June, 4, 2020

RAJA Trading Company, Inc.
% Yolanda Smith
Consultant
Smith Associates
1468 Harwell Ave
Crofton, Maryland 21114

Re: K200104
Trade/Device Name: Oxylight
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 14, 2020
Received: March 10, 2020

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,

Colin Kejing Chen
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200104

Device Name
OxyLight

Indications for Use *(Describe)*

The Oxylight 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.

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K200104
510(k) Summary

SPONSOR

Company Name: RAJA Trading Company Inc.
Company Address 801 South Olive Avenue
Suite 124
West Palm Beach, Florida 33401
Telephone: 561-868-4600
Fax: 561-258-0207
Contact Person: Robert J. Adipietro
Title: VP

Summary Preparation Date: June 4, 2020

DEVICE NAME

Trade Name: OxyLight
Common/Usual Name: LED Phototherapy, Microdermabrasion, Oxygen Spray
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation Number**:** 21 CFR 878.4810; 878.4820
Product Code: GEX, GFE
Device Class: Class II

Attachment	Regulation Name	Regulation No.	Product code	Class
Panel	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

Legally Marketed Equivalent Devices

LED BLUE Light – Primary	BioPhotas, Inc.	BioPhotas LifeLight	K122237
LED BLUE Light – Reference	Photo Therapeutics Ltd	Omnilux Blue	K030883
LED RED Light – Primary	Photo Therapeutics Ltd	Omnilux Revive	K030426
LED YELLOW – - Primary	Quantel Derma GMBH AM Wolfsmantel 46	LEDA – Applicator SCR 585	K090762

DEVICE DESCRIPTION

The Oxylight system is a skin therapy system that uses three major modalities delivered by different attachments powered from a single energy source and operated from a universal control unit. The treatments include, LED Light Panel Therapy (Class 2), Microdermabrasion (Class 1, 510k exempt) and Oxygen Spray. The Oxygen Spray is delivered through the same panel used for LED light therapy and separate handpieces.

DEVICE INDICATIONS FOR USE

The Oxylight 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.

COMPARISON OF TECHNICAL CHARACTERISTICS

LED PDT Blue Light Panel Component	**Subject Device**	**Primary Predicate Device**	**Reference Predicate Device**	**Substantial Equivalent**
Device Name	OxyLight	BioPhotas LifeLight	Omnilux Blue	
Applicant	RAJA Trading Company, Inc.	BioPhotas, Inc.	Photo Therapeutics Limited	
Listing	K200104	K122237	K030883	
Classification Name Class/Product Code/Regulation	Laser Instrument, Surgical Powered Class II/GEX/878.4810	Laser Instrument, Surgical Powered Class II/GEX/878.4810	Laser Instrument, Surgical Powered Class II/GEX/878.4810	Yes
Indications for Use	To treat dermatological conditions, specifically to treat mild to moderate acne vulgaris.	The blue light spectrum is intended to reduce mild to moderate acne vulgaris.	Dermatological conditions and specifically to treat moderate inflammatory acne vulgaris.	Yes
Wavelength of Blue Light	465 nm +/- 5nm	464 nm +/- 5nm	415 +/-5 nm	Yes
Energy Output in Joules/cm2	54 joules/cm2	19.6 joules/cm2	48 joules/cm^2	Different from the Primary Predicate Device but similar in technological characteristics to the reference predicate device.
Power Output Level mW/cm^2	45 milliwatts/cm^2	Unknown	40 milliwatts/cm^2	Different from the Primary Predicate Device but similar in technological

				characteristics to the reference predicate device.
Design and Mode of Action	Panel with an array of LED Lights	Panel with an array of LED Lights	Panel with an array of LED Lights	Yes
Panel Dimensions	41.4cm x 23cm x 19.2cm	Unknown	31.8cm x 35.6cm x 8.9cm	Yes
Recommended Treatment Time	20 minutes	30 minutes	20 minutes	Yes
Patient Contact	None	None	None	Yes
Laser Type	LED	LED	LED	Yes
Operation Interface	Display Screen	Unknown	Display Screen	Yes

Red LED Light Panel Component	**Subject Device**	**Predicate Device**	**Substantial Equivalent**
Device Name	OxyLight	Omnilux Revive	
Applicant	RAJA Trading Company, Inc.	Photo Therapeutics Limited	
Listing	K200104	K030426	
Classification Name Class/Product Code/Regulation	Laser Instrument, Surgical Powered Class II/GEX/878.4810	Laser Instrument, Surgical Powered Class II/GEX/878.4810	Yes
Indications for Use	Indicated for use in dermatology for treatment of superficial, benign vascular, and pigmented lesions.	Indicated for use in dermatology for treatment of superficial, benign vascular, and pigmented lesions.	Yes
Wavelength of Red Light	625 nm +/- 5nm	633 +/- 5 nm	Yes
Energy Fluency Joules/cm2	120 joules/cm2	126 joules/cm^2	Yes
Power Output at Skin Level mW/cm^2	100 milliwatts/cm^2	105 milliwatts/cm^2	Yes
Design and Mode of Action	Panel with an array of LED Lights	Panel with an array of LED Lights	Yes
Panel Dimensions	41.4cm x 23cm x 19.2cm	31.8cm x 35.6cm x 8.9cm	Yes
Recommended Treatment Time	20 minutes	20 minutes	Yes
Patient Contact	None	None	Yes
Laser Type	LED	LED	Yes
Operation Interface	Display Screen	Display Screen	Yes

Yellow LED PDT Light Panel Component	**Subject Device**	**Reference Predicate Device**	**Substantial Equivalent**
Device Name	OxyLight	LEDA - Applicator SCR 585	
Applicant	RAJA Trading Company, Inc.	Quantel Derma GMBH AM Wolfsmantel 46	
Listing	K200104	K090762	
Classification Name Class/Product Code/Regulation	Laser Instrument, Surgical Powered Class II/GEX/878.4810	Laser Instrument, Surgical Powered Class II/GEX/878.4810	Yes
Intended Use	Generally indicated for treatment of periorbital wrinkles and rhytides.	Generally indicated for treatment of periorbital wrinkles and rhytides.	Yes
Wavelength of Yellow Light	590 nm +/- 5nm	585 nm +/- 5nm	Yes
Energy Fluency Joules/cm2	42 joules/cm2	0.1 – up to 100 joules/cm2	Yes
Power Output at Skin Level mW/cm^2	35 milliwatts/cm^2	$4mW/cm^2$ – $120mW/cm^2$	Yes
Panel Dimensions	41.4cm x 23cm x 19.2cm	45cm x 41cm x 24 cm	Yes
Design and Mode of Action	Panel with an array of LED Lights	Panel with an array of LED Lights	Yes
Recommended Treatment Time	20 minutes	Unknown	Yes
Patient Contact Materials	None	None	Yes
Laser Type	LED	LED	Yes
Operation Interface	Display Screen	Display Screen	Yes

PERFORMANCE DATA

Safety Testing

Standard	Test Title	Test Article	Test Results
IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012	Medical electrical equipment Part 1: General requirements for basic safety and essential performance	OxyLight	Pass
EN 60601-1-2:2015 EN 61000-3-2:2014 EN 61000-2-3:2013	Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests	Sapphire 3 OxyLight*	Pass

EN 62304 – Medical devices software – software life cycle processes

ISO 14971:2012 – Medical devices – Application of risk management to medical devices. Clinical testing was not performed with this device.

*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.

CONCLUSION

The OxyLight is similar to the predicate devices in indications for use, principle of operation and technological characteristics. Differences do not introduce new issues of safety and effectiveness and are thus substantially equivalent to the predicate. Non-clinical tests (IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012, and EN 60601-1-2:2015) demonstrate that the proposed device is as safe and perform as well as the predicate devices. Therefore, the proposed device is Substantially Equivalent (SE) to the predicate devices.