August 29, 2022

LTBIO Co., Ltd.
℅ Jaden Keum
Regulatory Affairs Consultant
KMC, Inc.
Room no. 1709, 123, Digital-ro 26-gil, Guro-gu
Seoul, South Korea 08390

Re: K221189
Trade/Device Name: OLIZ LTB-1000A
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY
Dated: May 27, 2022
Received: May 31, 2022

Dear Jaden Keum:

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,

for Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K221189

Device Name
OLIZ LTB-1000A

Indications for Use *(Describe)*
The OLIZ LTB-1000A is intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY – K221189

This summary of 510(k) –safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: August 29, 2022

1. GENERAL INFORMATION

1.1 Submitter Information

- Submitter Name: LTBIO Co., Ltd.
- Address
  : 1058, B-dong, Seongnam SKV1 Tower, 14, Galmachi-ro 288beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13201, Republic of Korea
- Telephone Number: +82-31-608-1058
- Fax: +82-31-608-1060

1.2 Contact Person

- Name: Jaden Keum (Consultant / KMC, Inc.)
- Address: Rm. No. 1709, 123, Digital-ro 26-gil, Guro-gu, 08390, Republic of Korea
- Telephone Number: +82-70-8965-5554
- Fax: +82-2-2672-0579
- E-mail: js.keum@kmcerti.com

2. DEVICE INFORMATION

2.1 Trade/Device Name: OLIZ LTB-1000A

2.2 Regulation Number: 21CFR 890.5500

2.3 Device Common Name: Infrared lamp

2.4 Regulation Name: Infrared Lamp

2.5 Product Code: ILY

2.6 Device Class: Class II

2.7 Review Panel: Physical Medicine

3. PREDICATE DEVICE

Manufacturer	BioPhotas
Device Name (Trade Name)	Celluma3
510(k) Number	K152280

4. DEVICE DESCRIPTION

The OLIZ LTB-1000A is a highly shapeable LED panel designed to fit the contours of the target areas of the anatomy, covered with biocompatible material, which uses specific wavelengths of light. OLIZ LTB-1000A produces light in the near infrared region of the spectrum (850nm) intended to provide topical heating for temporary pain relief. This device provides a soothing vibration function for the purpose of enhancing the user's satisfaction.

5. INDICATIONS FOR USE

The OLIZ LTB-1000A is intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting relaxation of muscle tissue; and to temporarily increase local blood circulation.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

Feature	**Proposed Device LTBIO OLIZ LTB-1000A K221189**	**Predicate Device BioPhotas Celluma3 K152280**	**Analysis of Technological Differences**
Regulation No.	21CFR§890.5500, Infrared Lamp	21CFR§890.5500, Infrared Lamp	Same
Product Code	ILY	ILY, OHS, OLP	Same as predicate device except for product codes OHS and OLP which are regarding acne and wrinkle features that our products do not have. Thus this difference doesn't affect the safety and effectiveness.
Indications for use	The OLIZ LTB-1000A is intended to deliver heat in the	The BioPhotas Celluma3 is intended to deliver heat in	Same as predicate device

Feature	Proposed Device LTBIO OLIZ LTB-1000A K221189	Predicate Device BioPhotas Celluma3 K152280	Analysis of Technological Differences
	IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.	the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. The blue spectrum light is intended to reduce mild to moderate inflammatory acne vulgaris. The Celluma3 is intended to emit energy in the red and infrared spectrum for use in dermatology for the treatment of periorbital wrinkles.	except acne vulgaris and wrinkles function.
Mechanism of Action	Use of red light for elevating tissue temperature and IR light.	Use of visible blue light in treatment of acne, red light for elevating tissue temperature and IR light in improving appearance of periorbital wrinkles.	Same as predicate device except acne vulgaris and wrinkles function.
Maximum device surface temperature	Less than 40℃	Not publicly available	-
Wavelengths	655nm, 850nm	465nm, 640nm, 880nm	Predicate device includes blue light for acne treatment not available in the subject device.
Electrical power	Use Li-ion batteries (3.7v_1800mA x2)	110 – 120 V	This difference does not affect the performance of the product, and the safety has been proven by IEC 60601-1.

Treatment	15 min. Twice a day (Total 210 min. per week)	3 times a week for 30 min. 4 weeks (Total 90 min. per week)	This difference does not affect the performance and safety of the product when following the recommended usage times.
Electrical Safety	IEC 60601-1 & collateral standards	IEC 60601-1 & collateral standards	Same
Use	OTC	OTC	Same

7. PERFORMANCE Data

7.1 Non-Clinical performance test comparing with predicate device

The test results along with the comparison discussion to the predicate device demonstrated that the OLIZ LTB-1000A has met the system requirements. Also, according to the performance test, the device surface temperature is less than 40 ℃. The proposed device presented similar technological specifications to the presented predicate devices and therefore, is substantially equivalent to the predicate devices.

7.2 Bench test

Performance testing of the OLIZ LTB-1000A was conducted to verify that the device met all design specifications. The test results demonstrate that the OLIZ LTB-1000A complies with all requirements, including international and FDA-recognized consensus standards:

EN/IEC 60601-1 (FDA #19-4) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

EN/IEC 60601-1-2 (FDA #19-8) Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

EN/IEC 60601-1-11 (FDA #19-14) 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

EN/IEC 62304 (FDA #13-79) Medical device software - Software life cycle processes

ISO 10993-1 (FDA #2-258) Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

ISO 10993-5 (FDA #2-245) Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

ISO 10993-10 (FDA #2-174) Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

7.3 Clinical performance

Not applicable

8. CONCLUSION

Substantial Equivalence:

The indications for use and technological characteristics of the OLIZ LTB-1000A are substantially equivalent to the indications for use and technological characteristics of the predicate device.
The design and components in the OLIZ LTB-1000A are similar to predicate Celluma 3.
The differences do not negatively affect the safety or efficacy of the device as supported by the results of the performance tests. The performance specifications of the OLIZ LTB-1000A are substantially equivalent to those in the predicate device. The safety features and compliance with safety standards

in the OLIZ LTB-1000A are similar to the safety features and compliance with safety standards found in the predicate device. Patient contact materials were partly modified and tested for biocompatibility. Any differences in the technological characteristics do not raise new safety or effectiveness concerns. Consequently, it can be concluded that the OLIZ LTB-1000A is substantially equivalent to the predicate device, cleared under 510(k) K152280.