DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 1, 2017

Biophotas Inc
% Steven Baker
Consultant
ISMART Consulting US
1004 West Tuscany View Road #205
Midvale, Utah 84047

Re: k171323
Trade/Device Name: Biophotas Celluma3
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
Dated: May 3, 2017
Received: May 5, 2017

Dear Steven Baker:

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 (DICE) 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 (DICE) 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,

David Krause -S

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)*
K171323

Device Name
Biophotas Celluma3

Indications for Use *(Describe)*
The BioPhotas Celluma3 is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full face 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.

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Section 5: 510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92(c).

Submitter's Name: BioPhotas, Inc.
Submitter's Address: 1000 E. Howell Ave., Ste A, Anaheim, CA 92805
Phone: (714) 838-1956
Fax: (714) 838-1447

Date Prepared: April 30th, 2017
Date amended: August 29th, 2017

Device Trade Name: Biophotas Celluma^3

Device Common name: Light Based Over the Counter Wrinkle Reduction

Device Classification Information:

Regulation Number	Device Classification name	Device Class	Product Code	Classification Panel	Type
21 CFR 878.4810	Powered light based non-laser surgical instrument Laser surgical instrument for use in general and plastic surgery and in dermatology	Class 2	OHS - Light based OTC for wrinkle reduction.	General & Plastic Surgery	Traditional 510 (k)

Device Description

The Biophotas Celluma^3 is a portable, therapeutic device whose purpose is to provide even, cool, narrow-band wavelengths of polychromatic light (blue, 465nm red, 640nm and Near infra-red, 880nm) produced by super-luminous LEDs (light emitting diodes) to treat a variety of skin and musculoskeletal conditions.

The Celluma^3 uses a combination of visible red light (640nm) in combination with near infrared light (880nm) and is intended to improve the appearance of full-face wrinkles.

Near infra-red (880nm) is intended to provide topical heating for elevating tissue temperature: for the temporary relief of minor muscles and joint pain, arthritis and muscle spasm; relieving stiffness; promotion the relaxation of muscle tissue; and to temporarily increase local blood circulation.

The blue spectrum (465nm) is intended to reduce mild to moderate inflammatory acne vulgaris.

The Biophotas Celluma^3 is intended for use on areas of the body such as the full face, back, chest, knees or other areas where the therapeutic light may be beneficial.

The system comprises of a semi-rigid, shape-taking frame upon which is mounted an array of LEDs, this allows the device to be contoured to the treatment area. The LEDs are embedded within a biocompatible Poron® foam covering that holds a transparent polycarbonate cover recessed within it. The biocompatibility nature of Poron® allows the device to be placed in contact with the skin. Nevertheless, the design of the device provides for maintaining a small distance between the surface of the skin and the surface of the device.

The flexible LED panel is permanently connected by a three-foot long cable attached to a control panel that contains the circuitry and software that controls the device. The control panel contains several push buttons beneath a sealed cover. A power button that switches the device ON/OFF, a mode button that allows the user to select from 3 preprogrammed treatment modes; “Acne”, “Wrinkles”, and “Aches and Pains”, a pulse button which allows the user to switch between pulse (default setting) or non-Pulse and a Start button that activates the desired treatment mode. The control panel receives its power from a separate cable that connects via an AC adaptor for 110-220 Volts to a standard U.S. electrical power outlet. The control panel contains an automatic shut-off safety feature.

Indications/Intended Use

The BioPhotas Celluma^3 is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full face wrinkles.

Predicate devices

Pro X OTC 5 Light therapy device (K140471) Pulsaderm Wrinkle mask 28 (K163329) and Lightstim for Wrinkles (K120775)

The Pro X OTC 5 light therapy device, Pulsaderm Wrinkle mask 28, and Lightstim for wrinkles are all light therapy devices intended to emit energy in the visible and IR spectrums for the use in the treatment of full-face wrinkles.

All predicates devices are intended to treat the whole face.

Please note: The proposed device Biophotas Celluma^3 is technologically identical to the previously cleared Biophotas Celluma^3 device (K152280).
In this application, only the indication for use has been revised to expand the treatment of periorbital wrinkles to include full face wrinkles.

Technological characteristics:

The key technological characteristics of the subject device and predicate devices are summarized in the following table;

Property	Celluma [3]	K140471 Pro X OTC 5 Light Therapy device	K163329 Pulsaderm wrinkle mask 28	K120775 Lightstim for wrinkles	Significant difference
Device Manufacturer	Biophotas Inc	La Lumiere LLC	Pulsaderm LLC	LED intellectual properties LLC	NA
Device Trade Name	Celluma[3]	Pro X OTC 5 Light Therapy device	Pulsaderm wrinkle mask 28	Lightstim for wrinkles	NA
510(K) Number		K140471	K163329	K120775	NA
Device Product Code - Classification name	OHS - Light based OTC for wrinkle reduction	OHS - Light based OTC for wrinkle reduction	OHS - Light based OTC for wrinkle reduction	OHS - Light based OTC for wrinkle reduction	No significant difference
Device Classification	Class II	Class II	Class II	Class II	No significant difference
Intended use and Indications	The BioPhotas Celluma[3] is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full face wrinkles.	The Pro X OTC 5 Light therapy device is intended for the use in the treatment of facial wrinkles and for people with FP skin types I, II and III	The Pulsaderm wrinkle mask 28 is intended for the use in the treatment of facial wrinkles and for people with FP skin types I, II and III	The Lightstim for wrinkles is an Over the Counter handheld device intended to emit energy in the visible and IR spectrums intended for the use in the treatment of full-face wrinkles.	No significant difference
Intended Location of Use	Whole face	Whole face	Whole face	Whole face	No significant difference
Treatment area	Active treatment area of 15” x 8”	Approximately 8” x 11”	Approximately 8” x 11”	Active treatment area 4 sq inches	Difference in treatment area [1].

Property	Celluma [3]	K140471 Pro X OTC 5 Light Therapy device	K163329 Pulsaderm wrinkle mask 28	K120775 Lightstim for wrinkles	Significant difference
Energy Type	Light emitting diodes	Light emitting diodes	Light emitting diodes	Light emitting diodes	No significant difference
Peak Wavelength (FWHM)	Red: 640nm+/-25nm NIR: 880nm+/-50nm	Red: 620nm – 630nm NIR: 850nm	Red: 620nm – 630nm NIR: 850nm	Red: 605, 630nm, 660nm. NIR: 855nm	No significant difference wavebands are equivalent to the predicate devices
Intensity (mW/cm^2)	6.5 mW/cm^2	19.80 mW/cm^2	21.18 mW/cm^2	65 mW/cm^2	Difference in intensity between Celluma[3] and predicates[2]
Treatment Dose (J/cm^2)	11.7 J/cm^2	17.8 J/cm^2	19 J/cm^2	11.7 J/cm^2	Difference in treatment dose[3]
Treatment protocol (Treatment time)	3 treatments per week (1800 seconds) 4 weeks	Daily, 15 minutes (900 seconds)	Daily, 15 minutes (900 seconds)	Daily per area (180 seconds) 4 weeks	Cumulative treatment protocol is similar
Control	Device uses a timer and software to control treatment duration.	Device uses a timer and software to control treatment duration.	Device uses a timer and software to control treatment duration	Device uses a ON/OFF switch to control treatment duration	Difference in control function. Negated by performance testing to IEC 62304:2006
Electrical power	110-120V	Ni MH Batteries	Ni MH Batteries	110-120V	Difference in power supply. Negated by electrical safety testing
Electrical Safety	60601-1:2012 60601-1-2:2007	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	60601-1 part 1 60601-1-2 part 1-2	No significant difference

1,2,3,4 – See Differences pages 6-7

Similarities and Differences between the subject and predicate device:

Key Similarities

Indications for use

The proposed device BioPhotas Celluma^3 is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full face wrinkles.

The predicate devices are all Over the Counter light emitting diode devices intended to emit energy in the visible and IR spectrums intended for the use in the treatment of full-face wrinkles. All systems are intended to treat the whole face.

Wavelengths Produced

The predicate devices and the Biophotas Celluma^3 all use light emitting diodes to produce energy and all emit in the visible red and near infra-red regions of the spectrum to treat full face wrinkles.

Differences

1. **Difference in treatment area**

Biophotas Cellluma^3 and Pro X OTC 5 light Therapy device (K140471) and Pulsaderm wrinkle mask 28 (K163329) are similar in treatment area and are designed to cover the full face.
There is a difference between Biophotas Cellluma^3 and Lightstim for Wrinkles (K120775). Lightstim for wrinkles has a treatment area of (4’’^{2}) the Biophotas Celluma^3 has an active treatment area of 15” x 8”. The variance in treatment area does not create a significant difference since the user is required to move the Lightstim for wrinkles over the treatment area for the area (whole face) to receive the stated treatment dose.
In addition, it should be noted that the Lightstim for Wrinkles (K120775) has been successfully used as a predicate to clear panel devices. The LightStim Professional 2-Panel Light System(K150098) was cleared using (K120775) without additional clinical data.

2. **Energy Output**

Biophotas Cellluma^3 and Pro X OTC 5 Light Therapy device (K140471) and Pulsaderm wrinkle mask 28 (K163329) are similar in terms of output intensity and treatment dose. There is a difference between the output intensity of the Biophotas Celluma^3 and the Lightstim for wrinkles (K120775) however the total cumulative dose per treatment area is identical (11.7 J/cm^2).

3. Control

There is no difference in the control function of the Biophotas Celluma[3] and Pro X OTC 5 light Therapy device (K140471) and Pulsaderm wrinkle mask 28 (K163329), all use a timer to control the duration of the treatment. The Lightstim for wrinkles (K120775) uses a simple on/off switch that the user operates to control the time of the treatment. The Biophotas Celluma[3] Biophotas Celluma[3] software has been classified using the FDA level of concern matrix as Minor and the software contained within the Biophotas Celluma[3] has been tested to International standard 62304:2006 to ensure safety. Therefore, non-clinical performance testing negates any difference between the subject and predicate device K120775.

Non-clinical Performance testing

To demonstrate safety and effectiveness and substantial equivalence the Biophotas Celluma[3] system has undergone several non-clinical performance tests in line with recognized standards in terms of general requirements, biocompatibility, electrical safety and software.

The following non-clinical performance data is provided in support of the substantial equivalence determination;

Electrical safety and safety standards

To demonstrate safety and effectiveness of the Biophotas Celluma[3] and to demonstrate substantial equivalence to the predicate devices, Biophotas has completed several non-clinical performance tests. The Celluma[3] meets established requirements for overall design, electrical safety, software validation and usability studies 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:

- Electrical safety per IEC 60601-1
- EMC testing per IEC 60601-1-2
- Software validation per IEC 62304 and the FDA Guidance document
- Usability Study per IEC 62366

The Biophotas Celluma[3] and the predicate devices have satisfied product safety testing to the IEC 60601-1 standard, and the electromagnetic safety testing to the IEC 60601-1-2 standard.

Biocompatibility

Considering the intended use for the Biophotas Celluma[3] LED system only transient and limited contact with intact skin takes place. Biophotas Inc believes that the device is safe and compliant with the requirements of ISO 10993 and the FDA - Blue Book Memorandum #G95-1in terms of biocompatibility. This position is supported by ISO 10993-1:2009 annex B.

Software verification and validation testing

In accordance with IEC 62304: 2006 Medical device Software – software life cycle process Biophotas Inc has allocated a software safety classification of Class A for the Biophotas Celluma^3 LED system. The software has also been classified using the FDA level of concern matrix and the level of concern for the device software is: Minor.

Statement of Substantial Equivalence:

513(i) of the FD&C Act (21 U.S.C. 360c(i) states that for substantial equivalence a proposed device is required to have the same intended use and similar technological characteristics as the predicate device(s). Where there are differences in technological characteristics, these can be negated by appropriate clinical or scientific data demonstrating that the proposed device is as safe and effective as the predicate device, and that the proposed device does not raise any different questions of safety and effectiveness than the predicate device for the same intended use.

Biophotas Celluma^3 is technologically identical to the previously cleared Biophotas Celluma^3 device (K152280). In this application, only the indication for use has been revised to expand the treatment of periorbital wrinkles to include full face wrinkles, a logical extension given the fact that the subject device in both submission has a large panel covering the entire face. In addition, the mechanism of action of low level light therapy for the treatment of "wrinkles" is well known to be the same irrespective of area that is being treated.

Biophotas INC has demonstrated that the Biophotas Celluma^3 device has the same intended use as the predicate devices, and employs equivalent technology and similar technological parameters. Where there are slight differences in technological parameters, these fall within the range of the predicate devices and those devices cleared under the OHS device code, or have been negated by non-clinical performance testing.

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