Xuzhou Yongkang Electronic Science Technology Co., Ltd
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM. 608, No. 738, Shangcheng Rd., Pudong
Shanghai, 200120 Cn

Re: K191571
Trade/Device Name: UV Radiation Treatment System
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: June 14, 2019
Received: June 14, 2019

Dear Boyle Wang:

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,

Jessica Mavadia-Shukla
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191571

Device Name
UV Radiation Treatment System

Indications for Use *(Describe)*
The UV Radiation Treatment System models YK-6000A, YK-6000A-T, YK-6000B, andYK-6000B-T, are intended for use under the direction of a physician, for the treatment of vitiligo, psoriasis, and eczema. The devices are intended for treatment of these conditions on Fitzpatrick Skin Types (I-VI).

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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Tab #06 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

1.0 Submitter's information

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Date of Preparation: Feb.5,2020

Designated Submission Correspondent

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2.0 Device information

Trade name: UV Radiation Treatment System
Common name: Ultraviolet Lamp for Dermatologic Disorders
Classification name: Light, Ultraviolet, Dermatological
Model(s): YK-6000A,YK-6000A-T,YK-6000B,YK-6000B-T

3.0 Classification

Production code: FTC
Regulation number: 21 CFR 878.4630
Classification: Class II
Review Panel: General& Plastic Surgery

4.0 Predicate device information

Manufacturer: Xuzhou Kernel Medical Equipment Co., LTD.
Device: UV Phototherapy
510(k) number: K181805

5.0 Indication for Use Statement

The UV Radiation Treatment System models YK-6000A, YK-6000A-T, YK-6000B, andYK-6000B-T, are intended for use under the direction of a physician, for the treatment of vitiligo, psoriasis, and eczema. The devices are intended for treatment of these conditions on Fitzpatrick Skin Types (I-VI).

6.0 Device Description

The proposed device, UV Radiation Treatment System is a portable medical device that consists of tubes, irradiator, control circuit. It is a therapeutic product under the direction of a physician for individuals who require ultraviolet radiation for diagnosed skin disorders. It is for the partial treatment. It has four models: YK-6000A,YK-6000A-T,YK-6000B,YK-6000B-T,in which the model YK-6000A and YK-6000A-T emit UVA light and the model YK-6000B and YK-6000B-T emit UVB light.
This product has the features are as follows:
A. Use Philips special UV lamp as light source, with high stability and long service life;
B. Small bulk, lightweight, operation simply, patients can take with themselves;
C. There is glisten board inner radiation unit, which can raise radiant efficiency.

The UV Radiation Treatment System only can be used in Hospital, Clinic, Medical Center, Private Medical Practice, or Other Professional Medical Environments under direction of physician.

7.0 Non-Clinical Test Conclusion

Non clinical tests were conducted by lab bench testing to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:
IEC 60601-1:2012, Medical electrical equipment-Part 1: General requirements for basic safety, and essential performance.
IEC 60601-2-57: 2011 Medical electrical equipment Part2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/ aesthetic use.
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 62471:2006, Photobiological safety of lamps and lamp systems
ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Test for in

vitro cytotoxicity
ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Test for irritation and delayed-type hypersensitivity
ISO 10993-11:2017 Biological evaluation of medical devices- Part 11: Test for systemic toxicity

8.0 Clinical Test Conclusion

No clinical study is included in this submission.

9.0 Substantial Equivalence Comparison

Table1- Technological Characteristic Comparison

Item	Proposed device	Predicated device K181805	Remark
Product Code	FTC	FTC	SE
Regulation No.	21 CFR 878.4630	21 CFR 878.4630	SE
Class	II	II	SE
Intended Use	The UV Radiation Treatment System models YK-6000A, YK-6000A-T, YK-6000B, andYK-6000B-T, are intended for use under the direction of a physician, for the treatment of vitiligo, psoriasis, and eczema. The devices are intended for treatment of these conditions on Fitzpatrick Skin Types (I-VI).	The UV Phototherapy is intended for use, by or under the direction of a physician for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema). It is intended for use on all skin types (I-VI). It can be used in hospitals, clinics and households.	SE
Prescriptive	Yes	Yes	SE
Mode of operation	Portable	Handheld	Analysis
Shell material	ABS	ABS	SE
Treatment Area	Partial treatment excluding eyes	Partial treatment excluding eyes	SE
Treatment Time	5~20 min	0~30min	Analysis
UV spectral output	UVA or UVB	UVA or UVB	SE
Lamp configuration	1 9W UV tube	1 or 2 9W UV tube	Analysis
Power Source	AC outlet	AC outlet or DC jack	Analysis
Wavelength range（nm)	UVA:320~400 UVB: 300~320	UVA: 350～400 UVB: 310～315	Analysis

IPX – Rating / water resistance	IPX0	IP22	Analysis
Application Environment	Hospital, Clinic, Medical Center, Private Medical Practice, or Other Professional Medical Environments under direction of physician	Hospital, Clinic, Medical Center, Private Medical Practice, or Other Professional Medical Environments, Household use under direction of physician.	Analysis
Electrical Safety/Performance	Comply with IEC60601-1 and IEC 60601-2-57	Comply with IEC60601-1 and IEC 60601-2-57	SE
Home Use	Not applied	Comply with IEC 60601-1-11	Analysis
Sterile	N/A	N/A	SE
Single Use	No	No	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Biocompatibility	Cytotoxicity (ISO 10993-5:2009)	Under the conditions of the study, Comply with the requirements	SE
	Sensitization (ISO 10993-10:2010)		
	Irritation (ISO 10993-10:2010)		
	Pyrogen(ISO 10993-11:2017)		
	Acute Systemic Toxicity(ISO 10993-11:2017)		
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	SE

Analysis:
The predicate device has the models which can support household use. The proposed device is not recommended household use, it just can be used in the professional medical environments under the guidance of doctors. In addition, the proposed device is substantially equivalent to the predicate device. The differences between both devices are insignificant in terms of safety and effectiveness. Based on the nonclinical and clinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

10.0 Conclusion

The conclusions drawn from the comparison and analysis above demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicated device and raises no new questions of safety or effectiveness. The differences between both devices are insignificant in terms of safety and effectiveness.