March 18, 2022

LYMA Life Ltd.
% Allison Komiyama
Principal Consultant
AcKnowledge Regulatory Strategies, LLC
2251 San Diego Avenue, Suite B-257
San Diego, California 92110

Re: K210823
Trade/Device Name: LYMA Laser
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 9, 2022
Received: February 11, 2022

Dear Allison Komiyama:

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,

Purva Pandya
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)*
K210823

Device Name
LYMA Laser

Indications for Use *(Describe)*
The LYMA Laser is an Over-the-Counter (OTC) light based device intended for the use in treating 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
K210823

DATE PREPARED
March 17, 2022

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DEVICE INFORMATION

Proprietary Name/Trade Name:	LYMA Laser
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number:	21 CFR 878.4810
Class:	II
Product Code:	OHS
Review Panel:	General & Plastic Surgery
Premarket Review:	Surgical and Infection Control Devices (OHT4) General Surgery Devices (DHT4A)

PREDICATE DEVICE IDENTIFICATION
The LYMA Laser is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K120775	LightStim for Wrinkles / LED Intellectual Properties	✓
K120560	Trinity Wrinkle Remover / Carol Cole Company	

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION

The LYMA Laser is an Over-the-Counter (OTC) light based device intended for the use in treating full-face wrinkles. The LYMA Laser incorporates a near-infrared LED light source within the optimum Therapeutic Optical Window at 808 nm, optimized for Low Level Light Therapy, and a red LED light source at 620 nm. An optical lens that diffuses the light to produce narrowband, divergent distribution across an 8 cm^2 treatment area. The energy output of the 808 nm and 620 nm wavelengths is 62.5 mW/cm^2 which produces a beneficial treatment for full-face wrinkles.

INDICATIONS FOR USE

The LYMA Laser is an Over-the-Counter (OTC) light based device intended for the use in treating full-face wrinkles.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

LYMA Life believes that the LYMA Laser is substantially equivalent to the predicate devices based on the information summarized here:

- The subject device has the same intended use as the predicates (i.e., the treatment of full-face wrinkles)
- The subject device has a similar output as the predicates (i.e., 62.5 mW/cm^2)
- The subject device utilizes a similar near-infrared treatment wavelength and a similar red light wavelength as the predicates (i.e., 808 nm and 620 nm)
- The subject device utilizes the same treatment duration as the predicates (i.e., 3 minutes per treatment area)
- The subject device utilizes a similar irradiation, or treatment, area as the predicates (i.e., 8 cm^2)

We believe we have identified appropriate predicate devices with the same intended use, same or similar technological characteristics and the same treatment parameters. Therefore, this information supports the determination of substantial equivalence in safety and effectiveness between the subject and predicate devices.

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the LYMA Laser. The following tests were performed to demonstrate safety based on current industry standards:

Electromagnetic Compatibility and Electrical Safety: The subject device was tested in compliance to AAMI/ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2(2010)/(R)2012 *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* (which complies with IEC 60601-1); and 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.*

Additionally, testing to IEC 60825-1 *Safety of laser products - Part 1: Equipment classification and requirements* and an evaluation per ISO 10993-1 *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process* were provided.

SUMMARY OF USABILITY TESTING

To demonstrate that lay users can correctly operate the LYMA Laser, a usability study was completed. The study was split into two Parts. Part A examined the participants' abilities correctly self-identify whether they are appropriate users of the device based on the outer packaging (also known as the box label). Part B evaluated how well participants could comprehend the instructions for use and correctly operate the subject device.

This usability study evaluated the suitability of the LYMA Laser for over-the-counter (OTC) distribution. The ability of participants to correctly self-identify whether they are appropriate users of the device, comprehend labeling, and safely and effectively use the subject device was assessed in two independent parts of the study. The number of participants required to answer all questions correctly in each part was 21 out of 26, for an 80% success rate. The results of the usability testing (passing rates of 88% for the Self-Selection as well as the Labeling Comprehension and Proper Use of the Device sections) demonstrate that the LYMA Laser is suitable for OTC distribution and that lay users can correctly self-select themselves as users of the subject device.

CONCLUSION

Based on the testing performed and usability testing, it can be concluded that the subject device does not raise different questions of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed LYMA Laser are assessed to be substantially equivalent to the predicate devices.