March 15, 2023

Light Tree Ventures Europe B.V.
Alain Dijkstra
CEO
Laan van Ypenburg 108, 2497 GC, The Hague, The Netherlands
Hague, Netherlands 2500
Netherlands

Re: K230124
Trade/Device Name: LUSTRE ClearSkin Renew Pro Facewear Mask(Model: PR4001)
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: January 12, 2023
Received: January 17, 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)*
K230124

Device Name
LUSTRE ClearSkin Renew Pro Facewear Mask (Model: PR4001)

Indications for Use *(Describe)*
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.

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.

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510(k) Summary of K230124

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: Feb. 9, 2023

2. Submitter's Information

Company Name: Light Tree Ventures Europe B.V.
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Contact Person (including title): Alain Dijkstra (Manager)
Email: regulation@kaiyanmedical.com

Manufacturer

Company Name: Shenzhen Kaiyan Medical Equipment Co., Ltd
Establishment Registration Number: 3011644607
Address: Building#3 and Building#5, 40th of Fuxin Street, Huaide Community Fuyong Town, Baoan District, Shenzhen, Guangdong 518103, China
Phone: 0755-82129361
Fax No: 0755-25024651
Contact Person (including title): Alain Dijkstra (CEO)
Email: alaindijkstra@kaiyanmedical.com

Distributor

Distributor Name: Lusre Skin Ltd
Address: Alba Innovation Centre, Alba Campus, Livingston Scotland, UK, Eh547GA

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: +86 755 82129361
Email: regulation@kaiyanmedical.com

3. Subject Device Information

Type of 510(k): Traditional
Classification Name: Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based Over-The Counter Wrinkle Reduction (OHS)
Trade Name: LUSTRE ClearSkin Renew Pro Facewear Mask
Model Name: PR4001
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number: 21 CFR 878.4810
Regulatory Class: II

4. Predicate Device Information

Sponsor: Harpar Grace International
Trade Name: Shani Darden LED light therapy mask
Classification Name: Over-The-Counter Powered Light Based Laser For Acne (OLP), Light Based Over-The Counter Wrinkle Reduction (OHS)
510(k) Number: K214103
Review Panel: General & Plastic Surgery
Product Code: OHS, OLP
Regulation Number: 21 CFR 878.4810
Regulation Class: II

5. Device Description

LUSTRE ClearSkin Renew Pro Facewear Mask (Model: PR4001) is an over-the-counter light emitting diode (LED) device that emits energy for use in dermatology for the treatment of acne and wrinkles. The device has anti-wrinkle mode and anti-acne, the former is to emit red light (630nm) and infrared light (830nm) to treat wrinkles, the latter is to emit red light (630nm) and blue light (415nm) to treat mild to moderate acne. There is only one button on the outside of the mask, which have the functions of controlling startup, shutdown, and switching modes. The treatment lasts for 10 minutes by default, and after the treatment, the device will automatically shut down if it is not operated within five minutes. The product contents include an LED mask, Adjustable Velcro Straps, Removable Eye Protection, USB-C cable, cloth bag and user manual, the function of the Removable Eye Protection is to protect the eyes from the harm of led light.

6. Intended Use / Indications for Use

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.

7. Comparison to predicate device

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device**	**Remark**
Company	LIGHT TREE VENTURES EUROPE B.V.	Harpar Grace International	--
Trade Name	LUSTRE ClearSkin Renew Pro Facewear Mask	Shani Darden LED light therapy mask	--
510(k) Number	K230124	K214103	--
Product Code	OHS, OLP	OHS, OLP	Same
Regulation Number	878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology	878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology	Same
FDA Device Classification	Class II	Class II	Same
Use	Over the Counter	Over the Counter	Same
Intended use and Indications	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	The Shani Darden LED light therapy 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	Same

	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.	moderate acne vulgaris of the face. The Shani Darden LED light therapy 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.	
Intended Location of Use	Face	Face	Same
Energy Type	Light emitting diodes	Light emitting diodes	Same
Wavelengths	Red: 630±5nm Blue: 415±5nm NIF: 830±5nm	Red: 630nm±10nm Blue: 415nm±10nm NIF: 830nm±10nm	Same
Intensity (mW/cm^2)	Blue: 26 mw/cm^2 Red: 16 mw/cm^2	Blue: 28 mw/cm^2 Red: 16 mw/cm^2	Similar Note 1
	Red: 18 mw/cm^2 NIR: 12 mw/cm^2	Red: 18 mw/cm^2 NIR: 11 mw/cm^2	
Total Intensity (mW/cm^2)	Blue/Red 42 mw/cm^2	Blue/Red 44 mw/cm^2	Similar Note 1
	Red/NIR 30 mw/cm^2	Red/NIR 29 mw/cm^2	
Dose	Blue 15.6J/cm^2 Red 9.6J/cm^2	Blue 16.8J/cm^2 Red 9.6J/cm^2	Similar Note 1
	Red 10.8J/cm^2 NIR 7.2J/cm^2	Red 11J/cm^2 NIR 7J/cm^2	
Total Number of LEDs	80pcs	No publicly available	Different Note 3
LED Distribution	630nm+415nm (Double wick): 30pcs 630nm+830nm (Double wick): 50pcs	No publicly available	Different Note 3
Treatment time	10 minutes	10 minutes	Same
Treatment	Acne: 4 x weekly, 6 weeks	Acne: 4 x weekly, 6	Same

protocol		weeks	
Treatment protocol	Wrinkles: 5 x weekly, 6 weeks	Wrinkles: 5 x weekly, 6 weeks	Same
Software Controlled	Device uses a timer and software to control treatment duration	Device uses a timer and software to control treatment duration	Same
Power supply	Lithium battery: 3.7V, 1500mAh 5.55Wh Adapter Input: 100-240Va.c., 50/60Hz Adapter Output: 5Vd.c, 1A	Electrical Input to power adaptor: 100v-240v. 50/60Hz. Rated at 0.7A. Electrical Output from power adaptor: 12V, 1A	Different Note 2

Comparison in Detail(s):

Note 1: Though the "Intensity (mW/cm^2)", "Total Intensity (mW/cm^2)" and "Dose" of the subject device are slightly different from the predicate device, the treatment parameters of the subject device are very close to the predicate device and both of them meet the requirements of the IEC 60601-2-57. So, the minor difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Note 2: The "Power supply" of the subject device is using a Lithium-Ion battery and the predicate device is using a power adaptor, both the subject device and the predicate conduct the safety test according to the IEC 60601 series standards, and the test results are 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 3: Although there is no publicly available of the "Total Number of LEDs" and the "LED Distribution" for the predicate device, the subject device has the same / similar treatment parameters in "Intensity", "Total Intensity", "Dose" and "Treatment Time" with the predicate device. So, the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

8. Non-clinical test Summary

8.1 Summary of Electrical safety and EMC

LUSTRE ClearSkin Renew Pro Facewear Mask (Model: PR4001) 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: Electromagnetic disturbances - Requirements and tests	Edition 4.1 2020-09 CONSOLIDATED VERSION	12/21/2020
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

8.2 Summary of Biocompatibility

The component materials for Adjustable Velcro Straps, Removable Eye Protection, shell (Inner surface), and shell (Outer surface) of the subject device are identical to the corresponding component materials of the K2217752. So, the subject device can comply with the biocompatibility requirements of ISO 10993-5(Cytotoxicity), ISO 10993-10(Sensitization), and ISO 10993-23(Irritation).

9. Clinical test Summary

No clinical study is included in this submission.

Final Conclusion：

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devices K214103.