June 29, 2021

Biophotas INC
Patrick Johnson
CEO
1000 E. Howell Ave.
Ste A
Anaheim, California 92805

Re: K211038
Trade/Device Name: Biophotas Celluma RESTORE
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: March 31, 2021
Received: April 7, 2021

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 (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,

Purva Pandya
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)*
K211038

Device Name
Biophotas Celluma RESTORE

Indications for Use *(Describe)*
The BioPhotas Celluma RESTORE system is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood- Hamilton Classifications of IIa - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV.

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 K211038

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: 1000 E. Howell Ave., Ste A, Anaheim, CA 92805
Phone: 714-978-0080
Fax: 714 978 0085

Date Prepared: June 24th 2021.

Device Trade Name: Biophotas Celluma RESTORE

Device Common name: Lamp, non-heating, for promotion of hair growth

Device Classification Information:

Regulation Number	Device Classification name	Device Class	Product Code	Classification Panel	Type
21 CFR 890.5500	Infrared lamp per 21 CFR 890.5500	Class 2	OAP	General & Plastic Surgery	Traditional 510 (k)

Device Description

The BioPhotas Celluma RESTORE system uses visible red light (640nm) and is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood- Hamilton Classifications of IIa - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV.

In addition, the Biophotas Celluma RESTORE 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 as previously cleared under K122237, K131113, K152280 and K171323.

The system 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. 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 “Hair”, “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.

Indications/Intended Use

The BioPhotas Celluma RESTORE is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood- Hamilton Classifications of IIa - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in

females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick Skin Types I - IV.

Technological characteristics:

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

Property	Proposed device. RESTORE	K173729 Revian Red	K162782 iHelmet Hair Growth System	Significant difference
Device Manufacturer	Biophotas Inc	PhotonMD, Inc	Slinph Technologies Co., LTD	na
Device Trade Name	Biophotas Celluma RESTORE	Revian Red	iHelmet Hair Growth System, Model: LTD200S	na
510(K) Number	K211038	K173729	K162782	na
Device Product Code - Classification name	OAP	OAP	OAP	Identical
Device Classification	Class II	Class II	Class II	Identical
Rx/OTC	OTC	OTC	OTC	Identical
Intended use and Indications	The BioPhotas Celluma RESTORE is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick SkinTypes I - IV.	Revian Red is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa - V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig-Savin Scale I-1 to I-4, II-1, II-2 or frontal patterns of hair loss; both with Fitzpatrick SkinTypes I - IV.	iHelmet Hair Growth System (Model: LTD200S) is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications I - II, in males with androgenetic alopecia who have Norwood Hamilton Classifications IIa - V and for both, Fitzpatrick Classification of Skin Phototypes of I - IV.	Identical to K173729

Property	Proposed device RESTORE	K173729 Revian Red	K162782 iHelmet Hair Growth System	Significant difference
Intended Location of Use	Scalp	Scalp	Scalp	Identical to K173729
Treatment area	Active treatment area 475 cm^2	-	424.93 cm2 Mathematically Max. derived	Identical to K162782
Energy Type	Light emitting diodes	Light emitting diodes	Laser diodes	Identical to K173729
Peak Wavelength (FWHM)	Red: 640nm+/-25nm (615-665nm)	620 - 660 nm	650+/-10nm (640-660nm)	Proposed device is within the bandwidth of K173729
Intensity (mW/cm^2)	2.77 mW/cm^2	Not publicly available	2.3533 mW/cm^2 Mathematically Max. derived	Substantially equivalent to K162782
Treatment Dose (J/cm^2)	4.98 J/cm^2	Not publicly available	4.9420 J/ cm^2 Mathematically Max. derived	Substantially equivalent to K162782
Treatment protocol (Treatment time)	Each Treatment:30 min Total Treatment: every other day, for 16 weeks	Every day 10 minutes for 26 weeks	Each Treatment: 20-35 min Total Treatment: every other day, for 16 weeks	Substantially equivalent to K162782
Total treatment time.	1680 minutes	1820 minutes	1680 minutes	Substantially equivalent
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	Identical
Electrical power	110-120V	Uses 110 – 120 V rechargeable. Li Polymer battery	110 -120V	Substantially equivalent

Property	Proposed device RESTORE	K173729 Revian Red	K162782 iHelmet Hair Growth System	Significant difference
Electrical Safety	60601-1:2012 60601-1-2:2014	60601-1 60601-1-2	IEC 60601-1 and IEC 60601-1-2 IEC 60825-1	Identical
Biocompatibility	All patient contacting materials comply with ISO 10993-5, ISO 10993-10	All patient contacting materials are complied with ISO 10993-5, ISO 10993-10	All patient contacting materials are complied with ISO 10993-5, ISO 10993-10	Identical

Similarities and Differences between the subject and predicate device:

Key Similarities

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

Indications for use

The proposed device, BioPhotas Celluma RESTORE and Revian Red System K173729 use visible red light and are indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications I-1 to I-4, II-1, II-2 or frontal patterns of hair loss, and in males with androgenetic alopecia who have Norwood Hamilton Classifications IIa - V and for both, Fitzpatrick Classification of Skin Phototypes of I - IV.

The proposed device and both predicates K173729 Revian Red and K162782 iHelmet Hair Growth System are intended to treat the scalp.

Light technology and wavelengths produced.

The proposed device and K173729 Revian Red utilize Light emitting diodes as a light source and have equivalent wavebands of red light. (615-665nm and 620-660nm).

Treatment parameters

The proposed device, BioPhotas RESTORE, has a total treatment time that is within 93% of the predicate device K173729 Revian Red and identical to K162782 iHelmet Hair Growth System.

Electrical safety and safety standards

To demonstrate safety and effectiveness of the Biophotas Celluma RESTORE and to demonstrate substantial equivalence to the predicate devices, Biophotas Inc has completed several non-clinical performance tests. The RESTORE 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 RESTORE 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 RESTORE, 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.

Since the Biophotas Celluma does not utilize laser diodes it is exempt from testing to IEC 60825-1 Safety of laser products - Part 1: Equipment classification and requirements.

Differences

There are no key differences between the Biophotas Celluma RESTORE and predicate device Revian RED K173729.

Other Non-Clinical Performance testing

To demonstrate safety and effectiveness and substantial equivalence the Biophotas Celluma RESTORE system has undergone a number of 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.

Biocompatibility
The Biophotas Celluma RESTORE systems hardware is identical to the previously cleared versions (K122237, K131113, K152280 and K171323) in terms of the material, manufacturing, and tissue contact type and duration. There is no change in biocompatibility since the previously cleared versions. Therefore, biocompatibility test data is not needed in this submission.

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 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.

Labelling

The Biophotas Celluma RESTORE has been assessed against IEC 62366:2015 Medical devices Application of usability engineering to medical devices.

A usability and label comprehension study was conducted with 25 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. Further improvement of the user interface design as it relates to safety was deemed unnecessary and there were no suggested revisions to the version of the user manual tested.

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. 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 has demonstrated that the RESTORE device has the same intended use as the predicate device, employs identical technological characteristics and is as safe and effective as the predicate K173729 Revian Red.

Therefore, the Biophotas RESTORE, as designed, and manufactured, has been demonstrated to be substantially equivalent to the referenced predicate Revian Red System K173729.