May 16, 2023

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

Re: K223893
Trade/Device Name: Infrared Heat (Model: E0221)
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: 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)*
K223893

Device Name
Infrared Heat, model: E0221

Indications for Use *(Describe)*

The Infrared Heat (Model: E0221) is intended to emit energy in the red and infrared spectrum for 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.

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510(k) Summary of K223893

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
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Contact Person (including title): Alain Dijkstra (Manager)
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Application Correspondent:

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

Manufacturer

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

Distributor

Company: Smart Recovery Technologies LLC
Add: 132A Veterans Lane-451, Doylestown, PA 18901, USA

2. Subject Device Information

Trade Name: Infrared Heat, model: E0221
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 890.5500, 21 CFR 878.4810
Regulation Class: II

3. Predicate Device Information

Predicate Device (K171323)

Sponsor: BioPhotas, Inc.
Trade Name: BioPhotas Celluma3
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 878.4810

Regulation Class: II

Predicate Device (K201107)
Sponsor: GTG Wellness Co., Ltd.
Trade Name: Opera Lebody
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 878.4810
Regulation Class: II

4. Device Description
The Infrared Heat, model: E0221, is an over-the-counter light emitting diode (LED) device that emits 630nm and 830nm light to treat wrinkles. The device uses three types of LEDs and has two modes to reach those two functions. The user can control the treatment time or automatically shut it off within a set time.
The Infrared Heat components include the main unit device (a pad), an adjustable strap, a USB charging cord, goggles and a user manual.
The user wears the device in the area which needs to treat, and the device will shut down automatically a 10-minute after finishing treatment.

5. Intended Use / Indications for Use

The Infrared Heat (Model: E0221) is intended to emit energy in the red and infrared spectrum for use in the treatment of full face wrinkles.

6. Comparison to predicate devices
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 (K171323)	Predicate Device (K201107)	Remark
Company	Light Tree Ventures Europe B.V.	BioPhotas, Inc.	GTG Wellness Co., Ltd.	--
Trade Name	Infrared Heat	Biophotas Celluma3	Opera Lebody	--
Model	E0221	/	/	--
Classification Name	Laser surgical instrument for use in general and plastic surgery and in dermatology	Laser surgical instrument for use in general and plastic surgery and in dermatology	Laser surgical instrument for use in general and plastic surgery and in dermatology	Same
510(k) Number	K223893	K171323	K201107	--
Product Code	OHS	OHS	OHS	--

Indications for Use	The Infrared Heat (Model: E0221) is intended to emit energy in the red and infrared spectrum for use in the treatment of full face wrinkles.	The BioPhotas Celluma^3 is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full face wrinkles.	OPERA LEBODY is an over the counter device that is intended for the use in the treatment of full face wrinkles.	Same
Type of Use	Over-The-Counter use	Over-The-Counter use	Over-The-Counter use	Same
Light Source	LEDs	LEDs	LEDs	Same
Power Supply	Main unit: 3.7V, 1800mAh lithium battery, 6.66Wh Adapter Input: 100-240Va.c., 50/60Hz Adapter Output: 5Vd.c, 2A	110-120V	No publicity	Different, Note 1
Wavelength	630nm,830nm+/- 20nm	Red: 640nm+/-25nm NIR: 880nm+/-50nm	2 types: - Red (630nm) - IR (830nm)	Similar, Note 3
Panels Type	1 Panel	1 Panel	1 Panel (Mask)	Same
Output Power	630nm + 830nm: 30 mW/cm^2	6.5 mw/cm^2	50 mw/cm^2	Different, Note 2
Standard dose in Joules	18J/cm^2	11.7J/cm^2	30J/cm^2	Different, Note 2
LED distribution	Uniform distribution	Uniform distribution	Uniform distribution	Same
Treatment area	20*8	15*8	No publicity	Similar, Note 3

LED number	630nm: 30 830nm: 30	No public	Total 78 LEDs	Similar, Note 3
Treatment Time	10 minutes per day, 2-5 times per week	3 times a week for 30 min. 4 weeks	10 minutes daily, 3 days per week for 8 weeks	Different, Note 2
Operation interface	Device uses a timer and software to control treatment duration.	Device uses a timer and software to control treatment duration.	Device uses a timer and software to control treatment duration.	Same
Software	Yes	Yes	Yes	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 60601-1 IEC 62471	Same
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23	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, but 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 “Output Power”, “Standard dose in Joules”, and “Treatment Time” of the subject device and predicate devices are a little different, the “Output Power” and “Standard dose in Joules” of the subject device is not higher than Predicate Device (K201107), indicating the safety of the device, and not lower than Predicate Device (K171323), indicating the effectiveness of the device. Besides, the “Treatment Time” is similar to predicate device. So, the “Output Power”, “Standard dose in Joules”, and “Treatment Time” of the subject device and predicate devices does not affect the effectiveness and safety of the device.

Note 3: Although the “Wavelength”, “Treatment area” and “LED number” are slightly different from the predicate device, their treatment doses are all safe and effective, ang they all complied with the requirement of IEC 60601-2-57 and IEC 62471 standards. So, these slight differences will not raise any safety or effectiveness issues.

7. Test Summary

7.1 Non-Clinical Tests Performed

1) 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

2) Biocompatibility

The subject device is biocompatible for its intended use. They are complied with biocompatibility standards ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Sensitization) and ISO 10993-23 (Irritation).

3) 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.

4) Usability Testing

Usability testing was conducted on the Infrared Heat (Models: E0221), which complies with IEC 62366-1 and IEC 60601-1-6.

7.2 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.

8. Date of the summary prepared: May 13, 2023

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 K171323 and K201107.