



JAN 15 2014

**Traditional 510(k) Summary**

As required in 21CFR807.92, we hereby submit this 510(k) Summary:

**510(k) owner's name, address, phone, fax, contact person and prep date**

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

Phone: (714) 838 – 1956

Fax: (949) 606 – 8191

The contact person is Mr. Shepard G. Bentley, RAC

510(k) preparation date: 18 March, 2013

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

Trade Name and Proprietary Name: BioPhotas Celluma®

Common Name: Infrared Lamp

Classification Name: Lamp Infrared, Therapeutic Heating (ILY)

**Predicate Device:**

The legally marketed predicate for the BioPhotas Celluma® is:

**K122237**, BioPhotas LifeLight®

**Device Description:**

The BioPhotas Celluma® is a therapeutic device using wavelengths of polychromatic energy produced by super-luminous LEDs (light emitting diodes) to treat a variety of skin and body conditions. It is a pain-free means to address a variety of musculoskeletal concerns. The Celluma® spectrum 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; promotion of relaxation of muscle tissue; and to temporarily increase local blood circulation. The blue light spectrum is intended to reduce mild to moderate acne vulgaris. Use of the combination of blue, red and near infrared regions of the spectrum is intended to emit energy to treat various conditions, specifically indicated to treat mild to moderate inflammatory acne vulgaris.



**Device Identification and Characteristics:** The BioPhotas Celluma® is a portable, AC-powered, software operated device intended for use on areas of the body such as the back, face, knees or other areas where the therapeutic light may be beneficial. Drawing electrical energy through an AC power adaptor to a lightweight, flame-retardant plastic user interface console that connects by a cable to a flexible panel within which is mounted an array of LEDs which provide red light (640 nm) and near IR (880 nm) wavelengths necessary, the Celluma® provides topical heating to elevate tissue temperature for the temporary relief of minor muscle and joint pain, stiffness, minor arthritis pain or muscle spasms and to provide a temporary increase in local blood circulation.

Blue LEDs, adjacent to the other LEDs, mounted within the flexible panel provide blue spectrum light (463 nm) intended to reduce mild to moderate inflammatory acne vulgaris.

The flexible panel is designed to conform to the contour of the treatment site providing for ease of use for sites that may be difficult to reach for larger, more cumbersome devices. The patient-facing surface of the panel may contact the tissue of the patient, and is therefore composed of biocompatible Poron material.

**Environment of Use:** End users of the device are expected to include the following:

- Home Use – individuals suffering from various conditions as a result of aging, disease and/or trauma
- Medical professionals:
  - Dermatologists
  - Primary Care Physicians
  - Chiropractors
  - Physicians Assistants
- Medical Service Providers:
  - Spa
  - Nail Technicians and Estheticians
  - Massage Therapists
  - Physical Therapists

**Usability of the Device:** BioPhotas has performed a Usability Study to ensure the understanding of the proper use as well as any risks of misuse of the Celluma® by the public as an over-the-counter medical device product. The company undertook to study the selection for use of the device by a random population of prospective users to ensure adequate understanding of the proper uses of the device, specifically by means of a human factors/comprehension self-selection study. The study data show that the device design essentially mitigates anticipated risks of misuse and misunderstanding of the instructions for use.



**Nonclinical Testing:** The subject device has been tested for electrical and mechanical product safety to the IEC 60601-1 standard (2<sup>nd</sup> Edition) and electromagnetic compatibility to the IEC 60601-1-2 standard, and passed the testing without any failure. Furthermore, the subject device has been tested for biocompatibility to the applicable parts of the ISO 10993 standard, and has passed the testing without any failure. Finally, the software that has been developed for the subject device has been fully validated per FDA requirements for software validation. These test results serve to confirm that the Celluma does not raise any new issues of safety or effectiveness.

End of 510(k) Summary



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

Biophotas  
Mr. Shepard G. Bentley, RAC  
Consultant  
28241 Crown Valley Parkway, Suite 510(k)  
Laguna Niguel, California 92677

January 15, 2014

Re: K131113  
Trade/Device Name: BioPhotas Celluma®  
Regulation Number: 21 CFR 890.5500  
Regulation Name: Infrared lamp  
Regulatory Class: Class II  
Product Code: ILY, GEX  
Dated: December 14, 2013  
Received: December 17, 2013

Dear Mr. Bentley:

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

Page 2 – Mr. Shepard G. Bentley, RAC

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

**Joshua C. Nipper -S**

For  
Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



**Indications for Use**

*INDICATIONS FOR USE STATEMENT*

510(k) Number (if known): K131113

Device Name: Biophotas Celluma®

**Indications for Use:**

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.

Prescription Use         
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Neil R Ogden, SA ence of CDRH, Office of Device Evaluation (ODE)  
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(Division Sign-Off) for BSA

Division of Surgical Devices

510(k) Number K131113