July 30, 2018

Chongqing Peninsula Medical Technology Co., Ltd.
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion, No.121 Science Road
Guangzhou Science Park
Guangzhou, 510000 Cn

Re: K172273
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: June 30, 2018
Received: July 5, 2018

Dear Cassie Lee:

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,

Jennifer R. Stevenson -S3

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)*
K172273

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Chapter 5. 510(k) Summary

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

510(k) Owner's Name: Chongqing Peninsula Medical Technology Co., Ltd.
Establishment Registration Number: Applying
D-U-N-S Number: 545832254
Address: No.2-4, 2F Block I, Biological and Biochemical Park , 70-1&70-2# Ke Yuan 4th Road, Jiulongpo District, Chongqing, China
Tel: +86-15012578550
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Contact Person: Zhang Sudi
Email: zsd@peninsulalaser.com

Application Correspondent:

Contact Person: Ms. Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
Address: Suite 306, Kecheng Mansion, No.121 Science Road, Guangzhou Science Park, Guangzhou 510663, China
Tel: +86-20-61099984
Email: regulatory@glomed-info.com

2. Subject Device Information

Trade Name: 308nm Excimer System
Models: XECL-308C, XECL-308D
Common Name: Powered Laser Surgical Instrument
Classification name: Light, Ultraviolet, Dermatological
Review Panel: Dermatology, Physical Medicine
Product Code: FTC
Regulation Class: II
Regulation Number: 878.4630

3. Predicate Device Information

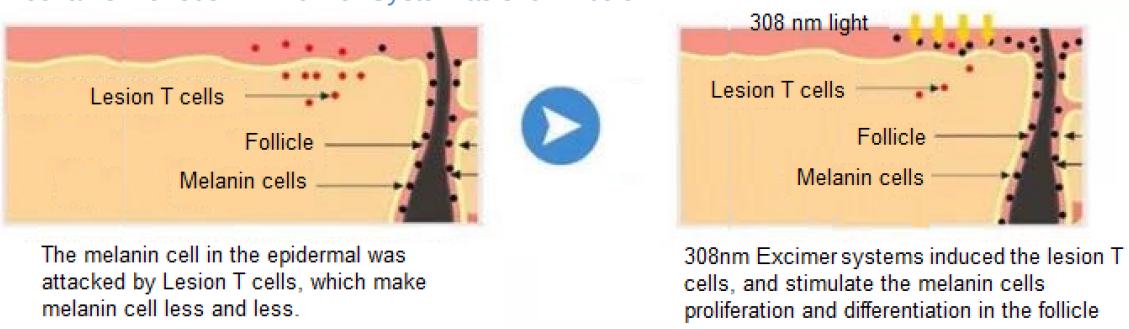
510(K) Number: K150752
Company Name: GME German Medical Engineering GmbH
Address: Grimmstrasse 23, Bavaria, Germany 90491
Trade/Device Name: GME ExSys 308
Models: --
Common Name: Ultraviolet Lamp for Dermatologic disorders

Regulation Number: 878.4630
Regulatory Class: II
Product Code: FTC

4. Device Description

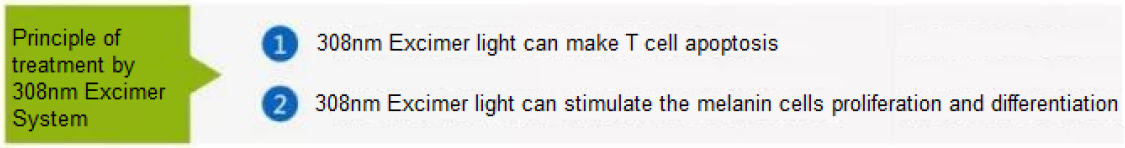
308nm Excimer System is an ultratraviolet light system designed to be used in Dermatological practice for the treatment of psoriasis and vitiligo. The lamp is axenon-chloride excimer lamp which utilizes a XeCl gas mixture to generate specific ultraviolet light at wavelength of 308 nm. It displays the treatment parameters. Users can set the device and fluence on the control touch screen and determine the machine's state and function under the help of colour-coded indicator light.

The mechanism of 308nm Excimer System as shown below:



The melanin cell in the epidermal was attacked by Lesion T cells, which make melanin cell less and less.

308nm Excimer systems induced the lesion T cells, and stimulate the melanin cells proliferation and differentiation in the follicle



5. Intended Use / Indications for 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.

6. Test Summary

308nm Excimer System has been evaluated the safety and performance by lab bench testing as following:

- IEC 60601-1:2005+A1:2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance,
- IEC 60601-1-2:2007/(R)2012, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic Compatibility
- IEC 60601-2-57 (First Edition): 2011 for use in conjunction with IEC 60601-1:2005, Medical electrical equipment -- Part 2: 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 62304: 2006 (First Edition), Medical device software, Software life- cycle processes.

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of 308nm Excimer System is 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.

Elements of Comparison	Subject Device	Predicate Device	Remark
Company	Chongqing Peninsula Medical Technology Co., Ltd.	GME German Medical Engineering Gmbh	--
Device Name and Model	308nm Excimer System, Models: XECL-308C, XECL-308D	ExSys 308 System, Models:--	--
Classification Name	Light, Ultraviolet, Dermatological	Light, Ultraviolet, Dermatological	SE
510(k) Number	K172273	K150752	--
Product code	FTC	FTC	SE
Intended Use & Indications for 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 GME 308nm Excimer 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) ±3 nm	308 nm+/-4nm	SE Note 2
Light Source	Xenon-Chlorine (XeCl) excimer lamp produces monochromatic UVB light	XeCl excimer lamp produces monochromatic UVB light	SE
Light Delivery	Light source in the Applicator handpiece	Light source is in the Applicator handpiece	SE
Cooling of light source	Air circulation cooling	Integrated air cooling	SE
Treatment Area	16 cm^2 (4 x 4 cm)	50x35 mm^2	SE Note 2
Maximum Beam Power	800 mW	875 mW	SE Note 2
Maximum Beam Power Density	50 mW/cm2	50 mW/cm2	SE
Beam Class	III	III	SE
Pulse Duration	1s to 40 s	1 sec – 40 sec	SE
Controls	Handswitch	Footswitch or handswitch	SE Note 1
Power Supply	Adapter Input: 100~240 Vac, 0.8 A, 50/60 Hz	Adaptor Input: 100~240 Vac, 50/60	SE Note 1

Elements of Comparison	Subject Device	Predicate Device	Remark
	Main unit input: 48 Vdc, 2.94 A, 135 VA max	Hz, 0.1 A Main Unit Input: 5 Vdc, 1 A	
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.	Applicator is disinfected between patients.	SE
Dosage Controls	Dosage (or energy density J/cm2), pulse duration	Dosage (or energy density J/cm2), 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	Comply with IEC 60601-1 and IEC 60601-2-57	SE
Weight	< 2.6 kg	12 kg	SE Note 1
Dimensions (H x W x D)	26 cm x 24 cm x 27 cm (For lamp) 5 cm x 9.5 cm x 18 cm (For Adapter)	25 cm x 30 cm x 30 cm	SE Note 1
Operating Environment	Temperature: 15~35°C, Humidity: ≤ 80%RH, Atmospheric Pressure: 86 ~ 106 kPa	Temperature: 5~45°C, Humidity: 20~65% RH	SE Note 1
Storage Environment	Temperature: -20~45°C, Humidity: 10-85%RH Atmospheric Pressure: 50 ~ 106 kPa	Temperature: 0~45°C, Humidity: 10~90% RH, Electrode Pad: 10~20°C	SE Note 1
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

Comparison in Detail(s):

Note 1:

Although the “Power Supply”, “Weight”, “Dimension”, “control”, “Operating Environment” and “Storage Environment” are a little different from the predicate devices, they all comply with IEC 60601-1 and IEC 60601-2-57 requirements. So the differences will not raise any safety or effectiveness issue.

Note 2:
Although some output specifications “Wavelength”, “Treatment area”, “Output Intensity”, and “Maximum Beam Power” are a little different from the predicate devices, they all comply with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-57 requirement. So the differences of function specification will not raise any safety or effectiveness issue.

Finial Conclusion:
The subject device “308nm Excimer System” is Substantial Equivalent to the predicate devices.

8. Date of the summary prepared: June 30, 2018