IEC60601-1 and IEC 60601-1-11，IEC 60601-2-83	Comply with IEC60601-1 and IEC 60601-2-57	Similar The Electrical Safety/ Performance of the proposed device is similar to the predicates K200971. The proposed device has passed safety testing. This difference will not improve the safety and effectiveness of the proposed equipment.
Sterile	N/A	N/A	Same

Single Use	No	No	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
Biocompatibility	Cytotoxicity (ISO10993-5:2009)	Cytotoxicity (ISO10993-5:2009)	Same
	Irritation (ISO 10993-23:2021)	Irritation (ISO 10993-10:2010)	Same
	Sensitization (ISO10993-10:2021)	Sensitization (ISO10993-10:2010)	Same
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Same
Discussion for Substantially Equivalent (SE)	The proposed device 308nm Excimer Phototherapy Device has the same purpose as the predicate device: Product Code, Indications for Use, Prescription Required, Mode of Operation, Wavelength, Irradiation mode, Cooling of light source, Treatment Time, Maximum dose, MED Dose Determination, Display, Operating Environment, Environmental for transportation and storage, Sterile, Single Use, EMC , Biocompatibility and Label and Labeling. These items can be controlled within the scope of application. 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, effective 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 308nm Excimer Phototherapy Device CN-308E, KN-4003B3, KN-4003B4, KN-5000C KN-5000D, KN-5000H, KN-5000K are the same as that for the predicate devices. Most technical specifications of the 308nm Excimer Phototherapy Device CN-308E, KN-4003B3, KN-4003B4, KN-5000C KN-5000D, KN-5000H, KN-5000K 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:

Electrical Safety and Electromagnetic Compatibility Testing – 308nm Excimer Phototherapy Device CN-308E, KN-4003B3, KN-4003B4, KN-5000C KN-5000D, KN-5000H, KN-5000K 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 60601-2-83:2019 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment.

● IEC 60601-1-11:2020 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

Photobiological Safety Testing – The 308nm Excimer Phototherapy Device CN-308E, KN-4003B3, KN-4003B4, KN-5000C KN-5000D, KN-5000H, KN-5000K have been tested and comply with IEC 62471:2006, Photobiological safety of lamps and lamp systems, 1st edition. This IEC standard incorporates the principles of the following ANSI IESNA recommended practices:
● RP 27.1:2005 Recommended practice for photobiological safety for lamps and lamp systems - General requirements.
● RP 27.2:2000 Recommended practice for photobiological safety for lamps and lamp systems - Measurement techniques.
● RP-27.3:2007 Recommended practice for photobiological safety for lamps and lamp systems – Risk group classification and labeling.

Biocompatibility test - The 308nm Excimer Phototherapy Device CN-308E, KN-4003B3, KN-4003B4, KN-5000C KN-5000D, KN-5000H, KN-5000K have been tested and comply with ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021.

Software Verification and Validation – Software documentation consistent with moderate level of concern was submitted in this 510(k). 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.

Equipment performance testing and verification– The 308nm Excimer Phototherapy Device CN-308E, KN-4003B3, KN-4003 B4, KN-5000C, KN-5000D, KN5000H, and KN-5000K were subjected to equipment performance testing (testing items include: Appearance; Spectral peak wavelength; UV irradiation intensity; UV irradiation dose; Effective irradiation zone, Timing and functions, Safety test: Continuous leakage current, Continuous leakage current, Continuous leakage current; Dielectric strength; Dielectric strength; Packaging inspection); At the same time, a device temperature test was conducted to verify that the skin surface temperature remained between 32-41℃ throughout the specified treatment time of 0-120 seconds. The device has passed

all the tests mentioned above, and based on these test results, the manufacturer believes that the 308nm Excimer Phototherapy Devices CN-308E, KN-4003B3, KN-4003B4, KN-5000C, KN-5000D, KN-5000H, and KN-5000K 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 308nm Excimer Phototherapy Device CN-308E, KN-4003B3, KN-4003B4, KN-5000C KN-5000D, KN-5000H, KN-5000K are determined to be Substantially Equivalent (SE) to the predicate device, in respect of safety and effectiveness.

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