March 27, 2023

Shenzhen Honpal Optoelectronic Technology Co., Ltd.
% Boyle Wang
Official Correspondent
Shanghai Truthful Information Technology Co., Ltd.
RM.1801,No.161,East Lujiazui Rd.,Pudong
Shanghai, Shanghai 200120
China

Re: K223882
Trade/Device Name: Narrowband UV Phototherapy Light Lamp (Model: HB-UPLL-01, HB-UPLL-02)
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: December 6, 2022
Received: December 27, 2022

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,

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)*
K223882

Device Name
Narrowband UV Phototherapy Light Lamp(Model:HB-UPLL-01, HB-UPLL-02)

Indications for Use *(Describe)*
The Narrowband UV Phototherapy Light Lamp 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.

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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510(k) Summary

K223882

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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Designated Submission Correspondent

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Email: Info@truthful.com.cn

Date of Preparation: Mar.21,2023

2.0 Device Information

Trade/Device name: Narrowband UV Phototherapy Light Lamp
Common name: Ultraviolet Lamp for Dermatologic Disorders
Classification name: Light, Ultraviolet, Dermatological
Model(s): HB-UPLL-01, HB-UPLL-02
Production code: FTC
Regulation number: 21 CFR 878.4630
Classification: Class II
Panel: General & Plastic Surgery

3.0 Predicate Device Information

Predicate Device#

Manufacturer: Xuzhou Kernel Medical Equipment Co., LTD.

Device: UV Phototherapy
510(k) number: K181805

Reference Device #
Manufacturer: ALLUX MEDICAL
Device: RESOLVE UVB PHOTOTHERAPY SYSTEM
510(k) number: K072035

4.0 Indication for Use Statement

The Narrowband UV Phototherapy Light Lamp 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.

5.0 Device Description

The proposed device, Narrowband UV Phototherapy Light Lamp is a portable medical device that consists of LED lamp, 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 excluding eyes. Irradiation time can be adjusted from 0~299s and the treatment status can be controlled by the button on the device. The light comb equipped on the device is intended for easier treatment of target skin covered by hair, such as the scalp. The device is available in two models: model HB-UPLL-01and model HB-UPLL-02.
The device can be used in hospitals, clinics and households.

6.0 Non-Clinical Test Conclusion

Non clinical tests were conducted 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:
IEC60601-1:2005+CORR.1:2006+CORR.2:2007+AM1:2012 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 60601-1-11:2015, 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
IEC 60601-2-57: 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.
IEC 62471:2006, Photobiological safety of lamps and lamp systems

Biocompatibility Test

ISO 10993-5:2009,Biological evaluation of medical devices- Part 5: Test for in vitro cytotoxicity
ISO 10993-10:2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 10993-23:2021, Biological evaluation of medical devices - Part 23: Tests for irritation

7.0 Clinical Test Conclusion

No clinical study is included in this submission.

8.0 Technological Characteristic Comparison Table

Table1-General Comparison

Item	Subject Device K223882	Predicate Device K181805	Reference Device K072035	Remark
Product Code	FTC	FTC	FTC	Same
Regulation No.	21 CFR 878.4630	21 CFR 878.4630	21 CFR 878.4630	Same
Class	II	II	II	Same
Intended Use/Indication for Use	The Narrowband UV Phototherapy Light Lamp 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.	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.	The Resolve™ UVB Phototherapy System is an ultraviolet light emitting medical device for localized phototherapeutic treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis. The Resolve™ UVB Phototherapy System is intended to be used with all Skin Types (I - VI).	Same
Prescriptive	Yes	Yes	Yes	Same
Mode of operation	Handheld	Handheld	Not Publicly Available	Same
Shell material	ABS	ABS	Not Publicly Available	Same
Treatment Area	Partial treatment excluding eyes	Partial treatment excluding eyes	Partial treatment excluding eyes	Same
Treatment Time	0~299s	0~180s	Not Publicly Available	Different
Test Frequency	3~5 times per week	3~5 times per week	Not Publicly Available	Same
Treatment Area	HB-UPLL-01: 30 cm^2	60cm^2/100cm^2/104cm^2	12.8 x 9.0 cm	Different

	HB-UPLL-02: 7 cm²			
Irradiation Intensity	HB-UPLL-01: UVB: 2.0 MW/cm² HB-UPLL-02: UVB: 1.2 MW/cm²	UVA: 1~50 MW/cm² UVB: 0.3~20 MW/cm²	1 mW/cm^2	Similar
Working distance	HB-UPLL-01:3cm; HB-UPLL-02:2cm	3 cm	Not Publicly Available	Same
UV spectral output	UVB	UVA or UVB	UVB	Same
Lamp configuration	1 or 2 UV tube	1 or 2 9W UV tube	Not Publicly Available	Same
Power Source	DC inlet	AC outlet or DC jack	AC outlet	Same
Wavelength range（nm)	UVB: 280~320	UVA: 350～400 UVB: 310～315	300-320nm	Similar
IPX – Rating / water resistance	IP22	IP22	Not Publicly Available	Same
Application Environment	Hospitals, Clinics and Households.	Hospitals, Clinics and Households.	Hospitals, Clinics and Households.	Same
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	Same
Home Use	Comply with IEC 60601-1-11	Comply with IEC 60601-1-11	Comply with IEC 60601-1-11	Same
Sterile	Non-sterile	Non-sterile	Non-sterile	Same
Single Use	No	No	No	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same
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	Same
	Sensitization (ISO 10993-10:2021)			
	Irritation (ISO 10993-23:2021)			

Analysis:

The Irradiation Intensity of the proposed device is different from the predicate devices, but the value range of UVB is within that of the predicate device K181805 and between the value of the predicate device and the reference device K072035. So the we can think the slight differences will not affect the substantive equivalence.

The output specifications as “Treatment area”, and “Treatment time” of the proposed device are a little different from the predicate devices, but they are considered substantially equivalent, they are completed the performance tests in accordance with same standards: IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-57,So there are no safety and effectiveness aspects concerned.

In conclusion, the technological characteristics, features, mode of operation, and intended use of the device substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

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 subject device is substantive equivalence to the predicate device.