DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 28, 2017

UVBIOTEK, LLC
Zhou Jinghua
Guangzhou Junyi Information Technology Co, Ltd.
Room 215, Huaming Building, Chebei Road
Guangzhou, Guangdong, China 511660

Re: K170187
Trade/Device Name: Photodynamic Therapy Device
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: July 3, 2017
Received: July 3, 2017

Dear Zhou Jinghua:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170187

Device Name
Photodynamic Therapy Device

Indications for Use *(Describe)*
The Photodynamic Therapy Device combination of Red (633nm±10nm) and Blue (417nm±10nm) is intended to emit energy in the red, blue regions of the spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

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.

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Section 5 - 510(k) Summary

Date of Summary Preparation: July 14/2017

1. Submitter's Identifications

Submitter's Name: UVBIOTEK, LLC
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2. Correspondent's Identifications

Correspondent's Name: Guangzhou Junyi Information Technology Co., Ltd.
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3. Name of the Device

Device Classification Name: Powered Laser Surgical Instrument
Product Name: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Trade Name: Photodynamic Therapy Device
Model: KN-7000A
Classification Panel: General & Plastic Surgery
Product Code: GEX
Device Classification: Class II

4. The Predicate Devices

K083183 Aklarus Phototherapy System

5. Device Description

The Photodynamic Therapy Device KN-7000A is a portable device which uses specific wavelengths of light, produced ***by*** light emitting diodes (LEDs), to manage aesthetic conditions. The device produces light in the red light region of the light spectrum ***(***633±10nm) and/or in the

blue light region of the light spectrum (417±10nm), intended to help reduce the appearance of mild to moderate acne. There are three irradiators available, Blue LED, Red LED and Blue/Red LED.

This device is mainly made up of the main frame, the irradiator, and the lifting stand.

After installing the KN-7000A Photodynamic Therapy Device, the phototherapy patient should be instructed to remove cosmetics, wash their face with water and wipe it dry before therapy. The special protective eyewear should be used to cover both eyes to prevent possible injury by the irradiator. Set treatment parameters on the main interface of the screen, operate the irradiator and make sure that the correct operating distance (6cm±1cm) from the patient's treatment area.

When using pure red, pure blue treatment head alternate irradiation, pure red LEDs irradiates 15 minutes per treatment, pure blue LEDs irradiates 13 minutes per treatment, twice weekly, 8 times per course of treatment; When using red and blue combination treatment head alternate irradiation, red LEDs irradiates 30 minutes per treatment, blue LEDs irradiates 22 minutes per treatment, twice weekly, 8 times per course of treatment.

6. Intended Use of Device

The Photodynamic Therapy Device combination of Red (633nm±10nm) and Blue (417nm±10nm) is intended to emit energy in the red, blue regions of the spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

7. Summary of Substantial Equivalence

Table 1

	Proposed Device	Predicate device	Comparison
510k Number	K170187	K083183	------
Product Code	GEX	ILY GEX	Same
Proprietary Name	Photodynamic Therapy Device	Aklarus Phototherapy System	------
Model	KN-7000A	Aklarus Phototherapy System	------
Manufacturer	Xuzhou Kernel Medical Equipment Co., Ltd.	Hill Laboratories	------
Indications for use	The Photodynamic Therapy Device combination of Red (633nm±10nm) and Blue (417nm±10nm) is intended to emit energy in the red, blue regions of the spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.	The Aklarus Blue (420nm +/-10nm), is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. The Aklarus combination of Red (628nm +/-10nm) and Blue (420nm +/-10nm)	Same. The indications for use of KN-7000A are contained in those of the predicate device.

		is intended to emit energy in the red, blue regions of the spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris. The Aklarus Anti-Aging Red (628nm +/-10nm) and Anti-Aging Infrared (880nm+/-10nm) Combination is intended to emit energy in the red and infra-red region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. The Aklarus Infrared (880nm +/-1Onm) is intended to emit energy in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; 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.	
Structural configuration	Portable	Portable	Same
Components	Main frame, irradiator, lifting stand	Main frame, irradiator, lifting stand	Same
Wavelength	Red light 633±10nm Blue light 417±10nm	Red 628nm±10nm Blue 420nm±10nm Infrared 880nm±10nm	Similar. Wavelength of red and blue light between KN-7000A and the predicate

			device are slightly different. These do not affect the effectiveness and safety.
Power Supply	100-240V, 50/60Hz±2%, 300VA	110-120V, 60Hz, 150VA	Similar. The voltage range of KN-7000A is wider than that of the predicate device.
Recommended method of therapy	When using pure red, pure blue treatment head alternate irradiation, pure red LEDs irradiates 15 minutes per treatment, pure blue LEDs irradiates 13 minutes per treatment, twice weekly, 8 times per course of treatment; When using red and blue combination treatment head alternate irradiation, red LEDs irradiates 30 minutes per treatment, blue LEDs irradiates 22 minutes per treatment, twice weekly, 8 times per course of treatment.	Twice weekly, 20 minutes per treatment	Similar. Recommended method of therapy of KN-7000A is more specific than that of the predicate device. The time of treatment is related to the irradiance dose, because the irradiance dose of red light and blue light of KN-7000A are same to the predicate device, the difference do not affect the effectiveness and safety.
Effective irradiance	Red light 633±10nm Blue light 417±10nm (1)Red head: 60mW/cm^2±10mW/cm^2 52J/cm^2 48W	(1)Red 628nm 20W +/ - 3W Standard dose 52J/cm^2 43mW/cm^2 (2)Blue 420nm 10W+/ - 3W Standard dose 26J/ cm^2	Similar. The wavelength of red light and blue light of KN-7000A are slightly different form those of

	(2)Blue head: 35mW/cm^2±10mW/cm^2 26J/cm^2 28W (3)Red/Blue head: ●Red LEDs 30mW/cm^2±10mW/cm^2 52J/cm^2 24W ●Blue LEDs 20mW/cm^2±10mW/cm^2 26J/cm^2 16W	22 mW/cm² (3)Infrared 880nm 16W +/ - 3W Standard dose 42 J/cm^2 35mW/cm²	the predicate device. The irradiance dose of red light and blue light of KN-7000A are same to the predicate device, so those differences do not affect the effectiveness and safety.
Effective irradiance area	800cm^2±10%	465cm^2±10%	Similar. The effective irradiance area of KN-7000A is larger than that of the predicate device. The effective irradiance area is related to the size of the treatment head, which does not affect the effectiveness and safety.
Working distance	6cm±1cm	1cm	Same
Operation interface	Display screen	Display screen	Same
Safety Classification	Class Ⅰ	Class Ⅰ	Same
Operation Mode	Continuous operation	Continuous operation	Same
Standard	IEC60601-1 IEC60601-1-2 IEC60601-2-57	IEC60601-1 IEC60601-1-2 IEC60601-2-57 IEC62471	Same
Non- sterile	Non- sterile	Non- sterile	Same
Microprocessor Control	Yes	Yes	Same

8. Substantial Equivalence:

The proposed device of KN-7000A has the same classification information, same indications and intended use, same design principle, similar product design and specifications, same irradiance dose of red light and blue light, same performance effectiveness, performance safety as the predicate device.

The differences only exist in such main contents: Wavelength of red and blue light between KN-7000A and the predicate device are slightly different. The effective irradiance area of KN-7000A and the predicate device is different. The two recommended method of therapy are different. The voltage range of KN-7000A is wider than that of the predicate device. These differences do not influence the effectiveness and safety of the device. According to the non-clinical and clinical test results, the proposed device is as safe, as effective and perform as well as the predicate device. Therefore the proposed device is Substantially Equivalent (SE) to the predicate device.

9. Performance Data:

The following testing was performed on the "KN-7000A" Photodynamic Therapy Device in accordance with the requirements of the design control regulations and established quality assurance procedures.

AAMI/ANSI ES60601-1: 2005/(R)2012 and A1:2012,, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance

IEC60601-1-2:2007 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility - Requirements and tests

IEC60601-2-57:2011 Medical Electrical Equipment-Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

Thermal performance test were carried out on human volunteers to show that skin temperature stays below 41 degrees C after 20 minutes of use.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

10. Conclusion:

Based upon the performance data, the subject device is determined to be substantially equivalent to the predicate device.

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