December 2, 2021

Raja Trading Company, Inc.
% Yolanda Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K202175
Trade/Device Name: OxyLight 2.0
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: GEX, GFE
Dated: January 6, 2021
Received: January 7, 2021

Dear Yolanda Smith:

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)*
K202175

Device Name
OxyLight 2.0

Indications for Use *(Describe)*
The Oxylight 2.0 is intended for dermatological use by physicians and healthcare professionals for the following:
LED Technology is intended for:
-Blue LED 465nm - to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.
-Red LED 625nm- for treatment of superficial, benign vascular and pigmented lesions.
-Yellow LED 590nm - treatment of periorbital wrinkles and rhytides.

Microdermabrasion is intended for exfoliation of the skin.

Oxygen spray is intended to refresh the skin.

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 is being submitted in accordance with requirements of 21CFR Section 807.92.

510(k) Number: K202175

1. Date of Preparation
   12/02/2021

2. Applicant

Name:	RAJA Trading Company Inc.
Address:	2801 Juniper Street, Suite 2, Fairfax, VA 22031
Contact Person:	Robert J. Adipietro
Title:	Vice President
Telephone:	561-868-4600
Fax:	561-258-0207
Email:	rja@rajamedical.com

3. Identification of the Proposed Device

Trade Name:	OxyLight 2.0
Common Name:	LED Phototherapy and Microdermabrasion
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification:	Class II
Product Code:	GEX, GFE
Regulation Number:	21 CFR 878.4810
Review Panel:	General& Plastic Surgery

Attachment	Regulation Name	Regulation No.	Product code	Class
LED Panel	Laser Instrument, Surgical Powered,	878.4810	GEX	2
LED Handpieces	Laser Instrument, Surgical Powered,	878.4810	GEX	2
Microdermabrasion Handpiece	Brush, Dermabrasion Powered	878.4820	GFE	Class I, 510k exempt
Oxygen Spray Handpieces	Not Applicable	Not Applicable	Not Applicable	General Wellness

4. Identification of Predicate Device

510(k) Number:	K200104
Product Name:	OxyLight
Manufacturer:	RAJA Trading Company Inc.

5. Device Description
   The subject device Oxylight 2.0 is a skin therapy system that was modified from the predicate device OxyLight cleared previously under K200104 for the LED Light Panel Therapy (Class 2), Microdermabrasion (Class 1, 510k exempt) and Oxygen Spray (General Wellness). The OxyLight 2.0 system includes two new LED handpieces called MyoLight. The MyoLight handpieces connect to the main unit. The small handpiece (diameter: 3.9 cm, Length: 14 cm) is generally used on the face and the large handpiece (diameter: 6.2 cm, Length: 15 cm) is generally used on the body.

6. Indications for Use
   The Oxylight 2.0 is intended for dermatological use by physicians and healthcare professionals for the following:
   LED Technology is intended for:
   -Blue LED - 465nm - to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.
   -Red LED 625nm- for treatment of superficial, benign vascular and pigmented lesions.

-Yellow LED 590nm - treatment of periorbital wrinkles and rhytides.

Microdermabrasion is intended for exfoliation of the skin.
Oxygen spray is intended to refresh the skin.

7. Substantially Equivalent (SE) Comparison

Specifications	**Subject Device**	**Predicate Device**	**Comment**
Device Name	OxyLight 2.0	OxyLight	N/A
510(k) Number	K202175	K200104	N/A
Applicant	RAJA Trading Company, Inc.	RAJA Trading Company, Inc.	N/A
Intended use/ Product Code	Powered laser surgical instrument, Power dermabrasion Class II/GEX/878.4810 Class I/GFE/878.4820	Powered laser surgical instrument, Power dermabrasion Class II/GEX/878.4810 Class I/GFE/878.4820	
Indications LED	-Blue LED Light - to treat dermatological conditions and specifically indicated to treat mild to moderate inflammatory acne vulgaris. -Red LED Light - for treatment of superficial, benign vascular and pigmented lesions. - Yellow LED Light - treatment of periorbital wrinkles and rhytides.	-Blue LED Light - to treat dermatological conditions and specifically indicated to treat mild to moderate inflammatory acne vulgaris. -Red LED Light - for treatment of superficial, benign vascular and pigmented lesions. - Yellow LED Light - treatment of periorbital wrinkles and rhytides.	Identical
Design and Mode of Action	Panel with an array of LED Lights. The LEDs emit blue (465 nm), red (625 nm) or yellow (590 nm) light. In addition, the OxyLight 2.0 includes 2 hand-held handpieces that house LED lights. The hand-held handpieces deliver the light to the skin as they are moved over the skin surface.	Panel with an array of LED Lights. The LEDs emit blue (465 nm), red (625 nm) or yellow (590 nm) light.	Similar
No. of LEDs	Panel – 840 Face Handpiece - 8 Body Handpiece - 18	Panel - 840	Similar power density and energy flux
Treatment Time	20 minutes	20 minutes	Identical
Light Source	LED	LED	Identical
Operation Interface	Display Screen	Display Screen	Identical
Wavelength (Blue)	465 nm +/- 5nm	465 nm +/- 5nm	Identical
Energy Output (Blue)	54 J/cm^2	54 J/cm^2	Identical
Power Output (Blue)	45 mW/cm^2	45 mW/cm^2	Identical
Wavelength (Red)	625 nm +/- 5nm	625 nm +/- 5nm	Identical
Energy Output (Red)	120 J/cm^2	120 J/cm^2	Identical
Power Output (Red)	100 mW/cm^2	100 mW/cm^2	Identical
Wavelength (Yellow)	590 nm +/- 5nm	590 nm +/- 5nm	Identical
Energy Output (Yellow)	42 J/cm^2	42 J/cm^2	Identical
Power Output (Yellow)	35 mW/cm^2	35 mW/cm^2	Identical

8. Non-Clinical Testing
   Non clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The following tests were conducted:

- IEC 60601-1:2005/A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance*;
- IEC 60601-1-2:2014/EN 60601-1-2:2015, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests**.
- Biocompatibility Tests per ISO 10993 and FDA Guidance
- Software Validation & Verification Test
- Bench Testing to verify the performance

*The OxyLight 2.0 was tested with the LED Handpieces under the name OxyLight. The OxyLight was cleared by the FDA K200104 with the LED Panel, Microdermabrasion and Oxygen Spray Modalities. The OxyLight 2.0 is the OxyLight with the addition of the LED handpieces.

**Sapphire 3 OxyLight is the same test article. Sapphire 3 is a trademark brand name that RAJA Trading Company, Inc. uses for its class of skin care devices. In addition, the OxyLight 2.0 was tested with the LED Handpieces under the name OxyLight. The OxyLight was cleared by the FDA K200104 with the LED Panel, Microdermabrasion and Oxygen Spray Modalities. The OxyLight 2.0 is the OxyLight with the addition of the LED handpiece.

9. Clinical Testing
   No clinical study is included in this submission.

10. Conclusion
    Based on the comparison and analysis above, the proposed subject device is determined to be Substantially Equivalent (SE) to the predicate device.