DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 2, 2016

Biophotas, Inc
% Mr. Robert Seiple
QPM Consulting, LLC
3817 Seville Rd
Denton, Texas 76205

Re: K152280
Trade/Device Name: Biophotas Celluma3
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY, OHS, OLP
Dated: December 30, 2015
Received: January 27, 2016

Dear Mr. Seiple:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K152280

Device Name
BioPhotas Celluma3

Indications for Use *(Describe)*
The BioPhotas Celluma3 is intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. The blue spectrum light is intended to reduce mild to moderate inflammatory acne vulgaris. The Celluma3 is intended to emit energy in the red and infrared spectrum for use in dermatology for the treatment of periorbital 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.

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."

K152280

510(k) Summary

Traditional 510(k) Summary
As required in 21CFR 807.92, we hereby submit this 510(k) Summary:

510(k) owners name, address, phone, fax, contact person:

The 510(k) owner is BioPhotas, Inc., 250 El Camino Real, #110, Tustin, CA 92780

Phone: (714) 838-1956 Fax: (714) 838-1447

The contact person: Mr. Patrick Johnson

Date Prepared: March 2nd 2016

Name of the device, trade name, proprietary name, and classification name:

Trade name: Celluma^3

Common name: Infrared Lamp

Classification name: Lamp Infrared, Therapeutic Heating (ILY), Over-The-Counter Powered Light Based Laser For Acne (OLP) and Light Based Over-The Counter Wrinkle Reduction (OHS). Note that the product does not employ laser light, but these product codes has been used for these devices.

Predicate Devices:

The legally marketed predicates for the BioPhotas Celluma^3 are:

- **K131113,** BioPhotas Celluma
- **K083183,** Aklarus Phototherapy System, Hill Laboratories, Frazer, PA.

Device Description:

The Celluma^3 is a highly shapeable LED panel designed to fit the contours of the target areas of the anatomy, covered with biocompatible material, which uses specific wavelengths of light to manage aesthetic and musculoskeletal conditions. Celluma^3 produces light in the near infrared region of the spectrum (880nm) intended to provide topical heating to tissue for pain relief. Blue light (464nm) is intended to help reduce the appearance of mild to moderate inflammatory acne. Red light (640nm) in combination with infrared light is intended to improve the appearance of wrinkles. Note that the Celluma^3 and the Celluma predicate device are technologically identical; only the indications for use have been revised to add treatment of periorbital wrinkles.

K152280

Indication for Use/Intended Use:

The BioPhotas Celluma^3 is intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting relaxation of muscle tissue; and to temporarily increase local blood circulation. The blue spectrum is intended to reduce mild to moderate inflammatory acne vulgaris. The Celluma^3 is intended to emit energy in the red and infrared region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

The Intended Use information from the predicate products is equivalent and is reproduced below:

K131113 BioPhotas Celluma

The BioPhotas Celluma device is intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. The blue spectrum is intended to reduce mild to moderate inflammatory acne vulgaris. Note that the Celluma^3 is technologically identical to the Celluma device, only the indication has been revised to include treatment for periorbital wrinkles.

K083183 – Aklarus Phototherapy System

The Aklarus Phototherapy system utilizes blue light (420 nm) and the combination of red (628 nm) and blue (420 nm) to treat dermatology conditions – specifically indicated to treat moderate inflammatory acne.

The Aklarus anti-aging Red (628nm and Anti-Aging Infrared (880nm) combination is intended for use in dermatology for the treatment of periorbital wrinkles.

The Aklarus Infrared (880 nm) is intended to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm,; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

Technological characteristics:

The BioPhotas Celluma^3 is a lightweight, portable light-emitting diode (LED) device which emits light energy. A blue LED array (464 nm) is used in treatment for mild to moderate inflammatory acne. A red LED array (640 nm) and an infrared LED array (880 nm) are used in combination for reduction of periorbital wrinkles. The near infrared LED array also provides mild topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscle pain.

Substantial Equivalence:

Table 5A – Device Comparison Chart

	BioPhotas Celluma K131113	BioPhotas Celluma[3] K number TBD	Aklarus Phototherapy System K083183	Significant Differences
Regulation	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	Identical
Regulation Name	Infrared Lamp	Infrared Lamp	Infrared Lamp	Identical
Indicated Use	Acne, Pain	Acne, Pain, Wrinkles	Acne, Pain, Wrinkles	Identical to Aklarus, Identical to Celluma except wrinkles added.

Indications For Use	The BioPhotas Celluma is intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. The blue spectrum light is intended to reduce mild to moderate inflammatory acne vulgaris.	The BioPhotas Celluma^3 is intended to deliver heat in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation. The blue spectrum light is intended to reduce mild to moderate inflammatory acne vulgaris. The Celluma3 is intended to emit energy in the red and infrared spectrum for use in dermatology for the treatment of periorbital wrinkles.	The Aklarus Blue (420nm +/-10nm), is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris. The Aklarus combination of Red (628nm+/-10nm) and Blue(420nm +/-10nm) is intended to emit in the red, blue regions of the spectrum for use in dermatology treatment of mild to moderate acne vulgaris. The Aklarus Anti-Aging Red (628nm +/-10nm) and Anti-Aging Infrared (880nm +/-10nm) combination is intended to emit energy in the red and infra-red region of the spectrum for use in dermatology for the treatment of periorbital wrinkles. The Aklarus Infrared (880nm +/-10nm) is intended to emit energy in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.	Identical to Aklarus, Identical to Celluma except wrinkles added.

	BioPhotas Celluma K131113	BioPhotas Celluma^3 K number TBD	Aklarus Phototherapy System K083183	Significant Differences
Mechanism of Action	Use of visible blue light in treatment of acne, red light for elevating tissue temperature.	Use of visible blue light in treatment of acne, red light for elevating tissue temperature and IR light in improving appearance of periorbital wrinkles.	Use of visible blue light in treatment of acne, red light for elevating tissue temperature and IR light in improving appearance of periorbital wrinkles.	Identical to Aklarus, Identical to Celluma except wrinkles added.
Wavelengths	465nm, 640nm, 880nm	465nm, 640nm, 880nm	420nm, 633nm, 830nm	Equivalence of blue light in the 400nm range previously established (K122237).
Electrical power	110 – 120 V	110 – 120 V	110 – 120 V	Identical
Treatment	3 times a week for 30 min. 4 weeks	3 times a week for 30 min. 4 weeks	Twice Weekly for 30 min. 4 weeks	Identical
Electrical Safety	ISO 60601-1 & collateral standards	ISO 60601-1 & collateral standards	ISO 60601-1 & collateral standards	Identical
Use	OTC	OTC	Prescription	Identical to the Celluma predicate, Aklarus is an older device.

Nonclinical Performance Data:

To demonstrate safety and effectiveness of the BioPhotas Celluma^3 and to demonstrate substantial equivalence to the predicate devices, BioPhotas has completed a number of non-clinical performance tests. The Celluma^3 meets established requirements for overall design, biocompatibility, electrical safety and software validation confirming that the design outputs meet design input requirements and established specifications.

The BioPhotas Celluma^3 successfully passed testing per internal verification/validation requirements and national/international standards illustrated below:

- Biocompatibility per 10993-1 (specifically 10993-5 & 10993-10)
- Electrical safety per IEC 60601-1
- EMC testing per IEC 60601-1-2
- Software validation per IEC 62304 and the FDA Guidance document

Clinical Performance Data:

A human clinical study was conducted to confirm device efficacy for the additional indication (treatment of periorbital wrinkles).

Test subjects visited a study center for thirty minute treatments, three times per week, for a period of four weeks, and a twelve week post-treatment follow up after the final treatment. Test subjects had photos taken at the start, at the end of the four week treatment, and at the final twelve week post-treatment follow up visit.

Upon completion of the clinical study, all photos were sent to the Clinical Investigators for determination of periorbital wrinkle reduction results, applying the Fitzpatrick Classification of Facial Wrinkling (Perioral and Periorbital).

One of the three Clinical Investigators (Board Certified Dermatologists), acted as the Principal Investigator and all three Clinical Investigators independently evaluated the test subjects' photos for inclusion and final results.

The eligible study population is comprised of test subjects with wrinkles within the Fitzpatrick Classification of Facial Wrinkling (Perioral and Periorbital) and ages between 30 to 75 years, who meet all inclusion criteria for enrollment. Fifty test subjects were recruited across seven esthetician locations, with seven or eight patients per study center. The final test subject count was forty-two with one site and seven test subjects dropping out of the study prior to completion. There were no adverse events observed or reported during the study.

The periorbital wrinkle levels were measured, and professional visual evaluation performed by the Clinical Investigators to evaluate the efficacy of the Celluma^3 on the improvements in periorbital wrinkles.

At least two out of three Clinical Investigators agreed that a majority of test subjects have experienced a one point or greater reduction of wrinkle severity on the Fitzpatrick Classification of Facial Wrinkling (Perioral and Periorbital) 12 weeks following the completion of treatment.

Clinical Study results confirmed at least a full point reduction in the appearance of periorbital wrinkles, along with high positivity rates from test subjects; therefore, has deemed the Celluma^3 efficacious, and demonstrating effectiveness.

Statement of Substantial Equivalence:

As defined by FDA, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared device(s). Alternatively the device may have the same intended use and different technological characteristics that have been demonstrated to show that the these differences do not raise any new or additional questions regarding its safety and effectiveness relative to the predicate device.

BioPhotas has demonstrated that the Celluma^3 device has the same intended use as the predicate device, employs very similar technological characteristics, which in addition to the human clinical study results, demonstrated that the device does not pose any additional questions regarding safety and efficacy relative to the predicate.

Therefore, the BioPhotas Celluma^3 as designed and manufactured, has been demonstrated to be substantially equivalent to the referenced predicate devices.

End of 510(k) Summary Section