March 24, 2025

XPLR Ltd.
% Doris Dong
Shanghai CV Technology Co., Ltd.
Room 805, No. 19 Dongbao Road, Songjiang Area, Shanghai
201613 China
Shanghai, 201613
China

Re: K250125
Trade/Device Name: Lmnt O2
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, OLP
Dated: January 15, 2025
Received: January 17, 2025

Dear Doris Dong:

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: 2025.03.24 23:53:11 -04'00'

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K250125

Device Name
LMNT O2

Indications for Use *(Describe)*
LMNT O2 is an over-the-counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. In addition, LMNT O2 indicated to emit energy in the blue region of the spectrum for use in dermatology for the treatment of mild to moderate acne.

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 #K250125.

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	
Date:	January 15, 2025
Type of 510(k) Submission:	Traditional 510(k)
Basis for 510(k) Submission:	New device
Owner:	XPLR ltd Ben ami 6 st, Tel Aviv, Israel Tel: +972-52-4200400 Email:Info@xplr-med.com Website:www.Xplr-med.com
Contact:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add: Room 805, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris.d@ceve.org.cn Tel: 86 21-31261348 / Fax: 86 21-57712250

2. Device Description

Proprietary Name:	LMNT O_2
Classification Name:	Light Based Over The Counter Wrinkle Reduction, Over-The-Counter Powered Light Based Laser For Acne
Regulation Number:	21 CFR 878.4810
Product Code:	OHS,OLP
Device Class:	II
Review Panel:	General & Plastic Surgery
Device Description:	LMNT O_2 is a hand held device that uses low power light spectrum at red and infrared LED, at wavelength of 633 ±15nm, 830 ±15nm distribution with no hot spots for the treatment of periorbital wrinkles. The device also uses blue LED, at wavelength of 415 ±15nm emitting optical power in a uniform distribution with no hot spots for the treatment of acne.Designed for home-use.
Indications for use:	LMNT O_2 is an over-the-counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. In addition, LMNT O_2 indicated to emit energy in the blue region of the spectrum for use in dermatology for the treatment of mild to moderate acne.

3. Predicate Device Identification

Predicate 510(k) Number:	K232656
Marketing clearance date:	11/14/2023
Product name:	BLU TOTALE (Model: ENEOB852)
Manufacturer:	Premier North America Inc.
Predicate 510(k) Number:	K181659
Marketing clearance date:	07/26/2018

4. Substantial Equivalence to Predicate device

	New Device	**Predicate Device**	**Predicate Device**	**Remark**
510(k) Number	To be assigned	K232656	K181659	--
Proprietary Name	LMNT O_2	BLU TOTALE	Avologi ENEO	--
Model	--	ENEOB852	--	--
Owner	XPLR ltd.	Premier North America Inc.	Premier North America Inc.	--
Product Code	OHS,OLP	OLP	OHS	Same
Classification	II	II	II	Same
Indications for use	LMNT O_2 is an over-the-counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. In addition, LMNT O_2 indicated to emit energy in the blue region of the spectrum for use in dermatology for the treatment of mild to moderate acne.	BLU TOTALE is an over the counter phototherapy device for use in dermatology for the treatment of mild to moderate acne.	Avologi ENEO is an over the counter device indicated to emit energy in the red and IR region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.	Same
Type	Hand-held	Hand-held	Hand-held	Same
Materials	Rigid ABS and stainless steel	Rigid ABS and stainless steel	Rigid ABS and stainless steel	Same
Target Population	Individuals with periorbita wrinkles and mild to moderate acne on the face.	Individuals with mild to moderate acne on the face.	Individuals with periorbita wrinkles	Same
Anatomical Sites	Entire face and periorbital area	Entire Face	Periorbital Area	Same
Light source	Light emitting diode (LED)	Light emitting diode (LED)	Light emitting diode (LED)	Same
Light spectrum region	Blue light,red and IR region of the spectrum	Blue light	red and IR region of the spectrum	Same
Wavelengths	633 ±15nm, 830 ±15nm,415±15nm	415±15nm	633 ±5nm, 830 ±5nm	Same
Waveform	Constant	Constant	Constant	Same
Visible light LEDs	Yes	Yes	Yes	Same

Energy source	36 pcs LEDs(12pcs 633nm LEDs + 12pcs 830nm LEDs+ 12pcs 415nm LEDs)over 10cm2	24 pcs LEDs over 15cm^2	24 pcs LEDs (12pcs 633nm LEDs + 12pcs 830nm LEDs) over 15cm2	Similar
Energy density	69mW/cm2 for 633nm 53mW/cm2 for 830nm 49mW/cm2 for 415nm	50mW/cm^2	69mW/cm2 for 633nm 55mW/cm2 for 830nm	Similar
Initial treatment course	Red light mode: For the first month (4 weeks), treatment should be performed 3 times a week for 15-20 minutes each time (5-7 minutes on each treatment zone). Blue light mode: 4 minutes per area, twice per week for 4 weeks (total of 8 treatments).	4 minutes per area, twice per week for 4 weeks (total of 8 treatments)	For the first month (4 weeks), treatment should be performed 3 times a week for 15-20 minutes each time (5-7 minutes on each treatment zone).	Same
Power supply	Lithium battery	Lithium battery	Lithium battery	Same

5. Non-clinical Testing

The LMNT O_2 has been evaluated the safety and performance by lab bench testing and conforms to the following international consensus standards:

Electrical safety:

- ANSI AAMI 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 60601-1:2005, MOD) [Including Amendment 2 (2021)];

EMC:

- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests;

Additional safety testing:

- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSION 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 TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems;

- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems;

Biocompatibility testing:

- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity;
- ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization;
- ISO 10993-11 Third edition 2017-09 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity;
- ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation;

Performance testing:

- Skin Temperature Testing
- LED Wavelength And Power Density Testing
- No hot spots Testing

6. Conclusions

The conclusion drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicate device K232656 and K181659.