July 3, 2023

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

Re: K230720
Trade/Device Name: LUSTRE 3XPRESS Light Beauty Therapy patches, model: PR6001, PR5001
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: OLP
Dated: June 6, 2023
Received: June 6, 2023

Dear Kim Laurens:

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)*
K230720

Device Name
LUSTRE 3XPRESS Light Beauty Therapy patches (Model: PR6001, PR5001)

Indications for Use *(Describe)*
The LUSTRE 3XPRESS Light Beauty Therapy patches (Model: PR6001, PR5001) is an Over-the-Counter (OTC) device intended for treatment of 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.

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510(k) Summary of K230720

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: June 13, 2023

2. Submitter's Information

Sponsor Name: Light Tree Ventures Europe B.V.
Establishment Registration Number: 3017422691
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

Distributor

Distributor Name: Lustre Skin Ltd
Address: Alba Innovation Centre, Alba Campus, Livingston Scotland, UK, EH547GA

Factory

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

Application Correspondent:

Contact Person: Alain Dijkstra
Company: Light Tree Ventures Europe B.V.
Address: Laan van Ypenburg 108, 2497 GC, The Hague, The Netherlands
Tel: +86 755 82129361
Fax: +86 755 25024651
Email: regulation@kaiyanmedical.com

3. Subject Device Information

Trade Name: LUSTRE 3XPRESS Light Beauty Therapy patches, model: PR6001, PR5001
Classification Name: Over-The-Counter Powered Light Based Laser For Acne
Review Panel: General & Plastic Surgery
Product Code: OLP
Regulation Number: 21 CFR 878.4810
Regulation Class: II

4. Predicate Device Information

Sponsor: Shenzhen Kaiyan Medical Co Ltd
Trade Name: DemarkQ WOW, DemarkQ POP
Classification Name: Over-The-Counter Powered Light Based Laser For Acne
510(K) Number: K203214
Review Panel: General & Plastic Surgery
Product Code: OLP

Regulation Number: 21 CFR 878.4810
Regulation Class: II

5. Device Description

The LUSTRE 3XPRESS Light Beauty Therapy patches, model: PR6001 and PR5001 is an over-the-counter light emitting diode (LED) device that emits energy to treat mild to moderate acne. The device uses two types of LEDs: 415 nm and 630nm.

The LUSTRE 3XPRESS Light Beauty Therapy patches components include the device containing two Light Beauty Therapy Patches, an USB Cable with an integrated controller, 120 Mini Dots, a Goggles, a Travel pouch and a User Manual. Among them, mini dots are used for fixed device, goggles are used to protect eyes, and travel pouch are used to store device.

There is a total of 24 LEDs for each model to provide a power intensity of about 30 mw/cm^2.

The user pastes the device on the treatment area, and the device will shut down automatically after a 3-minute after finishing treatment.

The two models are only different in shape. PR6001 is triangular and PR5001 is crescent.

6. Intended Use / Indications for Use

The LUSTRE 3XPRESS Light Beauty Therapy patches (Model: PR6001, PR5001) is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne.

7. Comparison to predicate device

Compare with the 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 the subject device and predicate devices do not raise new questions of safety or effectiveness.

Elements of Comparison	**Subject Device**		**Predicate Device (Primary predicated device)**		**Remark**
Company	Light Tree Ventures Europe B.V.		Shenzhen Kaiyan Medical Co Ltd		--
Trade Name	LUSTRE 3XPRESS Light Beauty Therapy patches		DemarkQ		--
Model	PR6001	PR5001	DemarkQ WOW (PBB)	DemarkQ POP(SJ-72)	--
Classification Name	Over-The-Counter Powered Light Based Laser For Acne		Over-The-Counter Powered Light Based Laser For Acne		Same
510(k) Number	K230720		K203214		--
Product Code	OLP		OLP		Same
Intended Use / Indications for Use	The LUSTRE 3XPRESS Light Beauty Therapy patches (Model: PR6001, PR5001) is an Over-the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne.		The DemarkQ is an Over the-Counter (OTC) device intended for treatment of mild to moderate inflammatory acne.		Same
Power Supply	Input: 100-240Va.c., 50Hz/60Hz, output: DC 5V, 2A		Power by: 2 x (3.7Vdc, 2700 mAh Lithium battery,	Power by: 3.7Vdc, 1500 mAh lithium	Different Note 1

		10.26Wh) Adapter Input: 100- 240Vac, 50/60Hz Adapter Output: DC 5V, 2A Main unit input: DC 5V, 2A	battery, 10.26Wh Adapter Input: 100-240Vac, 50/60Hz Adapter Output: DC 5V, 2A Main unit input: DC 5V, 2A	
Wavelengths	630 ± 10nm 415 ± 10nm	630nm±10nm 415nm±10nm		Same
Irradiance source	LED	LED		Same
Number of LEDs	For each model: Blue: 12 Red: 12 Total :24	112 each panel	Total 72	Different Note 2
Irradiance (mw/cm^2)	Red: 5 Blue: 25	Red: 5 Blue: 25	Red: 25 Blue: 25±5	Same
Treatment Time	3 minutes per treatment	3 minutes per treatment		Same
Location for USE	OTC	OTC		Same
EMC	IEC 60601-1-2	IEC 60601-1-2		Same
Safety	IEC 60601-1 IEC 60601-2-57 IEC 60601-1-11 IEC 62471	IEC 60601-1 IEC 60601-2-57 IEC 60601-1-11 IEC 62471		Same
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23 ISO 10993-11	ISO 10993-1, ISO 10993-5, ISO 10993-10		Similar Note 3

Comparison in Detail(s):

Note 1: Although the “Power Supply” is a little different from the predicate devices, they all complied with the IEC 60601-1 and IEC 60601-1-2 safety standards’ requirements. So, these slight differences will not raise any safety or effectiveness issues.

Note 2: The “Number of LEDs” is different from the predicate devices, it’s because the area of them is different. However, both of them have same “Irradiance”. So, these differences will not raise any safety or effectiveness issues.

Note 3: Although the “Biocompatibility” is a little different from the predicate devices, they all meet the

requirements of the ISO 10993-1 guidance requirement. So, these slight differences will not raise any safety or effectiveness issues.

8. Test Summary

8.1 Non-Clinical Tests Performed

Non-clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

- AAMI/ANSI ES60601-1 2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-11 Edition 2.1 2020-07 Medical Electrical Equipment --Part 1: General Requirements for Basic Safety and Essential Performance --Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment.
- IEC 60601-2-57 Edition 1.0 2011-01 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.
- IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems.
- IEC 62133-2 Edition 1.0 2017-02 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.
- IEC 60601-1-6 Edition 3.2 2020-07 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1 Edition 1.1 2020-06 Medical devices - Part 1: Application of usability engineering to medical devices

1) Biocompatibility

The subject device is biocompatible for its intended use. They are complied with biocompatibility standards ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Sensitization), ISO 10993-23 (Skin Irritation) and ISO 10993-11 (Acute Systemic Toxicity and Material-mediated Pyrogens).

2) Software verification and validation 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 concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

3) Cybersecurity

The subject device does not have any external interfaces, according to FDA guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", therefore there's no need for a cybersecurity evaluation.

4) Usability Testing

Usability testing was conducted on the LUSTRE 3XPRESS Light Beauty Therapy patches (Models: PR6001, PR5001), which complies with IEC 62366-1 and IEC 60601-1-6.

8.2 Summary of Clinical Performance

Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

9. Final Conclusion:

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devices K203214.