April 28, 2023

Light Tree Ventures Europe B.V.
Alain Dijkstra
Manager
Laan van Ypenburg 108, 2497 GC, The Hague, The Netherlands
Hague,
Netherlands

Re: K230042
Trade/Device Name: Q-Rejuvalight Pro Facewear (Model: P19-0023)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: OHS, OLP
Dated: February 27, 2023
Received: February 27, 2023

Dear Alain Dijkstra:

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/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,

Jianting Wang -S

Jianting Wang
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230042

Device Name
Q-Rejuvalight Pro Facewear (Model: P19-0023)

Indications for Use *(Describe)*
The Q-Rejuvalight Pro Facewear (Model: P19-0023) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary of K230042

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

1. Date of the summary prepared: April 3, 2023

2. Submitter's Information

Company Name: Light Tree Ventures Europe B.V.
Address: Laan van Ypenburg 108, 2497 GC, The Hague, The Netherlands
Contact Person (including title): Alain Dijkstra (Manager)
Tel: +86-135-10378748
Fax: +86-755-25024651
E-mail: regulation@kaiyanmedical.com

Manufacture

Company Name: Shenzhen Kaiyan Medical Equipment Co., Ltd
Address: Building#3 and Building#5, 40th of Fuxin Street, Huaide Community Fuyong Town, Baoan District, Shenzhen, Guangdong 518103, China

Distributor

Company Name: Qure Skincare Pty Ltd
Address: Level 1, 56 Clarence street NSW2000 Sydney Australia

Application Correspondent

Contact Person: Mr. Alain Dijkstra
Company Name: Light Tree Ventures Europe B.V.
Address: Laan van Ypenburg 108, 2497 GC, The Hague, The Netherlands
Tel: +86-135-10378748
Fax: +86-755-25024651
Email: regulation@kaiyanmedical.com

3. Subject Device Information

Type of 510(k): Traditional
Classification Name: Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP)
Trade Name: Q-Rejuvalight Pro Facewear

Model Name: P19-0023
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number: 878.4810
Regulatory Class: II

4. Predicate Device Information

Predicate Device 1:

Sponsor: LED Technologies, Inc.
Trade Name: dpl® Faceware
Classification Name: Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP)
510(k) Number: K183247
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number: 21 CFR 878.4810
Regulation Class: II

Predicate Device 2:

Sponsor: Light Tree Ventures Europe B.V.
Trade Name: LUSTRE ClearSkin Renew Pro Facewear Mask
Classification Name: Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light Based Laser For Acne(OLP)
510(k) Number: K230124
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number: 21 CFR 878.4810
Regulation Class: II

Predicate Device 3:

Sponsor: LED Technologies, Inc.
Trade Name: dpl® II Panel
Classification Name: Light Based Over The Counter Wrinkle Reduction (OHS)
510(k) Number: K171390
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 878.4810

Regulation Class: II

5. Device Description

The Q-Rejuvalight Pro Facewear is an over-the-counter light emitting diode (LED) device that emits energy for use in dermatology for the treatment of wrinkles and mild to moderate inflammatory acne. The device uses four types of LEDs for Wrinkles: 605nm, 630nm, 660nm, and 880nm and two types of LEDs for Acne: 415nm and 630nm. Each mode takes 3 minutes (±3s) for a course of treatment, and the mask will automatically turn off at the end of time.

The Q-Rejuvalight Pro Facewear components include the main device, head strap, eye rest, Latch, User Manual, Storage bag and USB power cord.

The Q-Rejuvalight Pro Facewear is applied directly to the skin to ensure consistent administration of light during each treatment. The device does not contain any user serviceable components.

6. Intended Use / Indications for Use

The Q-Rejuvalight Pro Facewear (Model: P19-0023) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.

7. Test Summary

Q-Rejuvalight Pro Facewear (Model: P19-0023) has been evaluated the safety and performance by lab bench testing as following:

Standard No.	Standards Title	Version	Date
ANSI AAMI ES60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	05/30/2022
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 equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 MOD)	Edition 2.1 2020-07 CONSOLIDATED VERSION	12/21/2020
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard:	Edition 4.0 2014-02	09/17/2018

Standard No.	Standards Title	Version	Date
	Electromagnetic disturbances - Requirements and tests		
IEC 60601-2-57	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	Edition 1.0 2011-01	03/16/2012
IEC 62133-2	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 - Part 2: Lithium systems	Edition 1.0 2017-02	12/23/2019
IEC 62471	Photobiological safety of lamps and lamp systems	First edition 2006-07	08/20/2012
ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Third edition 2009-06-01	12/23/2016
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Fourth edition 2021-11	12/19/2022
ISO 10993-23	Biological evaluation of medical devices - Part 23: Tests for irritation	First edition 2021-01	06/07/2021

8. Comparison to predicate device

Elements of Comparison	Subject Device	Predicate Device 1 (Primary)	Predicate Device 2 (Reference)	Predicate Device 3 (Reference)	Remark
Company	Shenzhen Kaiyan Medical Equipment Co., Ltd	LED Technologies, Inc.	Light Tree Ventures Europe B.V.	LED Technologies, Inc.	--
Trade Name	Q-Rejuvalight Pro Facewear	dpl® Faceware	LUSTRE ClearSkin Renew Pro Facewear Mask	dpl® II Panel	--
Classification Name	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light	Light Based Over The Counter Wrinkle Reduction(OHS), Over-The-Counter Powered Light	Light Based Over The Counter Wrinkle Reduction (OHS)	--

Elements of Comparison	Subject Device	Predicate Device 1 (Primary)	Predicate Device 2 (Reference)	Predicate Device 3 (Reference)	Remark
	Light Based Laser For Acne(OLP)	Based Laser For Acne(OLP)	Based Laser For Acne(OLP)		
510(k) Number	K230042	K183247	K230124	K171390	--
Product Code	OHS, OLP	OHS, OLP	OHS, OLP	OLP	Same
Intended Use / Indications for Use	The Q-Rejuvalight Pro Facewear (Model: P19-0023) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.	The dpl® Faceware is an Over-the-Counter (OTC) LED device intended for use in treating wrinkles and mild to moderate inflammatory acne.	The LUSTRE ClearSkin Renew Pro Facewear Mask is an over-the-counter device intended to emit energy in the red and blue region of the light spectrum, specifically indicated to treat mild to moderate acne vulgaris of the face. The LUSTRE ClearSkin Renew Pro Facewear Mask is an over-the-counter device intended to emit energy in the red and Near Infra-red spectrum and is intended for the use in the treatment of full-face wrinkles.	The dpl® II Panel is an Over-the-Counter (OTC) device intended for use in treating wrinkles.	Same
Power source	Input: 5V, 50/60Hz, 2A Li-ion Polymer Battery: 3.7V, 600mAh, 2.22Wh	LI-Ion Battery 5V USB & 3.7 V Battery	Lithium battery: 3.7V, 1500mAh 5.55Wh Adapter Input: 100-240Va.c., 50/60Hz Adapter Output: 5Vd.c, 1A	120-240V AC Power Adapter	Similar Note 1

Elements of Comparison	Subject Device	Predicate Device 1 (Primary)	Predicate Device 2 (Reference)	Predicate Device 3 (Reference)	Remark
Wavelengths	605nm, 630nm, 660nm, 880nm, 415nm	605nm, 630nm, 660nm, 880nm, 415nm	Red: 630±5nm Blue: 415±5nm NIF: 830±5nm	605nm, 630nm, 660nm, 880nm	Same
Power Density	Single wavelength: 605nm: 15±5mW/cm² 630nm: 20±5mW/cm² 660nm: 25±5mW/cm² 880nm: 10±5mW/cm² 415nm: 25±5mW/cm² Total: 70mW/cm²(wrinkle) 45mW/cm²(acne)	No publicly available	Red: 18 mw/cm² NIR: 12 mw/cm² Total: 30 mw/cm²(wrinkle) Blue: 26 mw/cm² Red: 16 mw/cm² Total: 42 mw/cm² (acne)	Total: 70.16mW/cm²(wrinkle)	Similar Note 2
Irradiance source	LEDs	LEDs	LEDs	LEDs	Same
Total Number of LEDs	80pcs	No publicly available	80pcs	No publicly available	Same
LED Distribution	630nm+415nm (Double wick): 30pcs 630nm+605nm (Double wick): 25pcs 660nm+880nm (Double wick): 25pcs	No publicly available	630nm+415nm (Double wick): 30pcs 630nm+830nm (Double wick): 50pcs		Similar Note 4
Treatment area	81(acne) 140(wrinkle)	81(acne) 135.8(wrinkle)	No publicly available	415cm²	Same
Treatment time	3 minutes per treatment	3 minutes per treatment	10 minutes	3 minutes per treatment	Same
Location for Use	Face	Face	Face	Face	Same
Environment of Use	OTC	OTC	OTC	OTC	Same
Safety and EMC	IEC 60601-1 IEC 60601-1-11 IEC 60601-1-2 IEC 60601-2-57 IEC 62133-2	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-11 IEC 60601-1-2 IEC 60601-2-57 IEC 62133-2	IEC 60601-1 IEC 60601-1-2	Similar Note 3

Elements of Comparison	Subject Device	Predicate Device 1 (Primary)	Predicate Device 2 (Reference)	Predicate Device 3 (Reference)	Remark
	IEC 62471		IEC 62471		
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-10	Same

Comparison in details:

Note 1:

The description in “Power supply” of the subject device is slightly different from the predicate device, both of them use a Lithium-Ion battery and are charged by the 5V USB. Besides, both the subject device and the predicate conducted the safety test according to the IEC 60601 series standards, and the test results are in compliance with safety standards’ requirements. So, the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Note 2:

Although there is no detailed information on the “Power Density” for each wavelength of predicate devices available, both the subject device and predicate device 3 have the same treatment wavelengths (605nm+630nm+660nm+880nm) and total power density designed in treating the wrinkles, both of the subject device and predicate device 2 have the same treatment wavelengths (630nm+415nm) and similar total power density designed in treating the acne. So, the slight difference between the subject device and the predicate devices will not raise any safety or effectiveness issues.

Note 3:

The description in “Safety and EMC” of the subject device is slightly different from the predicate device, both the subject device and the predicate conducted the electrical safety and electromagnetic compatibility tests according to the international series standards, and the test results are in compliance with standards’ requirements. So, the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Note 4:

Although the “LED Distribution” of the subject device is slightly different from the predicate devices, the subject device has the same/similar treatment parameters such as the treatment wavelengths and power density designed with the predicate devices. So, the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

9. Final Conclusion

The subject device Q-Rejuvalight Pro Facewear (Model: P19-0023) is as safe, as effective, and performs as well as or better than the legally marketed predicated devices K183247, K230124 and K171390.