



December 15, 2025

Erchonia Corporation  
Travis Sammons  
Clinical Affairs Manager  
112 Southchase Blvd.  
Fountain Inn, South Carolina 29644

Re: K252574

Trade/Device Name: Erchonia CLX (Model # CFL)  
Regulation Number: 21 CFR 878.5400  
Regulation Name: Low Level Laser System For Aesthetic Use  
Regulatory Class: Class II  
Product Code: OLI  
Dated: August 8, 2025  
Received: August 14, 2025

Dear Travis Sammons:

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.

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](mailto: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: 2025.12.15  
15:45:45 -05'00'

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)  
K252574

Device Name  
Erchonia CLX (Model # CFL)

Indications for Use (Describe)

The Erchonia CLX is indicated for use as a non-invasive dermatological aesthetic treatment for improving the appearance of submental fat.

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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**510(k) Summary**  
**K252574**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

**Owner Information**

**Name and Address of Sponsor / Manufacturer**

Erchonia Corporation  
112 Southchase Blvd.  
Fountain Inn, SC 29644  
Telephone: 321-473-1251  
Fax: 321-473-1608

**Establishment Registration Number**

2032513

**Name and Address of Official Correspondent**

Erchonia Corporation  
112 Southchase Blvd.  
Fountain Inn, SC 29644  
Contact: Travis Sammons  
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Fax: 321-473-1608  
Email: tsammons@erchonia.com

**Date Prepared**

12/14/2025

**Device Information**

Trade Name: Erchonia CLX (Model # CFL)  
Common Name: Fat Reducing Low Level Laser  
Classification Name: Low level laser system for aesthetic use. (21 CFR 878.5400)  
Classification: Class II  
Panel: General & Plastic Surgery  
Product Code: OLI

**Predicate Devices**

Erchonia Emerald cleared under K192544  
Erchonia Violet ZERONA® Z8 cleared under K243811

**Device Description**

The Erchonia® CLX Laser is intended for patients seeking a noninvasive, non-thermal alternative for fat reduction in the submental (chin) area, allowing them to resume daily activities without the downtime associated with surgery, pain, wounds, or compression garments. The CLX Laser delivers non-thermal, low-level laser energy that induces temporary pore in adipocytes, allowing fat and lipids to be released into the interstitial space, where they are naturally processed by the body's detoxification pathways. The CLX is built on the proven clinical foundation of previous Erchonia low-level laser devices, including the Violet ZERONA® Z8, ZERONA®, ZERONA®-AD, ZERONA® Z6 OTC, Verju, and Emerald.

The CLX Laser is a handheld device that incorporates two semiconductor diodes emitting green (520 nm ±10 nm) and violet (405 nm ±10 nm) light. Both diodes emit non-thermal light at 7.5 mW (±0.50 mW)

output, classified as Class 2 laser sources under IEC. The non-thermal light output from each diode is collected and directed through a proprietary, patented lens and then shaped into a uniform line beam by an internal refractor. The device is powered by a rechargeable internal battery and supplied with an inductive charging base driven by an external Class II medical-grade power supply. The device's control software, embedded in a RAM chip on the printed circuit board, manages all user interface operations. The graphical user interface (GUI) and touch-screen prompts allow for intuitive device control. The software has been developed and validated in accordance with the applicable FDA and ISO requirements for software design and validation.

**Intended Use**

Low level laser system for aesthetic use

**Indications for Use**

The Erchonia CLX is indicated for use as a non-invasive dermatological aesthetic treatment for improving the appearance of submental fat.

**Device Comparison Table**

Device	Erchonia CLX (Model # CFL)	Erchonia Emerald	Erchonia Violet ZERONA® Z8	Differences
<b>510(k) #</b>	K252574	K192544	K243811	
	Subject Device	Primary Predicate Device	Secondary Predicate Device	
<b>Manufacturer</b>	Erchonia Corp	Erchonia Corp	Erchonia Corp	None
<b>Laser Power Output</b>	Green: 7.5mW ± .50mW Violet: 7.5mW ± .50mW	16mW ± 1.25mW	23mW ± 2mW	Difference supported by clinical performance testing. <i>See Performance Testing – Clinical.</i>
<b>Wavelength</b>	Green: 520nm ± 10 nm Violet: 405nm ± 10 nm	Green: 532nm ± 10 nm	Violet: 405nm ± 10 nm	The subject device utilizes similar green and violet wavelengths as the predicate devices. Clinical study completed to support the combination of wavelengths in the subject device. <i>See Performance Testing – Clinical</i>
<b>Total Treatment Time Applied per Area</b>	15 minutes	0-30 minutes	20 minutes	Same as the primary predicate
<b>Treatment Frequency</b>	2 x week, 4 weeks	3 x week, 4 weeks	3 x week, 2 weeks	Similar to predicate devices
<b>Number of Laser Diodes</b>	2	10	8	The Erchonia Emerald and Erchonia Violet ZERONA® Z8 are intended for treatment of larger anatomical regions (waist, hips, and thighs). In contrast, the Erchonia CLX is specifically designed for targeted application to the smaller submental area and, as a result, requires fewer laser diodes to deliver treatment effectively.
<b>Total Joules per Treated Region</b>	13.5 Joules	14.4 Joules	13.8 Joules	Similar to predicate devices. Calculated from power and treatment time.
<b>Energy Source</b>	Diode laser energy collected then dispersed via line generating optics	Diode laser energy collected then dispersed via line generating optics	Diode laser energy collected then dispersed via line generating optics	None
<b>User Interface</b>	Touchscreen	Touchscreen	Touchscreen	None
<b>Intended Use</b>	Low level laser system for aesthetic use	Low level laser system for aesthetic use	Low level laser system for aesthetic use	None
<b>Indication for Use</b>	The Erchonia CLX is indicated for use as a non-invasive dermatological aesthetic treatment for improving the appearance of submental fat.	Erchonia® Emerald (Model# SHL) Laser is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference in individuals with a Body Mass Index (BMI) up to 40 kg/m <sup>2</sup>	The ZERONA® VZ8 is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference.	Difference supported by clinical performance testing. <i>See Performance Testing – Clinical.</i>
<b>Product Code</b>	OLI	OLI	OLI	None

### **Comparison of Technological Characteristics with the Predicate Devices**

The Erchonia CLX and the predicate devices (Erchonia Emerald, K192544 and Erchonia Violet ZERONA® Z8, K243811) share the same intended use, core Erchonia low-level laser technology, mechanism of action, and energy source. Specifically, all devices utilize diode laser energy collected then dispersed via line-generating optics to disrupt adipocytes and promote the release of fat without damaging surrounding tissues.

The CLX device emits green and violet wavelengths, identical to those of the predicate devices, ensuring equivalent photochemical interactions with adipocytes. The CLX contains fewer diodes due to its focused indication for the submental area, as compared to the predicate devices which target larger anatomical regions. New clinical data demonstrate the CLX is safe and effective for this more targeted application. Importantly, the subject device and the predicate devices share similar Total Treatment Time Applied per Area, Treatment Frequency, and Total Joules per Treated Region, further supporting substantial equivalence.

### **Performance Standards**

The Erchonia® CLX (Model # CFL) complies with FDA's performance standards for light-emitting products (21CFR 1040.10 and 21 CFR 1040.11 by Laser Notice #50).

### **Sterilization and Shelf-Life**

The device is not provided sterile.

The device is not affected by shelf-life because it is an electro-mechanical device that is not sterile and whose components will not degrade over time while simply sitting in storage prior to initial use.

### **Performance Testing-Animal**

No animal testing conducted

### **Performance Testing-Clinical**

**BACKGROUND:** The purpose of this clinical study was to evaluate the efficacy of the Erchonia® CLX Laser in providing noninvasive fat reduction in the submental area.

**STUDY DESIGN:** The study was a prospective open-label dual-center design with post-study independent blinded primary outcome analysis.

**SUBJECTS:** The primary intent-to-treat (ITT) analysis population comprised thirty (30) subjects. Subjects were healthy females aged 18 to 65 years who presented with visible fat bulges in the submental area and who subsequently satisfied all qualification criteria including agreeing to maintain body weight within  $\pm 5\%$  and to refrain from partaking in any other treatment to promote body contouring and/or weight loss during study participation. Subjects in the study ITT population were Caucasian (100%) females (100%) with an average age of 45.55 years and average BMI of 32.73 kg/m<sup>2</sup>.

**STUDY TREATMENT:** Subjects received eight (8) 15-minute treatments with the Erchonia® CLX to the submental region over four (4) consecutive weeks; two (2) procedures per week; each at least two days apart and performed at the test site. All subjects received active study treatment.

**STUDY RESULTS:** Primary efficacy outcome assessment involved blinded, de-coded and randomized post-study evaluation of before (Pre-Treatment) and after (Week 16 12-Weeks Post-Treatment Endpoint) subject digital photographs by three (3) Independent Blinded Evaluators. Attainment of primary efficacy outcome success was pre-established as the

proportion of accurately identified subject pre- and post-treatment photographs by at least two of the three (2 of 3) Independent Blinded Evaluators, with a clinically important outcome pre-defined as at least 2 of the 3 Blinded Independent Evaluators correctly identifying the order of a subject's Pre-Treatment and Week 16 12-WeeksPost-Treatment photographs for 80% or more of subjects (Responder Rate of  $\geq 80\%$ ). Responder Rate for the primary ITT subject population was 86.67% (26 of 30 subjects).

**ADVERSE EVENTS:** There were no study device- or treatment-related adverse events or other safety-related events reported or recorded throughout the course of this clinical study. Therefore, the application of the Erchonia® CLX for the intended indication and patient population did not raise any safety concerns.

**CONCLUSION:** These study results support the claim of the Erchonia® CLX as an effective non-invasive treatment to affect the appearance of fat in the submental area.

### **Biocompatibility**

Not applicable. The device does not come in contact with the skin or any other bodily tissue.

### **Risk Assessment**

The Erchonia® CLX Laser is acceptable in accordance with IEC 60601 and IEC 60825, by virtue of Engineering and third-party verification. All identified risks have been mitigated to ensure the lowest acceptable risk possible using the ISO 14971 standard framework.

### **Performance Data**

Safety and electromagnetic compatibility (EMC) testing was conducted on the Erchonia EVRL Laser, which shares the same platform as the Erchonia CLX. The Erchonia CLX and Erchonia EVRL devices share identical components, with the sole difference being the wavelength of emitted light. The CLX emits green and violet wavelengths, whereas the EVRL emits red and violet wavelengths. This variation in emission wavelength does not impact the safety or EMC characteristics of the device. Accordingly, the testing conducted under the following standards is directly applicable to the CLX:

- IEC 60601-1 (General Requirements for Basic Safety and Essential Performance)
- IEC 60601-1-6 (Usability)
- IEC 60601-1-11 (Home Use)
- IEC 60601-1-2 (EMC Requirements)
- IEC 60825-1 (Laser Safety)

### **Compliance with Voluntary Standards**

The Erchonia® CLX Laser complies with the following voluntary standards:

IEC 60601-1-2:2014+AMD1:2020 Edition 4.1

IEC 60601-1:2005+AMD1:2012+AMD2:2020 Edition 3.2

IEC 60601-1-11:2015+AMD1:2020 Edition 2.1

IEC 60825-1:2014 Edition 3.0

### **Conclusion**

In conclusion, the Erchonia CLX Laser shares the same or similar technological characteristics with the predicate devices Erchonia Emerald (K192544) and Erchonia Violet ZERONA Z8 (K243811), including wavelength, treatment frequency, total joules per treated region, energy source, and mechanism of action. Clinical data provided in this submission confirm that minor technological differences do not raise new concerns regarding safety or effectiveness and sufficiently support the intended use. Additionally, extensive research on Erchonia's green and violet wavelengths—analogueous to those used by the subject

device—has demonstrated their safety and effectiveness for non-invasive fat reduction under the OLI product code. Therefore, the Erchonia CLX Laser is substantially equivalent to the predicate devices and is safe and effective for its intended indication for use as a non-invasive dermatological aesthetic treatment for improving the appearance of submental fat.