Xuzhou Kernel Medical Equipment Co., LTD.
Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CN

January 11, 2019

Re: K181805
Trade/Device Name: UV Phototherapy
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: November 30, 2018
Received: December 10, 2018

Dear Diana Hong:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R Ogden -S

Digitally signed by Neil R Ogden -S
Date: 2019.01.11 09:28:12 -05'00'

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)*
K181805

Device Name
UV Phototherapy

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Tab #7 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K181805

1. Date of Preparation: 01/07/2019

2. Sponsor Identification

Xuzhou Kernel Medical Equipment Co., LTD.
Kernel Mansion, Economic Development District, Xuzhou, Jiangsu Province, China

Establishment Registration Number: 3008393409

Contact Person: Jing Wang
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: UV Phototherapy
Common Name: Ultraviolet lamp for dermatologic disorders

Regulatory Information

Classification Name: Light, Ultraviolet, Dermatological
Classification: II
Product Code: FTC
Regulation Number: 21 CFR 878.4630
Review Panel: General& Plastic Surgery

Intended Use Statement:

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.

Device Description

The proposed device is a hand held ultraviolet phototherapy device, intended for partial treatment excluding eyes. Irradiation time can be adjusted from 0~30min 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 sixteen specifications. The device model KN-4003AL2S, KN-4003BL2S, KN-4003AL2DS, KN-4003BL2DS, KN-4006AL1S, KN-4006BL1S, KN-4006AL1DS and KN-4006BL1DS are designed with SD card. The recommended treatment can be written into the SD card by a physician. The device can be used in hospitals, clinics and households.

5. Identification of Predicate Device

510(k) Number: K132643
Device Name: UV Phototherapy

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

- 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
- 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 60601-2-57: 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 60601-1-11 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 62133:2012 Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes - Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From Them, For Use In Portable Applications [Including: Corrigendum 1 (2013)]

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device K132643
Product Code	FTC	FTC
Regulation Number	21 CFR 878.4630	21 CFR 878.4630
Intended Use	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 UV phototherapy, model KN-4001/KN-4002/KN-4003/KN-4004/ KN4005/KN4006, deliver ultraviolet (UV) light to targeted affected skin. It is intended for use, by or under the direction of a physician, for the treatment of psoriasis, vitiligo, and atopic dermatitis (eczema) on all skin types (I-VI).
Single Use	No	No
Sterile	N/A	N/A
Mode of operation	Handheld	Handheld
Treatment area	Partial treatment excluding eyes	Partial treatment excluding eyes
Treatment Time	0~30min	0~30min
Treatment times	3~5 times per week	3~5 times per week
Lamp quantities	1 or 2	1 or 2
UV spectral	UVA or UVB	UVA or UVB
Biocompatibility	No cytotoxicity No irritation No sensitization No evidence of acute toxicity No pyrogen	Comply with ISO 10993
Electrical safety	Comply with IEC60601-1	Comply with IEC60601-1
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.