December 19, 2024

Shanghai SIGMA High-tech Co., Ltd.
% He Owen
Consulant
Microkn Medical Technology Service (Shanghai) Co.,Ltd.
Room 901, Huafa Center, 889 Pinglu Road, Jing 'an District
Shanghai, Shanghai 200040
China

Re: K242908
Trade/Device Name: UV Phototherapy Device (Group A: SQ308PCHFD, SQ308PCQFD, SQ308PCPFD, SQ308PCNFD, SQ308PCMFD); UV Phototherapy Device (Group B: SQ308PHTFF, SQ308PHSFF, SQ308PHRFF, SQ308PHZFG, SQ308PPUFF, SQ308PPVFF, SQ308PPWFG)
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet lamp for dermatologic disorders
Regulatory Class: Class II
Product Code: FTC
Dated: August 26, 2024
Received: September 24, 2024

Dear He Owen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2024.12.19 12:50:56 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242908

Device Name
UV Phototherapy Device (Group A: SQ308PCHFD, SQ308PCQFD, SQ308PCPFD, SQ308PCN FD, SQ308PCM FD); UV Phototherapy Device (Group B: SQ308PHTFF, SQ308PHSFF, SQ308PHRFF, SQ308PHZFG, SQ308PPUFF, SQ308PPVFF, SQ308PPWFG)

Indications for Use *(Describe)*
UV phototherapy device is intended to be used for the treatment of psoriasis, vitiligo and atopic dermatitis (eczema). It is to be used on intact skin only. Patients shall use it at home under the guidance of the physician.

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

Prepared on: 2024-12-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Shanghai SIGMA High-tech Co., Ltd.
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Correspondent Contact	Mr. He Owen
Correspondent Contact Email	fda@microkn.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	UV Phototherapy Device (Group A: SQ308PCHFD, SQ308PCQFD, SQ308PCPFD, SQ308PCNFD, SQ308PCMFD); UV Phototherapy Device (Group B: SQ308PHTFF, SQ308PHSFF, SQ308PHRFF, SQ308PHZFG, SQ308PPUFF, SQ308PPVFF, SQ308PPWFG)
Common Name	Ultraviolet lamp for dermatologic disorders
Classification Name	Light, Ultraviolet, Dermatological
Regulation Number	878.4630
Product Code(s)	FTC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223882	Narrowband UV Phototherapy Light Lamp	FTC
K191571	UV Radiation Treatment System	FTC
K170489	Clarify Medical Phototherapy System	FTC

K040062 / K090097	Levia Phototherapy System / LH-75T Phototherapy System	FTC
K200971	308nm Excimer System	FTC

Device Description Summary

21 CFR 807.92(a)(4)

UV phototherapy device is intended to be used for the treatment of psoriasis, vitiligo, atopic dermatitis, and eczema. It is to be used on intact skin only. Patients shall use it at home under the guidance of the doctor.
Users can set UV irradiation dose through the button input of the controller, and confirm the light emission by pressing the start button. The controller will control the light emitting time of the LED light source according to the set dose. The light emission will stop automatically after the UV irradiation dose reaches the set value.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

UV phototherapy device is intended to be used for the treatment of psoriasis, vitiligo and atopic dermatitis (eczema). It is to be used on intact skin only. Patients shall use it at home under the guidance of the physician.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device has the same indications for use in comparison to the predicate devices. It has been evaluated in Substantial Equivalence Discussion.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed device and the predicate device have the same indications for use, mode of operation. There are a little differences in application environment, power source, dimensions, peak wavelength radiation intensity, time range, treatment area.

But these differences will not result in differences on safety and performance between purposed device and the predicated device.
The predicate devices have the models which can support household use. Some models just can be used in the professional medical environments under the guidance of doctors. The proposed device can be applied in physician office and household. For the proposed device has passed IEC 60601-1-11 test, the performance and safety in home has been fully verified.
Based on the nonclinical and clinical tests performed, the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device. 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.
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 as a same level, and they all comply with the standards: IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-57, and range between the predicate devices K223882 and K191571, and reference devices K200971, K170489 and K040062 / K090097. So we can consider that the slight differences in specification will not raise any safety or effectiveness issue.
The "Dimensions", "Operating Environment" and "Storage Environment" are a little different or not clear from the predicate device, but they all comply with IEC 60601-1 and IEC 60601-2-57 requirements. The differences will not raise any safety or effectiveness issues.
The peak wavelength of the proposed device is different from the predicate devices. The wavelength of proposed device is 308nm ±2nm, the wavelength range of predicate devices (280~320nm and 320~400nm) and reference devices (300~320nm) can cover it, so we can consider the slight differences will not affect the substantive equivalence.
The value of dose per minute of proposed device is 0.48~3 J/cm2, while the value of predicate devices and reference devices is 0.072~3 J/cm2. The value of proposed device does not exceed predicate devices and reference devices. So that the slight differences in specification will not raise any safety or effectiveness issue.
The Max. Irradiation Power range of all models of proposed device is 27~486mW, while the maximum value of predicate devices and reference devices is 1000mW(K200971);
The treatment area of proposed device are (30±2) *(30±2) mm2 and (45±2) *(45±2) mm2, while the maximum area of predicate devices is 30cm^2(K223882);
The radiation intensity range of all models of proposed device is 8±20%~50±20%, while the maximum radiation intensity of reference devices is 90-100 mW/ cm2 (K040062 /K090097).
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 the value of proposed device does not exceed predicate devices and reference devices, they can be considered substantially equivalent, and they all comply with the standards: IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-57, and the Max. Irradiation Power does not exceed the reference device K200971 and K192642. So that the slight differences in specification will not raise any safety or effectiveness issue.

The software limits the maximum dosage of the proposed device to no more than 5 J/cm2, it is different from the predicate devices, but the maximum dosage value does not exceed the reference device K200971. So that the slight differences in specification will not raise any safety or effectiveness issue.

The proposed device is substantial equivalence as the predicate devices K223882 and K191571 and reference devices K200971, K170489 and K040062 / K090097.
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 proposed device is substantive equivalence to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

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+AMD1:2012+AMD2:2020 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 60601-2-83:2019+A1:2022, Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices-Part 5: Test for vitro cytotoxicity
ISO 10993-10 Third edition 2010-08-01 Biological evaluation of medical devices-Part 10: Test for irritation and skin sensitization
ISO 10993-23 First edition 2021-01 iological evaluation of medical devices-Part 23: Test for irritation