March 9, 2023

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

Re: K223642
Trade/Device Name: LED Lip Perfector, model: ZC-05
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, ILY
Dated: February 15, 2023
Received: February 15, 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)*
K223642

Device Name
LED Lip Perfector (Model: ZC-05)

Indications for Use *(Describe)*
The LED Lip Perfector (Model: ZC-05) is an Over-the-Counter (OTC) device intended to treat fine lines and wrinkles and increase in circulation within the perioral 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary of K223642

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: March 3, 2023

2. Submitter's Information

Sponsor Name: Light Tree Ventures Europe B.V.
Establishment Registration Number: 3017422691
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E-mail: regulation@kaiyanmedical.com

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

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: LED Lip Perfector, model: ZC-05
Trademark: CurrentBody Skin™
Classification Name: Light Based Over-The-Counter Wrinkle Reduction
Review Panel: General & Plastic Surgery
Product Code: OHS, ILY
Regulation Number: 21 CFR 878.4810
Regulation Class: II

4. Predicate Device Information

Sponsor: LED Technologies, Inc.
Trade Name: reVive Perioral LED Light Therapy System
Classification Name: Light Based Over-The-Counter Wrinkle Reduction device
510(K) Number: K172662
Review Panel: General & Plastic Surgery
Product Code: OHS, ILY
Regulation Number: 21 CFR 878.4810
Regulation Class: II

5. Device Description

The LED Lip Perfector (Model: ZC-05) is an over-the-counter light-emitting diode (LED) device that emits energy for dermatology to treat fine lines and wrinkles and increase circulation within the perioral region. The device contains four types of LEDs: 605nm, 630nm, 660nm, and 850nm The LED Lip Perfector components include the main device, charging base, power cord, alternative mouthpiece, user manual, and storage bag. There is only one button on the top edge of the main unit. Short press the power button to turn on the device, and long press the power button to turn off the device.

This device only has one treatment mode. The LED Lip Perfector is applied to the skin to ensure consistent light administration during each treatment. The device is sold Over the Counter (OTC).

6. Intended Use / Indications for Use

The LED Lip Perfector (Model: ZC-05) is an Over-the-Counter (OTC) device intended to treat fine lines and wrinkles and increase in circulation within the perioral region.

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.	LED Technologies, Inc.	--
Trade Name	LED Lip Perfector	reVive Perioral LED Light Therapy System	
Model	ZC-05	/	--
Classification Name	Light Based Over-The-Counter Wrinkle Reduction	Light Based Over-The-Counter Wrinkle Reduction device	--
510(k) Number	Applying	K172662	--
Product Code	OHS, ILY	OHS, ILY	Same
Intended Use / Indications for Use	The LED Lip Perfector (Model: ZC-05) is an Over-the-Counter (OTC) device intended to treat fine lines and wrinkles and increase in circulation within the perioral region.	The reVive® Perioral LED Light Therapy system is an Over-the-Counter (OTC) device intended for the treatment fine lines and wrinkles, and increase in circulation within the perioral region.	Same
Design	Hand-held device	Hand-held device	Same
Type of use	Over-The-Counter Use	Over-The-Counter Use	Same
Treatment Distance	Applied directly to the skin	Applied directly to the skin	Same
Treatment Sites	Perioral region	Perioral region	Same

Change in energy (the addition of battery)	Yes	Yes	Same
Power Supply	3.7V lithium battery	3.7V lithium battery	Same
Treatment Range	3 minutes per treatment	3 minutes per treatment	Same
Wavelengths	605nm, 630nm, 660nm, 850nm	605nm, 630nm, 660nm, 880nm	Different, Note
Location for USE	OTC	OTC	Same
Number of LEDs	Total 56 LEDs 605nm: 14 660nm: 14 630nm: 14 880nm: 14	Total 56 LEDs 605nm: 14 660nm: 14 630nm: 14 880nm: 14	Same
Energy Level	67.7±10% mW/cm²	67.7 mW/cm²	Same
Treatment Area	24 cm²	24 cm²	Different
Irradiance source	LED	LED	Same
Visible light LEDs	Yes	Yes	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

Note:
Although the “Wavelengths” of subject device is a little different from the predicate device, they are both have a same intended use and the “Energy Level” is the same. So, the differences between the subject device and predicate device will not raise any safety or effectiveness issue.

8. Test Summary

The LED Lip Perfector (Model: ZC-05) has been evaluated the safety and performance by lab bench testing as following:

Standards No.	Standard Title	Version	Date	Recognition Number	Location
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020	/	/	Attachment 9

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	Attachment 9
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	Attachment 9
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	60601-1-2 Edition 4.1 2020-09	12/21/2020	19-36	Attachment 9
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	Attachment 9

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	Attachment 9
ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Third edition	2009-06-01	2-245	/
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Third Edition	2010-08-01	2-174	/

9. Final Conclusion

The subject device is as safe, as effective, and performs as well as the legally marketed predicated devices K172662.