



February 13, 2026

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

Re: K243854

Trade/Device Name: Contour Light (CL-100)
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
Regulatory Class: Class II
Product Code: OLI
Dated: June 23, 2025
Received: January 16, 2026

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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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

Digitally signed by
TANISHA L. HITHE -S
Date: 2026.02.13
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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

Indications for Use

510(k) Number (if known)
K243854

Device Name
Contour Light (CL-100)

Indications for Use (Describe)

The Contour Light CL-100 device is intended 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)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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Contour Research, LLC

510(k) Summary

#K243854

Applicant Name: Contour Research, LLC
Applicant Address: 200 Virginia Street #8, Reno, NV 89501
Applicant Contact Telephone: (949) 939 – 7584
Applicant Contact: Mr. Douglas Dreier
Applicant Contact Email: doug@contourlight.com

Correspondent Name: Bentley Biomedical Consulting, LLC
Correspondent Address: 28241 Crown Valley Parkway, Suite 510(k), Laguna Niguel, CA 92677
Correspondent Telephone: (949) 374 – 9187
Correspondent Contact: Mr. Shepard G. Bentley, RAC
Correspondent Contact Email: sbentley@bentleybiomed.com

Device Trade Name: Contour Light (CL-100)
Common Name: Low level laser system for aesthetic use
Classification Name: Fat Reducing Low Level Laser
Regulation Number(s): §878.5400; §890.5500
Product Code(s): OLI, ILY

Predicate Number: K202955
Predicate Trade Name: Contour Light CL-100
Preparation date: 2/11/2026

Device Description Summary:

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 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 medical-grade power adaptor, and cables that connect to the energy source.

Intended Use / Indications for Use:

The Contour Light CL-100 device is intended 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, or promoting relaxation of the muscle tissue, and to temporarily increase local blood circulation.

Contour Research, LLC

Indications for Use Comparison

Subject Device K243854	Predicate Device K202955	Comparison
<p>The Contour Light CL-100 device is intended for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.</p> <p>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.</p>	<p>The Contour Light CL-100 device is intended for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.</p> <p>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.</p>	Same
OTC	Rx	The predicate device is indicated for Rx use only.

Technological Comparison

Attribute	Subject Device K243854	Predicate Device K202955	Comparison
Fat reducing wavelength	635nm	635nm	Same
Pain relief wavelength	880nm	880nm	Same
Output Intensity/ Irradiance (mW/cm ²)	70 mW/cm ²	70 mW/cm ²	Same
Recommended Treatment Time	30 minutes	30 minutes	Same
Non-invasive?	Yes	Yes	Same

Contour Research, LLC

Non-Clinical and/or Clinical Tests Summary

The subject device has undergone extensive human factors & usability engineering testing to identify representative users from its intended OTC market. In close consultation with clinically trained professionals, a Health Assessment Questionnaire (HAQ) was developed for the purpose of screening prospective users. During this stage, the sponsor learned that indeed a few prospective users would opt to use the device although contraindicated and therefore revised the labeling for clarity. Finally, the study confirmed with 15 users that the CL-100 instructions were sufficiently clear to achieve the desired effect of the intended use. These results were confirmed with a graded examination of the users, which all passed.

Conclusions

The Contour Research, LLC Contour Light CL-100 device has an intended use with red light that is identical to the original Contour Light CL-100, except for offering it as an Over-The-Counter product. The device has a safe history of use, and data obtained from usability studies provide a conclusion that the use of the Contour Light CL-100 is substantially equivalent to the predicate device.