February 1, 2023

Xuzhou Kernel Medical Equipment Co., Ltd.
℅ Shanfeng Jiang
Regulation Control Manager
Guangzhou Junyi Information Technology Co., Ltd.
Room 304, Building A, No. 62 Nanyun 2nd Road, Science Town
Huangpu District, Guangzhou City, Guangdong 510663
China

Re: K222751
Trade/Device Name: LED Light Therapy Device, KN-7000L
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: December 5, 2022
Received: December 5, 2022

Dear Shanfeng Jiang:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Jianting Wang -S

Jianting Wang
Acting 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)*
K222751

Device Name
LED Light Therapy Device

Indications for Use *(Describe)*
LED Light Therapy Device use of the red, blue, Yellow and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions.
The red light (633±10nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions.
The blue light (417±10 nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.
The Yellow light (599±10nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles and rhytides.
The infrared light (835±15nm wavelength) is generally use for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

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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Section 5 - 510(k) Summary

K222751

Date of Summary Preparation: September 12, 2022

Update to current: January 31, 2023

1. Submitter's Identifications

Submitter's Name: Xuzhou Kernel Medical Equipment Co., Ltd.
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Contact E-mail Address: mananger@kernelmed.com
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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
Telephone: +86-20-82329549
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3. Name of the Device

Device Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Trade Name: LED Light Therapy Device
Model: KN-7000L
Classification Panel: General & Plastic Surgery
Product Code: GEX
Device Classification: Class II
Regulation Number:21 CFR878.4810

4. The Predicate Devices

K190938 Phototherapy Systems
K200104 Oxylight

5. Device Description

5.1 Device introduction:

The LED Light Therapy Device uses specific wavelengths of light, produced by LEDs (Light

emitting diodes), to manage aesthetic conditions. The device produces light in the red light region of the spectrum (633±10nm), in the blue light regions of the light spectrum (417±10nm), yellow light area (590 ± 10nm) and infrared light region of light spectrum (835±15nm).

The LED Light Therapy Device instrument is equipped with two irradiators. The RBY irradiator has five panels, each of which emits three different colors of light sources (red light, blue light, yellow light); RBI irradiator has five panels, each panel emits three different colors of light sources (red light, blue light, infrared light).

5.2 Composition : The instrument is mainly composed of a main frame, an irradiator, and a lifting stand.

5.3 Equipment functions:

- Light source is extensible according to the areas to be treated to realize large-area irradiation.
- Light source is arranged in matrix, making it more suitable for facial treatment.
- Fixing and electrical connection of the light source is realized through a quick connector, making the replacement more convenient and fast.
- Design of free-lifting cantilever allows the light source to stay at any position and angle.
- 10.4" touch screen simplifies the operation and eliminates the need for professional training.
- 5 commonly used treatment schemes can be stored to avoid repeated setting.
- Warm voice guide makes it easy for you to operate.
- Effective irradiance of the light source can be adjusted according to the treatment need.
- Double switch protection of power switch and power-on password, no need to worry about being misused.
- Non-invasive operation, no damage to skin cells.
- No special care is required after treatment, and makeup can be applied normally.

5.4 Instrument type:

Protection against electric shock: Class I.
Operating mode: continuous operation.
An enclosed apparatus that is not protected against liquid ingress.
Equipment that cannot be used in the presence of flammable anesthetic gas mixed with air or with oxygen or nitrous oxide.

5.5 Main performance indicators

Power supply: AC 100-240V±10%, 50/60 Hz±2%
Input power: 600VA
Fuse specification, model & rating:T8.0AL/250V Φ5*20
Structure: wheeled
Display mode: LCD display
Effective irradiation area: 900cm^2±10%
Irradiation distance: 6cm±1cm
Spectral peak wavelength:
Red light: 633 nm±10 nm;
Blue light: 417 nm±10 nm;

Yellow light: 590 nm±10 nm;
Infrared: 835nm±15nm.
Effective irradiance: The error between the effective irradiance and the nominal value indicated in the nameplate shall be no more than ±25%, and the effective irradiance shall be not more than 200mW/cm^2.
Red light: 20～96mW/cm^2;
Blue light: 10～120mW/cm^2;
Yellow light: 5～35mW/cm^2;
Infrared ≤ 70mW/cm^2.
Red/IR: 20～166mW/cm²，
Blue/IR: 10～190mW/cm²
Working noise:
Under normal working conditions, the noise generated by the instrument shall not exceed 60dB (A).
Stand adjustment:
Under normal working condition, the stand can be adjusted up, down, left and right, and the irradiator can be fixed at any angle.
Timing and functions
The device has a timer with an error not greater than ±2% of the set value, Continuous working time ≤ 99min;
The function of manually stopping radiation output can be realized through the software pause and stop buttons.
Replaceable irradiator.
Treatment can be preset.
The instrument has a calibration function.
The instrument has a time mode.
The instrument has a dose mode.
The instrument has two functions of continuous output and pulse output.

5.6 The list of accessories

No.	Name	Quantity	Unit
1	Main frame	1	Unit
2	Irradiator （Irradiator BRY or Irradiator BRI for option）	2	Pcs
3	Protective goggles (for doctors, patients)	2	Pieces
4	Power cord	1	Pcs.
5	Fuse	2	Pcs.
6	Tools (hex wrench (8mm, 4mm, 5mm and 2mm) and screwdriver, 1 for each)	1	Set
7	M3*10 screw	4	Pcs.
8	M6*15 hexagon socket head cap screw	6	Pcs.
9	Upper hole plug, lower hole plug, seal plug	2 for each	Pcs.
10	Instructions for Use	1	Copy

11	Certificate of Conformity	1	Copy

6. Intended Use of Device

LED Light Therapy Device use of the red, blue, Yellow and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions.

The red light (633±10nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions.

The blue light (417±10 nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

The Yellow light (599±10nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles and rhytides.

The infrared light (835±15nm wavelength) is generally use for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

7. Summary of Substantial Equivalence

Table 1 Comparison to Predicate Device for KN-7000L

	Proposed Device	**Predicate device**	**Predicate device**	**Comparison**
510k Number	K222751	K190938	K200104	------
Product Code	GEX	GEX	GEX	Same
Proprietary Name	LED Light Therapy Device	Phototherapy System	Oxylight	------
Model	KN-7000L	HS-770	/	------
Manufacturer	Xuzhou Kernel Medical Equipment Co., Ltd.	Shanghai Apolo Medical Technology Co., Ltd.	RAJA Trading Company, Inc.	------
Indications for Use	LED Light Therapy Device use of the red, blue, Yellow and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions. The red light(633±10nm wavelength) is generally indicated to treatment of superficial, benign vascular, and pigmented lesions. The blue light(417±10 nm wavelength); is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne	Phototherapy Systems use of the red, blue and infrared regions of the spectrum is intended to emit energy to treat dermatological conditions. The blue light (415nm wavelength) is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris The red light (630nm wavelength) is generally indicated to treatment of superficial, benign vascular,	The Oxylight is intended for dermatological use by physicians and healthcare professionals for the following: LED Technology is intended for: -Blue LED – 465nm – to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. -Red LED 625nm- for treatment of superficial, benign vascular and pigmented lesions. -Yellow LED 590nm - treatment of periorbital	Same

	vulgaris. The Yellow light(599±10nm wavelength)is generally indicated to treat dermatological conditions and specifically indicated for treatment of periorbital wrinkles and rhytides. The infrared light (835±15nm wavelength)is generally use for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.	and pigmented lesions The infrared light (835nm wavelength) is generally use for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.	wrinkles and rhytides.	
Wavelength(s) (nm)	RBY irradiator : (Red light 633 ± 10nm, blue light 417 ± 10nm, yellow light 590 ± 10nm). RBI irradiator: (Red 633 ± 10nm, blue 417 ± 10nm, infrared 835 ± 15nm)	Red light 630 ± 15nm Blue light 415 ± 15nm Infrared 835 ± 15nm	Red light 625nm Blue light 465nm Yellow light 590nm	Substantially equivalent Kn-7000L Wavelength(s) is basically the same as K190938 and K200104.
Panels Type	RBY Irradiator has 5 panels: Red light:465EA LEDs; blue light: 470EA LEDs;	3 panel: 180EA LEDs 4 Panel: 240 EA LEDs. The panels may emit the three	Three type, each head type has only one light.	Substantially equivalent Kn-7000L Panels Type is basically the same as

	yellow light: 465EA LEDs; RBI irradiator: has 5 panels: Red light:465EA LEDs; blue light: 470EA LEDs; infrared: 465EA LEDs; The panels may emit the three light (red, blue infrared) individual or in combination.	light (red, blue, infrared) individual or in combination	Red, Blue, yellow.	K190938 and K200104.
Output Power	Each panel has three different kinds of light-emitting diodes, and the energy power of the diode is 0.5W	Each LED lamp bead has 4 diodes that emit different colors, the energy power of a diode is 3W.	unknown	The Output Power of the proposed device is different from the subject predicate K190938. The proposed device has passed the safety test. This difference will not improve the safety and effectiveness of the proposed device.
Maximum power density in mW（mW/CM²）	Red light: 20～96 mw/cm ² Blue light: 10～120 mw/cm ² Yellow light: 5～35 mw/cm ² Infrared: ≤ 70 mw/cm ² Red/IR: 166mW/cm², Blue/IR: 190mW/cm²	(1) Red light: 115mW/cm², (2) Blue light: 120mW/cm², (3) IR: 70mW/cm², (4) Red/IR: 120mW/cm², (5) Blue/IR: 150mW/cm².	(1) Red: 100mW/cm² (2) Blue: 45mW/cm2 (3) Yellow 35W/cm2	Substantially equivalent Substantially equivalent-within size ranges of predicate devices.
Standard does in Joules	Red light: 155J/cm2, Blue light: 144J/cm2, Yellow light: 42J/cm2, IR: 84J/cm2, Red/IR: 199J/cm2	(1) Red light: 138J/cm2, (2) blue light: 144J/cm2, (3) IR: 84J/cm2, (4) Red/IR: 144J/cm2 (5) Blue/IR: 180J/cm2	(1) Red: 120J/cm2 (2) Blue: 54J/cm2 (3) Yellow: 42J/cm2	Substantially equivalent Substantially equivalent-within size ranges of predicate devices.

	Blue/IR: 228J/cm2			
Adjustable dose range	Red light: 20～96 J/cm2 Blue light: 10～120 J/cm2 ² Yellow light: 5～35 J/cm2 Infrared: ≤ 70 J/cm2 Red/IR: 20～166 J/cm2， Blue/IR: 10～190 J/cm2	(1) Red light: 1-242J/cm2, (2) blue light: 1-180J/cm2, (3) IR:1-147J/cm2, (4) Red/IR: 1-144J/cm2, (5) Blue/IR:1-180J/cm2	(1) Red light: 1-240J/cm2, (2) blue light: 1-108J/cm2, (3) Yellow IR:1-84J/cm2,	Substantially equivalent Substantially equivalent-within size ranges of predicate devices.
Numbers of LEDs	Red light:465EA LEDs; Blue light: 470EA LEDs; Yellow light: 465EA LEDs; Infrared: 465EA LEDs;	3 panels: 180EA, 4 panels: 240EA	unknown	Substantially equivalent Substantially equivalent-within size ranges of predicate devices.
Effective irradiation area:（CM²）	900 cm² ±10%	756cm² and 1008cm²	500cm² and 860cm²	Substantially equivalent-within size ranges of predicate devices.
Structural style	Wheeled	Wheeled	Wheeled	Same
Structure composition	Main frame, irradiator, lifting frame.	Main frame, irradiator, lifting frame	Irradiator and support	Same
Power supply	AC 100-240V 50/60Hz	AC 100-240V 50/60Hz 10A	AC 100-240V 50/60Hz	Same
Treatment time	20min (Recommended treatment time)	20min (Recommended treatment time)	20min (Recommended treatment time)	Same
Operation interface	Display Screen	Display Screen	Display Screen	Same
Software	Yes	Yes	Yes	Same
Safety classification	Class I	Class I	Class I	Same
Standard	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57	Same All devices meet the requirements of effectiveness,

	IEC 62471	IEC 62471	IEC 62471	safety.

8. Substantial Equivalence discussion:

The indication for use of the KN-7000L LED Light Therapy Device are the same as that for the predicate devices. Most technical specifications of the KN-7000L LED Light Therapy Device 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 – KN-7000L LED Light therapy equipment has been tested and meets the following standard requirements of medical equipment:

● IEC60601-1: 2005+2005+CORR.1:2006+CORR.2:2007+A1:2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance.
● IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests.
● IEC 60601-2-57:2011 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests.

Photobiological Safety Testing – The KN-7000L LED Light Therapy Device 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.

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.

10. Conclusion:

Based on comparing to predicate device, the proposed device of KN-7000L are determined to be Substantially Equivalent (SE) to the predicate device, in respect of safety and effectiveness.

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