May 24, 2021

Rohrer Aesthetics, LLC
Mark Rohrer
President
105 Citation Court
Birmingham, Alabama 35209

Re: K210535
Trade/Device Name: UltraLight LED System
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
Regulatory Class: Class II
Product Code: OLI
Dated: April 29, 2021
Received: May 3, 2021

Dear Mark Rohrer:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K210535

Device Name

UltraLight LED System

Indications for Use *(Describe)*

LED red light: The UltraLight "red light" is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. The UltraLight "red light" is also indicated for use in dermatology for the treatment of superficial, benign vascular, and pigmented lesions.

LED blue light: The UltraLight "blue light" is indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

LED green light: The UltraLight "green Light" is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.

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

This 510(K) Summary for the UltraLight LED System is prepared in accordance with the requirements of 21 CFR 807.92.

Applicant:	Rohrer Aesthetics, LLC
Address:	Rohrer Aesthetics, LLC 105 Citation Court Birmingham, AL 35209
Contact Person:	Mr. Mark Rohrer
Telephone:	205-356-1172 – phone mrohrer@rohreraesthetics.com
Preparation Date:	May 21, 2021
Device Trade Name:	UltraLight LED System
Common Name:	Low Level Laser System for Aesthetic Use
Regulation Name:	Low Level Laser System for Aesthetic Use
Regulation Number:	21 CFR 878.5400
Product Code:	OLI
Predicate Devices:	K180338 (Cellulize), K160880 (Photonica Professional), and K030883 (Omnilux Blue)
Regulatory Class:	Class II
Device Description:	The UltraLight LED System is a low level laser system for aesthetic use. The device can emit three different wavelengths (i.e., red light @ 633 nm, blue light @ 415 nm, and green light @ 532 nm) to achieve its intended purpose. All three wavelengths have different indications for use. The device works by illuminating the skin with a single wavelength of red, blue, or green light. The device utilizes a 28.8cm X 38.0 cm irradiation board to deliver light directly to the desired target. The device is activated and controlled through the LCD control panel.
Indications for Use:	LED red light: The UltraLight “red light” is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. The UltraLight “red light” is also indicated for use in dermatology for the treatment of superficial, benign vascular, and pigmented lesions. LED blue light: The UltraLight “blue light” is indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

LED green light: The UltraLight "green Light" is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.

Comparison of Technical Specifications:

Characteristic – Red Light Mode	UltraLight LED System (510K Pending)	Photonica Professional (K160880)
Wavelength	633nm±6nm	635±2nm
Bandwidth	10nm	10nm
Output Intensity/Irradiance	105mW/cm^2	105mW/cm^2
Recommended Treatment Time	8 or 20 min	8 or 20 min
Standard Energy	126 J/cm^2	126 J/cm^2
Console Dimension	35cm×71cm×122cm	167cm×62cm×61cm
Weight	54kg	52kg
Power Source	100 – 120vac, 3 amps, 50/60Hz	110vac, 3amps, 60Hz
Operating Temperature	+5C – +35C	+5C – +35C
Cooling Mechanism	Forced Air Ventilation	Forced Air Ventilation

Characteristic – Blue Light Mode	UltraLight LED System (510K Pending)	Ominlux Blue (K030883)
Wavelength	415nm±5nm	415±5nm
Bandwidth	22nm	22nm±3nm
Output Intensity/Irradiance	40mW/cm^2	33.33 – 47.62 mW/cm^2
Recommended Treatment Time	20 min	20 min
Max. Energy	48 J/cm^2	40 J/cm^2
Console Dimension	35cm×71cm×122cm	37cm×18cm×49cm
Weight	54kg	12kg
Power Source	100 – 120vac, 3 amps, 50/60Hz	100–120vac, 3 amps, 50/60Hz
Operating Temperature	+5C – +35C	+5C – +35C
Cooling Mechanism	Forced Air Ventilation	Forced Air Ventilation

Characteristic – Green Light Mode	UltraLight LED System (510K Pending)	Cellulize (K180338)
Wavelength	532nm±3nm	532±3nm
Bandwidth	10nm	10nm
Output Intensity/Irradiance	95.14 mW/cm^2	95.14 – 105 mW/cm^2
Recommended Treatment Time	8 or 20 min	8 or 20 min
Max. Energy	45.7 J/cm^2 in 8 min 114 J/cm^{2}in 20 min	50 J/cm^2 in 8 min 126 J/cm^2 in 20 min
Console Dimension	35cm×71cm×122cm	183.2cm×62.2cm×61cm
Weight	54kg	52kg
Power Source	100 – 120vac, 3 amps, 50/60Hz	100–120vac, 3 amps, 50/60Hz
Operating Temperature	+5C – +35C	+5C – +35C
Cooling Mechanism	Forced Air Ventilation	Forced Air Ventilation

Comparison of Indications for Use:

	UltraLight LED System (510K Pending)	Photonica Professional (K160880)
Red Light Mode	For use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. The UltraLight "red light" is also indicated for use in dermatology for the treatment of superficial, benign vascular, and pigmented lesions.	For use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. Photonica Professional is also indicated for use in dermatology for the treatment of superficial, benign vascular, and pigmented lesions.

	UltraLight LED System (510K Pending)	Ominlux Blue (K030883)
Blue Light Mode	Is indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.	Is indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

	UltraLight LED System (510K Pending)	Cellulize (K180338)
Green Light Mode	Is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.	Is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.

Performance Data:
(Non-Clinical Testing)

The following performance data were provided in support of the substantial equivalence determination:

IEC 60601-1 Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance

IEC 60601-1-2 Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility

Bench Performance Data to support technical specifications of the device.

Results of Clinical Study:

A human clinical study was not required for this device since the technical specifications of the device are comparable to the technical specifications of the predicates.

Conclusion:

The UltraLight LED System is substantially equivalent to the Photonic Professional (K160880), the Omnilux Blue (K030883) and the Cellulize (K180338).