December 15, 2020

Xuzhou Kernel Medical Equipment Co., Ltd.
℅ Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.608, No.738, Shangcheng Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K200971
Trade/Device Name: 308nm Excimer System
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: October 15, 2020
Received: October 19, 2020

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,

Purva Pandya
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)*
K200971

Device Name
308nm Excimer System

Indications for Use *(Describe)*
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.

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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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: Dec.10th,2020

Designated Submission Correspondent

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2.0 Device Information

Trade name: 308nm Excimer System
Common name: Ultraviolet Lamp for Dermatologic Disorders
Classification name: Light, Ultraviolet, Dermatological
Model(s): KN-5000C; KN-5000D

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

Predicate Device Information 1:
Manufacturer: Chongqing Peninsula Medical Technology Co.,Ltd.
Device: 308nm Excimer System

510(k) number: K172273

Predicate Device Information 2:
Manufacturer: Chongqing Peninsula Medical Technology Co.,Ltd.
Device: 308nm Excimer System (Model: XECL-308E)
510(k) number: K192642

5.0 Indication for Use Statement

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.

6.0 Device Description

The proposed device, 308nm Excimer System is a new type of ultraviolet light therapy instrument, which could emit high levels of UV light. It has the following features:

- High intensity UV light.
- The instrument is suitable for small area treatment with good targeting.
- 8 inches Super Large color touch LCD screen which make the operation display more convenient；
- Manual MED tests can also be performed according to the skin characteristics of the patient.
- One-click Control light source Output.
- Powerful user management capabilities.
- Can realize the export and view of user information；
- Multi-spec treatment handle light filter. The user can choose filter according to the size of the treatment area. Avoid excess radiation output.
- Fingerprint entry makes it easy for doctors to quickly access patient information (for KN-5000D)；
- Accurate calibration system. Enhanced reliability of instrument dose output (KN-5000D applicable).

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

7.0 Clinical Test Conclusion

No clinical study is included in this submission.

8.0 Substantial Equivalence Comparison

Table1- Technological Characteristic Comparison

Item	Proposed device K200971	Predicated device 1 K172273	Predicated device 2 K192642	Remark
Product Code	FTC	FTC	FTC	SE
Regulation No.	21 CFR 878.4630	21 CFR 878.4630	21 CFR 878.4630	SE
Class	II	II	II	SE
Intended Use	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.	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.	The 308nm Excimer System(model: XECL-308E) is an Ultraviolet Light Emitting Medical Device.It is intended to be used for the treatment of psoriasis,vitiligo, atopic dermatitis, and leukoderma. It is to be used on intact skin only.	SE
Prescription Required	Yes	Yes	Yes	SE
Weight	5kg（Treatment handle:1.4kg）	< 2.6 kg	Not publicly available	--
Dimensions (H x W x D)	34.1cm×29.7cm×22.1cm(For Host) 34.1cm×29.7cm×	26 cm x 24 cm x 27 cm(For lamp) 5 cm x 9.5 cm x 18	548.0mm*253.6 mm*181.4mm	--

	28.0cm(After placing the Treatment handle)	cm (For Adapter)		
Mode of Operation	Continuous operation	Continuous operation	Not publicly available	SE
Wavelength	308 nm ± 2nm	308 nanometers (nm) ±3nm	308±2 nm	SE
Light Source	Xenon-Chlorine (XeCl) excimer lamp produces monochromatic UVB light	Xenon-Chlorine (XeCl) excimer lamp produces monochromatic UVB light	Xenon-Chlorine (XeCl) excimer lamp produces monochromatic UVB light	SE
Irradiation mode	Handheld irradiation	Handheld irradiation	Handheld irradiation	SE
Cooling of light source	Air cooling	Air cooling	Cooling fan	SE
Treatment Area	20cm²±10%	16 cm² (4 x 4 cm)	6cm²~28.8 cm²	Analysis 1
Max.UV Irradiation Intensity	50 mW/cm²	50 mW/cm²	50 mW/cm²	SE
Max. Irradiation Power	1000 mW	800 mW	1440 mW	Analysis 1
Treatment Time	0~120s	1s to 40 s	1-140s	Analysis 1
Maximum dose	5 J/cm²	2 J/cm²	7 J/cm²	Analysis 2
Power Source	AC100-240V, 50/60Hz Input Power: KN-5000C: 160VA KN-5000D: 200VA	Adapter Input: 100~240Vac, 50/60 Hz Main unit input: 48 Vdc,2.94 A,135 VA max	Not publicly available	Analysis 3
Power Calibration Method	KN-5000D: Automatic calibration KN-5000C:NA	Internal, automatic	Not publicly available	SE
MED Dose Determination	Manual MED test	Menu driven	Not publicly available	Analysis 4
Display	8 inches touch LCD screen	Touch Screen Control Panel	Not publicly available	SE
Security Type	Classification by type of anti-electric shock: Class	Classification by type of anti-electric shock:	Not publicly available	SE

	I; Classification according to the degree of anti-electric shock: Type B.	Class I; Classification according to the degree of anti-electric shock: Type B.		
Patient Leakage Current	Complied with IEC 60601-1 and IEC 60601-2-57	Complied with IEC 60601-1 and IEC 60601-2-57	Complied with IEC 60601-1 and IEC 60601-2-57	SE
Operating Environment	Temperature：5～35℃ Relative humidity：≤85% Atmospheric pressure:：700hPa～1060hPa	Temperature: 15~35°C, Humidity:≤ 80%RH, Atmospheric Pressure: 86 ~ 106 kPa	Temperature: 5℃～30℃ Humidity:≤80%RH Atmospheric Pressure: 700 ~ 1060 hPa	Analysis 4
Storage Environment	Ambient temperature: -40 ~ 55 ℃ Relative humidity: ≤ 90% Atmospheric pressure: 500 ~ 1060hpa	Temperature: -20~45°C, Humidity: 10-85%RH Atmospheric Pressure: 50 ~ 106 kPa	Temperature: 0℃～40℃ Humidity:≤85%RH Atmospheric Pressure: 700 ~ 1060 hPa	Analysis 4
Electrical Safety/Performance	Comply with IEC60601-1 and IEC 60601-2-57	Comply with IEC60601-1 and IEC 60601-2-57	Comply with IEC60601-1 and IEC 60601-2-57	SE
Sterile	N/A	N/A	N/A	SE
Single Use	No	No	No	SE
EMC	Comply with IEC 60601-1-2	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	Under the conditions of the study, Comply with the requirements	SE
	Irritation (ISO 10993-10:2010			
	Sensitization (ISO 10993-10:2010)			
Label and Labeling	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	Conforms to FDA Regulatory Requirements	SE

Comparison Discussion:

Analysis1:
Although some output specifications as “Max Power Output”, “Treatment area”, and “Treatment time” of the proposed device are a little different from the predicate devices, but they are considered substantially equivalent, and they all comply with the standards: IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-57, and range between the predicate device K172273 and predicate

device K192642. So the we can think that the slight differences in specification will not raise any safety or effectiveness issue.

Analysis 2:
The software limits the maximum dosage of the proposed device to no more than 5 J/cm^2,it is different from the predicate devices, but the value range between the predicate device K172273 and predicate device K192642. So the we can think that the slight differences in specification will not raise any safety or effectiveness issue.

Analysis 3:
The “ Power Source” is a little different from the predicate devices, but they all comply with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-57 requirements. So the differences will not raise any safety or effectiveness issue.

Analysis 4:
The ” Power Source”, “MED Dose Determination” and “Operating and Storage Environment” are a little different from the predicate devices, but they all comply with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-57 requirements. So the differences of function specification will not raise any safety or effectiveness issue.

Final Conclusion:
Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device. The proposed device “308nm Excimer System” is Substantial Equivalent to the predicate devices.

9.0 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.