May 13, 2020

Chongqing Peninsula Medical Technology Co., Ltd.
% Cassie Lee
Manager
Guangzhou GLOMED Biologcial Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District, Guangzhou
Guangzhou, 510000 Cn

Re: K192642
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: March 8, 2020
Received: March 17, 2020

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 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,

Colin Kejing Chen, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K192642

Device Name
308nm Excimer System (Model: XECL-308E)

Indications for Use *(Describe)*
The 308nm Excimer System (model: XECL-308E) is an Ultraviolet Light Emitting Medical Device. It is intended to be used for the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. 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 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.
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Application Correspondent:
Contact Person: Ms. Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China
Tel: +86 20 8266 2446
Email: regulatory@glomed-info.com

2. Subject Device Information

Trade Name: 308nm Excimer System
Models: XECL-308E
Common Name: Light, Ultraviolet, Dermatological
Classification name: Ultraviolet lamp for dermatologic disorders
Review Panel: Dermatology, Physical Medicine
Product Code: FTC
Regulation Class: II
Regulation Number: 878.4630

3. Predicate Device Information 1

510(K) Number: K173436
Company Name: Luma Therapeutics
Trade/Device Name: Luma Light System
Common Name: Light, Ultraviolet, Dermatological
Regulation Number: 878.4630
Regulatory Class: II
Product Code: FTC
Intended Use: / Indications for Use: The LUMA™ Light System is an Ultraviolet Light Emitting Medical Device. It is intended for use in localized phototherapeutic treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis, and leukoderma on all skin types (I-VI).

Predicate Device Information 2

510(K) Number: K172273
Company Name: Chongqing Peninsula Medical Technology Co., Ltd.

Trade/Device Name: 308nm Excimer System
Common Name: Light, Ultraviolet, Dermatological
Regulation Number: 878.4630
Regulatory Class: II
Product Code: FTC
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.

Predicate Device Information 3
510(K) Number: K191086
Company Name: Clarteis
Trade/Device Name: Exciplex
Common Name: Light, Ultraviolet, Dermatological
Regulation Number: 878.4630
Regulatory Class: II
Product Code: FTC
Intended Use: / Indications for Use: The Exciplex is intended to be used for the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. The reusable polycarbonate/ABS reduction tips and reusable silicone masks are for use on intact skin only.

4. Device Description
The 308nm Excimer System (model: XECL-308E)is an Ultraviolet Light Emitting Medical Device. It is intended for use in localized phototherapeutic treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis, and leukoderma on all skin types (I-VI). The system including a main body, power line, handpiece holder, XeCl lamp, handpiece, and output light window adapter. The handpiece includes a contains light emitting diodes (LEDs), which create an array of narrowband UVB light centered at a wavelength mainly between 308±2 nm. The device should be operated by a professional doctor in the hospital for the treatment.

5. Intended Use / Indications for Use
The 308nm Excimer System (model: XECL-308E) is an Ultraviolet Light Emitting Medical Device. It is intended to be used for the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. 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 60601-1-2:2014, 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

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3 (Reference device)	Remark
Company	Chongqing Peninsula Medical Technology Co., Ltd.	Luma Therapeutics	Chongqing Peninsula Medical Technology Co., Ltd.	Clarteis	--
Device Name and Model	308nm Excimer System, Model: XECL-308E	Luma Light System,	308nm Excimer System	Exciplex	--
Classification Name	Ultraviolet lamp for dermatologic disorders	Ultraviolet lamp for dermatologic disorders	Ultraviolet lamp for dermatologic disorders	Ultraviolet lamp for dermatologic disorders	SE
510(k) Number	Applying	K173436	K172273	K191086	--
Classification	Class II	Class II	Class II	Class II	SE
Product code	FTC	FTC	FTC	FTC	SE
Intended Use & Indications for Use	The 308nm Excimer System (model: XECL-308E) is an Ultraviolet Light Emitting Medical Device. It is intended to be used for the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. It is to be used on intact skin only.	The LUMA™ Light System is an Ultraviolet Light Emitting Medical Device. It is intended for use in localized phototherapeutic treatment of dermatologic conditions such as psoriasis, vitiligo, atopic dermatitis (eczema), seborrheic dermatitis, and leukoderma on all skin types (I-VI).	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 Exciplex is intended to be used for the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. The reusable polycarbonate/ABS reduction tips and reusable silicone masks are for use on intact skin only.	SE
Wavelength	308±2 nm	300 – 320 nm	308±3 nm	308 nm	SE
Light Source	Xenon-Chlorine (XeCl) excimer lamp produces monochromatic UVB light	LED lamps	Xenon-Chlorine (XeCl) excimer lamp produces monochromatic UVB light	Excimer device that emits UVB light	SE
Light Delivery	Light source in the Applicator handpiece	Light source in the Hand piece (light module)	Light source in the Applicator handpiece	/	SE
Delivery Method	Treatment window	Treatment window	/	Output window	SE
Cooling of	Cooling fan	/	Air circulation	/	--

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3 (Reference device)	Remark
light source			cooling		
Treatment Area	6cm^2~28.8 cm^2	20.2 cm^2	16 cm^2 (4 x 4 cm)	25 cm^2 (5 x 5 cm)	SE Note1
Max Power Output	50 mW/cm^2	4.2 – 7.2 mW/cm^2	50 mW/cm^2	100 mW/cm^2	SE Note1
Treatment time	1-140s	Timer to control treatment duration stored in the software based on prescription	1-40s	/	SE Note1
Controls	Hand-switch	Hand piece (light module) with wireless connection to mobile phone Physician sets frequency and duration of treatments by programming app in phone	Hand-switch	/	SE
Use Environment	Physician Office	Home / Physician Office	/	/	SE
User Interface	Touch Screen Control	Touch screen on the Mobile Device	Touch Screen Control Panel	/	SE Note2
Dimensions (H x W x D)	548.0mm*253.6 mm*181.4mm	/	For lamp: 26 cm x 24 cm x 27 cm For Adapter: 5 cm x 9.5 cm x 18 cm	/	--
Operating Environment	Temperature: 5℃～30℃ Humidity: ≤80%RH Atmospheric Pressure: 700 ~ 1060 hPa	/	Temperature: 15~35°C, Humidity: ≤ 80%RH, Atmospheric Pressure: 86 ~ 106 kPa	/	--
Storage Environment	Temperature: 0℃～40℃ Humidity: ≤85%RH Atmospheric Pressure: 700 ~ 1060 hPa	/	Temperature: -20~45°C, Humidity: 10-85%RH Atmospheric Pressure: 50 ~ 106 kPa	/	--

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Predicate Device 3 (Reference device)	Remark
Electrical Safety	Comply with IEC 60601-1 and IEC 60601-2-57	Complied with IEC 60601-1 and IEC 60601-2-57	Comply with IEC 60601-1 and IEC 60601-2-57	Complied with IEC 60601-1 and IEC 60601-2-57	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE

Comparison in Detail(s):

Note 1:

Although some output specifications as “Max Power Output”, “Treatment area”, and “Treatment time” of the subject 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 device K173436 and predicate device K191086. So the we can think that the slight differences in specification will not raise any safety or effectiveness issue.

Note 2:

Although the “User Interface” of subject device is a little different from the predicate devices, but both predicate device and subject device have passed the evaluation complied with IEC 60601-1, these parameters are not impact on the safety and effectiveness, so we considered they are equivalent as the differences will not raise any safety or effectiveness issue.

Finial Conclusion:

The subject device “308nm Excimer System (model: XECL-308E)” is in the same design principle and utilizing identical Light Source (UV lamps) as the predicate devices. The "Indications for use/Intended use" and technological characteristics (as Light Source, Wavelength, Delivery Method, Treatment area, Treatment time and Use Environment) are the same or similar to those of the predicate devices. So the subject device is Substantial Equivalent to the predicate devices K173436, K172237 and K191086.

8. Date of the summary prepared: May 12, 2020