February 21, 2025

LYMA Life Ltd.
% Lucie Dalet
Principal Consultant
Rqm+
2790 Mosside Boulevard
Suite 800
Monroeville, Pennsylvania 15146

Re: K243330
Trade/Device Name: LYMA Laser PRO
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: October 23, 2024
Received: October 24, 2024

Dear Lucie Dalet:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.02.21 13:58:41 -05'00'

Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243330

Device Name
LYMA Laser PRO

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

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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"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."

LYMA

510(k) SUMMARY

DATE PREPARED
February 18, 2025

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION

Proprietary Name/Trade Name:	LYMA Laser PRO
Common Name:	Light Based Over The Counter Wrinkle Reduction
Regulation Number:	21 CFR 878.4810
Class:	II
Product Code:	OHS
Premarket Review:	OHT4 / DHT4A – General Surgery Devices
Review Panel:	General & Plastic Surgery

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

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K210823	LYMA Laser / LYMA Life Ltd.	✓
K230042	Q-Rejuvalight Pro Facewear (Model: P19-0023) / Light Tree Ventures Europe B.V.	

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

DEVICE DESCRIPTION
The LYMA Laser PRO is a compact, handheld laser device intended to provide low-level laser light therapy (LLLT) for the treatment of wrinkles. The LYMA Laser PRO system is composed of a handheld casing enclosing three low-level, 808nm laser diodes, and three red light-emitting diodes (LED). The device also includes one white LED that inform the user about device status during operation, and optical lenses that diffuse the laser light across a larger treatment window.

LYMA

The LYMA Laser PRO includes a rechargeable battery and is provided with a power cable.

INDICATIONS FOR USE

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

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

	Subject Device	**Primary Predicate Device**	**Secondary Predicate Device**
	LYMA Life, Ltd. **LYMA Laser PRO** K243330	LYMA Life, Ltd. **LYMA Laser** K210823	Light Tree Ventures Europe B.V. **Q-Rejuvalight Pro Facewear** K230042
Indications for Use	The LYMA Laser PRO is an Over-the-Counter (OTC) light based device intended for the use in treating face wrinkles.	The LYMA Laser is an Over-the-Counter (OTC) light based device intended for the use in treating full-face wrinkles.	The Q-Rejuvalight Pro Facewear (Model: P19-0023) is an Over-the-Counter (OTC) device intended for treatment of wrinkles and mild to moderate inflammatory acne.
Product Code / Regulation	OHS / 21 CFR 878.4810	OHS / 21 CFR 878.4810	OHS, OLP / 21 CFR 878.4810
Regulation Description	Laser surgical instrument for use in general and plastic surgery and in dermatology	Same	Same
Anatomical Sites	Full face	Same	Same
Environment of Use	OTC	Same	Same
Energy source	Laser diodes, LEDs	Same	LEDs
Laser Class	Class 3R	Class 1	N/A
Wavelength	Laser diodes: 808 nm ± 2 nm Red LEDs: 620 nm	Same	Wrinkles: 605nm, 630nm, 660nm, and 880nm Acne: 415nm and 630nm
Output Mode	Continuous	Same	N/A
Treatment area	20.4 cm^2	8.55 cm^2	For wrinkles: 140 cm^2
Treatment Dose	12.8 J/cm^2	11.3 J/cm^2	12.6 J/cm^2
Radiant Power	1400 mW	500 mW	Unknown
Irradiance	71 mW/cm^2	62.5 mW/cm^2	Total for wrinkles: 70 mW/cm^2
Power supply	3.6 V/ 5000 mA rechargeable Li-ion battery (non-removable)	3.6V / 3500 mA rechargeable Li-ion battery (removable)	5V, 50/60Hz, 2A Li-ion Polymer Battery: 3.7V, 600mAh, 2.22Wh
Treatment regimen	3 minutes per treatment area, every day for 8 weeks After 8 weeks, 3 minutes per treatment area, 3 times per week.	Same	3 minutes per treatment

The subject device has the same intended use and Indications for Use statement as the primary predicate device. The LYMA Laser PRO uses a similar design and identical materials as the device cleared in K210823. Both the subject and primary predicate devices are handheld devices using laser diodes to output infrared light at a wavelength of 808 ± 2 nm. The subject device is

able to treat a larger area at a higher irradiance level than the primary predicate device. However, the output irradiance is similar to the secondary predicate device cleared in K230042. The technological differences do not raise new types of questions of safety and effectiveness. The different technological characteristics of the subject device have undergone testing to ensure the device is as safe and effective as the predicates.

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate safety based on current industry standards:

Biocompatibility: Biocompatibility assessment was conducted per ISO 10993-1:2018 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*

Electrical, Mechanical, and Thermal Safety: The subject device was tested and shown to conform with the following safety and performance standards:

- IEC 60601-1:2005/AMD1:2012/AMD2:2020 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- IEC 60601-1-6:2010/AMD1:2013/AMD:2020 *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*
- IEC 60601-1-11:2015/AMD1:2020 *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*
- IEC 60601-2-22:2019 *Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*

Laser Safety: The subject device was tested and shown to conform with IEC 60825-1:2014 *Safety of laser products - Part 1: Equipment classification and requirements*

Electromagnetic Compatibility: The subject device was tested and shown to conform with IEC 60601-1-2:2014/AMD1:2020 *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*

SUMMARY OF CLINICAL TESTING

Clinical testing was not necessary to demonstrate substantial equivalence.

CONCLUSION

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