May 19, 2021

Contour Research, LLC
℅ Shepard Bentley
Consultant
Bentley Biomedical Consulting, LLC
28241 Crown Valley Parkway, Suite 510(k)
Laguna Niguel, California 92677

Re: K202955
Trade/Device Name: Contour Light CL-100
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
878.5650
Regulatory Class: Class II
Product Code: OLI
Dated: September 29, 2020
Received: September 30, 2020

Dear Shepard 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. 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 post-marketing 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: 06/30/2020

See PRA Statement below.

510(k) Number (*if known*)
K202955

Device Name

Contour Light CL-100

Indications for Use (*Describe*)

The Contour Light CL-100 device 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 device is indicated to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, and pain and stiffness associated with arthritis, for promoting relaxation of the muscle tissue, and to temporarily increase local blood circulation.

Type of Use (Select one or both, as applicable)

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over -The-Counter Use (Part 21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies on to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Contour Light CL-100

1. Submission Sponsor

Contour Research, LLC
200 Virginia Street, #8
Reno, NV 89501

Doug Dreier
CEO
Cell: 949 939 7584
Office: 855 932 6686

doug@contourlight.com

2. Submission Correspondent

Shepard G. Bentley, RAC
28241 Crown Valley Parkway
Suite 510(k)
Laguna Niguel, CA 92677
949 374 9187
sbentley@bentleybiomed.com

3. Date Prepared

29 SEPT 2020

4. Device Identification

Trade or Proprietary Name:	Contour Light CL-100
Common or Usual Name:	Low Level Light System for Aesthetic Use Infrared Lamp
Regulation Number:	21 CFR §878.5400 21 CFR §890.5500
Product Codes:	OLI, ILY
Class:	II

Legally Marketed Predicate Device(s)

Device name:	Strawberry and Cream Low Level Laser system
510(k) number:	K130341
Manufacturer:	Laser Lipo Ltd

Device name:	Zerona Z6 OTC
510(k) number:	K143007
Manufacturer:	Erchonia Corporation

Device name:	BioPhotas LifeLight
510(k) number:	K122237
Manufacturer:	BioPhotas, Inc.

5. Indication for Use Statement

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 minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation.

6. Device Description

The Contour Light CL-100 is a low level laser (red light LED) system that applies 635nm light for the purpose of reducing the circumference of the hips, waist and thighs for aesthetic benefit, and 635nm and 880nm light for the purpose of temporarily elevating skin temperature.

The Contour Research, LLC Contour Light CL-100 device applies a light emitting diode (LED) technology, and is used to perform red light LED-based circumferential reduction of the hips, thighs and waist in adults, or red light and IR LEDs for temporary elevation of skin temperature, within a treatment time of 30 minutes. The device is comprised of a panel of LEDs that is adjustable to conform generally to the outer dimensions of the individual being treated, a software controlled console that is used to select and maintain the application of the LED light, a power adaptor, and cables that connect to the energy source. The device is powered by connecting it to an 85-264 VAC, at 3 amps, 47-63 Hz. power source.

Operator Controls:

The device is controlled by an operator. The operator controls include additional safety measures including an EMERGENCY STOP button. If activated, the Emergency Stop halts the program and shuts off the power that is delivering the LED light to the individual being treated.

7. Substantial Equivalence Discussion

The following table compares the Contour Light CL-100 with the predicate devices.

Table 5A – Comparison of Characteristics

Attribute	Subject Device	Predicate Device	Predicate Device	Predicate Device	Comparison
Manufacturer	Contour Research, LLC	Lipo Laser Ltd	Erchonia Corporation	BioPhotas, Inc.	-
Trade Name	Contour Light CL-100	Strawberry and Cream Low Level Laser system	Zerona Z6 OTC	LifeLight	-
510(k) Number	K202955	K130341	K143007	K122237	-
Product Code	OLI, ILY	OLI	OLI	ILY	Comparable
Regulation Number	§878.5400, §890.5500	§878.5400	§878.5400	§890.5500	Comparable
Clinical/Design Features					
Indications for Use	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 device is intended to deliver heat in the IR spectrum to provide topical	The low level laser model Strawberry and Strawberry and Cream can be used for the non-invasive temporary reduction in waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use.	The Zerona® Z6 OTC device is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.	The BioPhotas LifeLight 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	The subject device indication for use is essentially identical to the first indication for use of the Zerona® predicate device, and essentially identical to the first indication for use of the IR predicate device (LifeLight).

	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.			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 the appearance of mild to moderate acne vulgaris.	
Non-invasive?	Yes	Yes	Yes	Yes	Same
Lamp Specifications					
Wavelength	635nm 880nm	660nm	635nm	464nm, 640nm, 880nm	Similar
Output Intensity/Irradiance (mW/cm^2)	4.1mW/cm^2 0.5mW/cm^2	5-10mW/cm^2	<1mW/cm^2	10.9 mW/cm^2 for 465nm	Similar
Recommended Treatment Time (Minutes)	30 minutes	10 – 20 minutes	0-9.9 minutes	30 minutes	Similar

8. Non-Clinical Performance Data

To demonstrate the safety and effectiveness of Contour Light CL-100 device and to show substantial equivalence to the predicate devices, Contour Research, LLC completed the following non-clinical tests. Results confirm that the design and performance specifications for the device are met. Reports as applicable are filed with their respective sections. The Contour Light CL-100 passed test requirements as identified below:

- Electrical safety testing per IEC 60601-1 – Passed
- Electromagnetic Disturbance testing per IEC 60601-1-2 – Passed
- Software verification and validation per IEC 62304/FDA Guidance – Completed.
- Shelf Life Testing – Supports useful device life of 5 years
- Internal Design Validation Testing

9. Clinical Performance Data

None submitted.

10. Conclusions

The Contour Research, LLC Contour Light CL-100 device has an intended use with red light that is essentially identical to the K130341 and K143007 devices' first intended use, and it also has an intended use that is essentially identical to the K122237 predicate device's intended use with infrared light. The proposed device and its predicates share similar technological characteristics for achieving the desired effects, and the minor differences in technological characteristics do not raise new types of questions regarding safety and effectiveness for its indications for use. Performance testing has demonstrated the Contour Light CL-100 is as safe and effective as the predicate devices. Therefore, the Contour Light CL-100 device is substantially equivalent to the predicate devices.