December 8, 2022

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

Re: K221444
Trade/Device Name: LED Eye Perfector, model: EY-36A, EY-36B
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
Dated: November 10, 2022
Received: November 10, 2022

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)*
K221444

Device Name
LED Eye Perfector (Model: EY-36A, EY-36B)

Indications for Use *(Describe)*
The LED Eye Perfector (Model: EY-36A, EY-36B) is an Over-the-Counter (OTC) device intended for use in treating wrinkles within the periorbital region.

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 K221444

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

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
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E-mail: regulation@kaiyanmedical.com

Distributor

Company Name: CurrentBody.com Ltd
Address: Unit D6, Stanley Green Business Park, Commercial Avenue, Cheadle Hulme SK8 6QH

Factory

Company Name: Shenzhen Kaiyan Medical Equipment Co., Ltd
Address: Building 3, No.40, 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

2. Subject Device Information

Trade Name: LED Eye Perfector, model: EY-36A, EY-36B
Trademark: CurrentBody SkinTM
Classification Name: Light Based Over-The-Counter Wrinkle Reduction
Review Panel: General & Plastic Surgery
Product Code: OHS

Regulation Number: 21 CFR 878.4810
Regulation Class: II

3. Predicate Device Information

Predicate Device (Primary comparison device)

Sponsor: LED Technologies, Inc
Trade Name: dpl® SpectraLite
Classification Name: Light Based Over-The-Counter Wrinkle Reduction
Common Name: dpl® SpectraLite
510(K) Number: K171386
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 878.4810
Regulation Class: II

Predicate Device (Second comparison device)

Sponsor: Zhongshan Bisen Plastic Electronic Products Co., Ltd.
Trade Name: RED Light Device
Classification Name: Light Based Over The Counter Wrinkle Reduction
Common Name: Light Emitting Diode (LED) Device
510(K) Number: K162489
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 878.4810
Regulation Class: II

4. Device Description

The LED Eye Perfector, model: EY-36A and EY-36B is an over-the-counter light-emitting diode (LED) device that emits energy for dermatology to treat wrinkles within the periorbital region. The device uses four types of LEDs, and for model EY-36A: 605 nm, 633 nm, 660nm, 830 nm, for EY-36B: 605 nm, 625 nm, 660nm, and 880 nm. The treatment time can be controlled by the user, or automatically shut off within a set time.

The LED Eye Perfector components contain the main unit device, charging base, USB charging cord, velcro straps and goggles.

There is a total of 40 LEDs to provide a power intensity of about 65 mW/cm^2.

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

There are no differences between the two models other than the output wavelength.

5. Intended Use / Indications for Use

The LED Eye Perfector (Model: EY-36A, EY-36B) is an Over-the-Counter (OTC) device intended for use in treating wrinkles within the periorbital region.

6. Comparison to predicate device and conclusion

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 comparison device)**	**Predicate Device (Second comparison device)**	**Remark**
Company	Light Tree Ventures Europe B.V.		LED Technologies, Inc	Zhongshan Bisen Plastic Electronic Products Co., Ltd.	--
Trade Name	LED Eye Perfector		dpl® SpectraLite	RED Light Device	--
Model	EY-36A	EY-36B	EY-40	BZ-0606	--
Classification Name	Light Based Over-The-Counter Wrinkle Reduction		Light Based Over-The-Counter Wrinkle Reduction	Light Based Over The Counter Wrinkle Reduction	Same
510(k) Number	Applying		K171386	K162489	--
Product Code	OHS		OHS	OHS	Same
Intended Use / Indications for Use	The LED Eye Perfector (Model: EY-36A, EY-36B) is an Over-the-Counter (OTC) device intended for use in treating wrinkles within the periorbital region.		The dpl® SpectraLite is an Over-the-Counter (OTC) device intended for use in treating wrinkles within the	The RED Light Device is an OTC device indicated to emit energy in the red and IR region of the spectrum for	Same

			periorbital region.	use in dermatology for the treatment of periorbital wrinkles.	
Power Supply	Main unit: 3.7V, 420mAh lithium battery, 1.55Wh Adapter Input: 100-240Va.c., 50/60Hz Adapter Output: 5Vd.c, 1A		120-240V 5VDC Power Adapter	Adaptor:100~240V AC 50/60Hz Lithium battery: 2x3.7V	Similar Note 1
Wavelengths	605 nm, 633 nm, 660nm, 830 nm	605 nm, 625 nm, 660nm, 880 nm	605 nm, 625 nm, 660nm, 880 nm	Red: 633 ±5nm Infrared: 830 ±5nm	Similar Note 2
Modes	On/Off		On/Off	Not applicable	Same
Irradiance source	LED		LED	LEDs	Same
Visiblle light LEDs	Yes		Yes	Yes	Same
Treatment Area	40 cm^2		28 cm^2	17cm^2	Different Note 2
Energy Level	65 mW/cm²		61.59 mW/cm²	125 mW/cm^2 70 mW/cm^2 (633 nm); 55 mW/cm^2 (830 nm)	Different Note 2
LED distribution	Uniform distribution	Uniform distribution	Uniform distribution	No publicity	Same
Treatment Time	3 minutes per treatment		3 minutes per treatment	For the first month (4 weeks), treatment should be performed 3 times a week for 15-20 minutes	Same

			each time. (5-7 minutes on each treatment zone).	
Target Population	Individuals with wrinkles on their face within the periorbital region.	Individuals with wrinkles on their face within the periorbital region.	Individuals with periorbital lines and wrinkles	Same
Location for USE	OTC	OTC	OTC	Same
EMC	IEC 60601-1-2	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 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 10993-1, ISO 10993-5, ISO 10993-10	ISO 10993-1, ISO 10993-5, ISO 10993-10	Same

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: Although the “Wavelengths”, “Treatment Area” and “Energy Level” are a little different from the predicate devices, they all complied with the IEC 60601-1, IEC 60601-1-2, IEC 60601-2-57, and IEC 62471 safety standards’ requirements. So, these slight differences will not raise any safety or effectiveness issues.

7. Test Summary

LED Eye Perfector (Model: EY-36A, EY-36B) has been evaluated the safety and performance by lab bench testing as following:

Standards No.	Standard Title	Version	Date	Recognition Number

ANSI AAMI ES60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012	07/09/2014	19-4
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 systems used in the home healthcare environment	Edition 2.1 2020-07	12/21/2020	19-38
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	12-242
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	12/21/2020	19-36
IEC 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	Edition 3.2 2020-07	12/21/2020	5-132

IEC 62471	Photobiological safety of lamps and lamp systems	First edition 2006-07	08/20/2012	12-249
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	19-33
ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Third edition 2009-06-01	12/23/2016	2-245
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Third Edition 2010-08-01	07/26/2016	2-174

8. Date of the summary prepared: November 10, 2022

9. <u>Final Conclusion:</u>

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devices K171386 and K162489.