December 15, 2020

Shenzhen GSD Tech Co., Ltd.
Zoe Yao
Quality Management Department
Building A, JUNSD Hi-Tech Park, West of Bao'An RD.
Watch & Clock Base, Guangming District
Shenzhen, Guangdong 518106
China

Re: K202827
Trade/Device Name: 308nm Excimer UV-light Skin Therapy System
Regulation Number: 21 CFR 878.4630
Regulation Name: Ultraviolet Lamp For Dermatologic Disorders
Regulatory Class: Class II
Product Code: FTC
Dated: October 19, 2020
Received: October 19, 2020

Dear Zoe Yao:

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 and Part 809); 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
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)*
K202827

Device Name
308nm Excimer UV-light Skin Therapy System

Indications for Use *(Describe)*
The 308nm Excimer UV-light Skin Therapy 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 510(k) Summary is being submitted in accordance with requirements of Title 21 CFR Section 807.92.

1. Submitter information

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Establishment Registration Number: 3006580954

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Date Prepared: Dec. 8, 2020

2. Device information

Trade name: 308nm Excimer UV-light Skin Therapy System
Model number: GP908B, GP908D
Regulation number: 21CFR 878.4630
Regulation name: Ultraviolet Lamp For Dermatologic Disorders
Common name: Light, Ultraviolet, Dermatological
Regulatory class: II
Panel: General & Plastic Surgery
Product code: FTC

3. Predicate device information

510(k) Number: K172273
Device Name: 308nm Excimer System
Manufacturer: Chongqing Peninsula Medical Technology Co., Ltd.

4. Device description

The 308nm Excimer UV-light Skin Therapy System is ultraviolet light emitting medical device.

The model GP908B is a desktop device, consisting of a main body, handpiece, footswitch and power cord.

The model GP908D is a handheld device, consisting of a main body, power cord and adapter.

308nm Excimer UV-light Skin Therapy System is designed to be used in dermatological practice for the treatment of psoriasis and vitiligo. The lamp is axenon-chloride excimer lamp which utilizes a XeCl gas mixture to generate

specific ultraviolet light at wavelength of 308 nm. Users can set the device parameter and determine the machine's state and function on the control touch screen.

5. Indications for Use

The 308nm Excimer UV-light Skin Therapy System is intended to be used for the treatment of psoriasis and vitiligo. It is to be used on intact skin only.

6. Technological characteristics and substantial equivalence:

Description	Subject device	Predicate device	Remark
Company	SHENZHEN GSD TECH CO.,LTD	Chongqing Peninsula M edical Technology Co., Ltd.	/
Device name and model	308nm Excimer UV-light Skin Therapy System Models: GP908B, GP908D	308nm Excimer System, Models: XECL-308C, XECL-308D	/
510 (k) number	/	K172273	/
Classification name	Ultraviolet Lamp For Dermatologic Disorders	Ultraviolet Lamp For Dermatologic Disorders	SE
Product code	FTC	FTC	SE
Regulation number	21 CFR 878.4630	21 CFR 878.4630	SE
Class	II	II	SE
Indications for use/ Intended use	The 308nm Excimer UV-light 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.	SE
Mode of operation	Continuous light source	Continuous light source	SE
Wavelength	308 nanometers (nm) ±2 nm	308 nanometers (nm) ±3 nm	SE
Light source	Xenon-Chlorine (XeCl) excimer lamp produces monochromatic UVB light	Xenon-Chlorine (XeCl) excimer lamp produces monochromatic UVB light	SE
Light delivery	Light source in the Applicator handpiece	Light source in the Applicator handpiece	SE
Cooling of light source	Air circulation cooling	Air circulation cooling	SE
Treatment area	GP908B: 22.62cm^2(3.9cm*5.8cm)	16 cm ²(4 x 4 cm)	SE Note 1

	GP908D: 16cm^2(4×4cm)		
Maximum Beam Power	GP908B: 1131mW GP908D: 800mW	800 mW	SE
Maximum Beam Power Density	50 mW/cm^2	50 mW/cm^2	SE
Beam class	III	III	SE
Pulse Duration	GP908B: 1s to 40s GP908D: 1s to 40s	1s to 40 s	SE
Controls	GP908B: handswitch and footswitch GP908D: handswitch	Handswitch	SE Note 1
Electrical Requirements	Adapter Input: 100~240Vac, 0.8 A, 50/60 Hz	Adapter Input: 100~240Vac, 0.8 A, 50/60 Hz	SE
Power Calibration Method	Internal, automatic	Internal, automatic	SE
MED Dose Determination	Menu driven	Menu driven	SE
Sterilization Aspects	Optical head reducer mask is disinfected between patients.	Optical head reducer mask is disinfected between patients.	SE
Dosage Controls	Dosage (or energy density J/cm^2), pulse duration	Dosage (or energy density J/cm^2), pulse duration	SE
Display	Touch Screen Control Panel	Touch Screen Control Panel	SE
Patient Leakage Current	Complied with IEC 60601-1 and IEC 60601-2-57	Complied with IEC 60601-1 and IEC 60601-2-57	SE
Dimensions (H*W*D)	GP908B: 49.5cm×43cm×35cm GP908D: 36.5cm*31.8cm*40cm	26cm*24cm*27cm (for lamp) 5cm*9.5cm*18cm (for adapter)	SE Note 2
Operation Environment	Temperature: 5℃～+30℃ Humidity: ≤80%RH Atmospheric pressure: 86~106kPa	Temperature: 15~35℃ Humidity: ≤80%RH Atmospheric pressure: 50~106kPa	SE Note 2
Storage Environment	Temperature: -20℃～+55℃ Humidity: ≤93% Atmospheric pressure: 50~106kPa	Temperature: -20~45℃ Humidity: 10-85%RH	SE Note 2
Electrical Safety	Comply with IEC 60601-1 and IEC 60601-2-57	Comply with IEC 60601-1 and IEC 60601-2-57	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE

Note 1: Although some output specifications (treatment area, controls) are a little different from the predicate devices, they all comply with the requirements of

IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-57.

Note 2: The "Dimensions", "Operating Environment" and "Storage Environment" are a little different 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.

7. Nonclinical tests submitted

- Safety test

IEC 60601-1:2005/A1:2012

Medical electrical equipment Part1: General requirements for basic safety and essential performance

- EMC test

IEC 60601-1-2:2014

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances-Requirements and tests

- Reliability test

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

- Biocompatibility test

ISO 10993-5:2009

Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2010

Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

- Software Validation & Verification Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent design flaws could directly result in minor injury to the patient or operator.

None of the tests demonstrated any design characteristics that violate the requirements of the Reviewer Guidance or show any safety hazards. It is our conclusion that the subject device tested met all relevant requirements of the aforementioned tests.

8. Conclusion

The subject devices have the same intended use and same technological characteristics as the predicate device. Moreover the differences between the subject and predicate don't raise new questions of safety or effectiveness. Thus, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.