November 21, 2023

Patrick Johnson
CEO
15501 Red Hill Ave., #200
Tustin, California 92780

Re: K232977
Trade/Device Name: Biophotas Celluma CONTOUR
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
Regulatory Class: Class II
Product Code: OLI, OHS, ILY
Dated: September 21, 2023
Received: September 21, 2023

Dear Patrick Johnson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tanisha L. Hithe -S
Tanisha L. Hithe -S
2023.11.21
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Tanisha Hithe
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)*
K232977

Device Name
BIOPHOTAS Celluma CONTOUR

Indications for Use *(Describe)*
The BIOPHOTAS Celluma CONTOUR is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.
The BIOPHOTAS Celluma CONTOUR is intended to deliver heat in the near infra-red 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 BioPhotas Celluma CONTOUR 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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510(k) Summary
(K232977)

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

Submitter's Name: BioPhotas, Inc.
Submitter's Contact: Patrick Johnson
Submitter's Address: 15501 Red Hill Ave., #200, Tustin, CA 92780
Phone: 714-978-0080
Email: patrick.johnson@biophotas.com

Device Classification Information :

Device Trade Name: Biophotas Celluma CONTOUR
Device Common name: Low Level Light System for Aesthetic Use
Regulation Number: 21 CFR 878.5400
21 CFR 890.5500
21 CFR 878.4810
Regulatory Class: Class II
Product Code: OLI, ILY, OHS
Classification Panel: General & Plastic Surgery

Predicate device(s) **Contour Light CL-100 device (K202955)**
Biophotas Celluma ^{3} (K171323).
Biophotas Celluma (K131113).

Date Prepared: November 14th, 2023.

Device Description

The BioPhotas Celluma CONTOUR is a Light emitting diode (LED) system that applies 640nm light for the purpose of reducing the circumference of the hips, waist, and thighs for aesthetic benefit, 640nm and 880nm light for the purpose of temporarily elevating skin temperature and 640nm and 880nm light for the purpose of treating full face wrinkles.

The BioPhotas Celluma CONTOUR comprises of a flexible, 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 foam covering that holds a transparent polycarbonate cover recessed within it. The biocompatibility nature of allows the device to be placed in contact with the skin.
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 "Contour" "wrinkles" and "Aches and Pains", 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.

Indication for Use statement

The BIOPHOTAS Celluma CONTOUR is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.

The BIOPHOTAS Celluma CONTOUR is intended to deliver heat in the near infra-red 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 BioPhotas CONTOUR is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full-face wrinkles.

Technological characteristics:

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

Property	Proposed device. Biophotas Celluma CONTOUR	Contour Light CL-100	Biophotas Celluma [3]	Biophotas Celluma	Significant difference
Device Manufacturer	Biophotas Inc	Contour Research, LLC	Biophotas Inc	Biophotas Inc	na
Device Trade Name	Biophotas Celluma CONTOUR	Contour Light CL-100	Biophotas Celluma[3]	Biophotas Celluma	na
510(K) Number	K232977	K202955	K171323	K131113	na
Device Product Code - Classification name	OLI, ILY, OHS	OLI, ILY	OHS	ILY	Identical to both predicates
Regulation Number	21 CFR 878.5400 21 CFR 890.5500 21 CFR 878.4810	21 CFR 878.5400 21 CFR 890.5500	21 CFR 878.4810	21 CFR 890.5500	Identical
Device Classification	Class II	Class II	Class II	Class II	Identical
Rx/OTC	OTC	RX	OTC	OTC	Different
Intended use and Indications	The BIOPHOTAS Celluma CONTOUR is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. The BIOPHOTAS Celluma CONTOUR is intended to deliver heat in the near infra-red spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary	The Contour Light CL-100 is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. The Contour Light CL-100 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	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.	The BIOPHOTAS Celluma is intended to deliver heat in the near infra-red 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.	Identical

Property	Proposed device. Biophotas Celluma CONTOUR	Contour Light CL-100	Biophotas Celluma 3	Biophotas Celluma	Significant difference
	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 BioPhotas Celluma CONTOUR is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full-face wrinkles.	minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.			
Non invasive	Yes	Yes	Yes	Yes	Identical
Energy Type	Light emitting diodes	Light emitting diodes	Light emitting diodes	Light emitting diodes	Identical
Peak Wavelength (FWHM)	Red: 640nm+/-25nm (615-665nm) 880nm +/50nm (830nm – 930nm)	635nm 880nm	Red: 640nm+/-25nm NIR: 880nm+/-50nm	Red: 640nm+/-25nm NIR: 880nm+/-50nm	Proposed device is within the bandwidth of predicates
Intensity (mW/cm^2)	640nm - 4.2mW/cm^2 880nm - 0.7mW/cm^2	635nm - 4.1mW/cm^2 880nm – 0.5mW/cm^2	640nm - 4.2 mW/cm^2 880nm 0.7mW/cm2	640nm - 4.2 mW/cm^2 880nm 0.7mW/cm2	Equivalent
Treatment protocol (Treatment time)	30 minutes	30 minutes	30 minutes	30 minutes	Identical
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 timer and software to control treatment duration	Identical
Electrical power	90 – 264 VAC	85-264 VAC	90 – 264 VAC	90 – 264 VAC	Equivalent

Similarities and Differences between the subject and predicate device:

Key Similarities

Please note: The proposed device Biophotas Celluma CONTOUR is technologically similar to the previously cleared Biophotas Celluma devices (K122237, K131113, K152280, K171323 and K211038). In this application, the software of the device has been modified to allow a red light only mode "Contour".

Indications for use

The proposed device, BioPhotas Celluma CONTOUR and Contour Light CL-100 device (K202955) use visible red light and are indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.

The proposed device and predicate are both intended to be used in the hip, waist, and thigh area.

Both devices are 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 proposed BioPhotas Celluma CONTOUR is identical to the Biophotas Celluma^3 in that they are 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.

The proposed BioPhotas Celluma CONTOUR is identical to the Biophotas Celluma (K131113) in that both devices are 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.

Light technology and wavelengths produced.

The predicate device Contour Light CL-100 (K202955) Celluma^3 (K171323) Celluma (K131113) and Biophotas Celluma CONTOUR utilize Light emitting diodes as a light source and have equivalent wavebands of red light (615-665nm and 635nm) and 880nm (830nm – 930nm) and have equivalent output intensities.

Treatment parameters

BioPhotas Celluma CONTOUR and Contour Light CL-100 device (K202955) have identical treatment times and deliver equivalent doses of light over the 30 minutes treatment. BioPhotas Celluma CONTOUR in full face wrinkle mode is identical to Biophotas Celluma^3 (K171323) in terms of identical treatment times and equivalent doses of light over the 30 minutes treatment.

BioPhotas Celluma CONTOUR in aches and pain mode is identical to Biophotas Celluma (K131113) in terms of identical treatment times and equivalent doses of light over the 30 minutes treatment.

Differences

The only difference between the Biophotas Celluma CONTOUR and predicate device Contour Light CL-100 K202955 is that the Biophotas CONTOUR is available "Over the counter" (OTC) whereas the Contour Light CL-100 K202955 is only available as prescriptive (Rx). This difference has been mitigated by Biophotas INC through the provision of a labeling comprehension study to demonstrate that the Biophotas CONTOUR can be used successfully by lay persons.

Electrical safety and safety standards

To demonstrate safety and effectiveness of the Biophotas Celluma CONTOUR and to demonstrate substantial equivalence to the predicate devices, Biophotas Inc has completed several non-clinical performance tests. Biophotas Celluma CONTOUR 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 CONTOUR successfully passed testing per internal verification/validation requirements and national/international standards illustrated below:

- Electrical safety per IEC 60601-1: ed 3.1
- EMC testing per IEC 60601-1-2: ed 4
- Software validation per IEC 62304:2015 and the FDA Guidance document.

The Biophotas Celluma CONTOUR and the predicate device have satisfied product safety testing to the IEC 60601-1 standard, and the electromagnetic safety testing to the IEC 60601-1-2 standard.

Other Non-Clinical Performance testing

To demonstrate safety and effectiveness and substantial equivalence the Biophotas Celluma CONTOUR system has undergone several non-clinical performance tests in line with recognized standards in terms of general requirements, biocompatibility, labeling, and software.
The following non-clinical performance data is provided in support of the substantial equivalence determination.

Biocompatibility

The hardware of the Biophotas Celluma CONTOURis identical to the previously cleared versions (K122237, K131113, K152280, K171323 and K211038) in terms of the material, manufacturing,

and tissue contact type and duration. There is no change in biocompatibility since the previously cleared versions.

Software verification and validation testing

In accordance with IEC 62304: 2015 Medical device Software – software life cycle process Biophotas Inc has allocated a software safety classification of Class A for the 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.

Labeling and label comprehension

The Biophotas Celluma CONTOUR has been assessed against IEC 62366:2015 Medical devices Application of usability engineering to medical devices.
A usability comprehension study was conducted with 24 test subjects. Each test subject was provided with the product packaging and the User's Manual and device and allowed to read the labeling provided and interact with the product.
Following the subject's review of the User Manual, packaging, and the device the subject was asked a series of questions to address comprehension and understanding of the User Manual.

No new use errors, hazards, hazardous situations, or hazard-related use scenarios were discovered. Improvement of the user interface design as it relates to safety was deemed unnecessary.

Clinical performance testing

No Clinical performance data was included in the submission.

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 non-clinical performance testing 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. Therefore, the Biophotas CONTOUR as designed, and manufactured, has been demonstrated to be substantially equivalent to the referenced predicate Contour Light CL-100 K202955.

Biophotas has demonstrated that its CONTOUR device (K232977) as designed, and manufactured has the same intended use as the predicate devices, employs identical technological characteristics and is as safe, and as effective as the legally marketed predicates Contour Light CL-100 (K202955) and Biophotas Celluma ^{3} (K171323) and (K131113).