



September 12, 2025

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

Re: K251843

Trade/Device Name: Erchonia EURL

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In
Dermatology

Regulatory Class: Class II

Product Code: OLP

Dated: May 9, 2025

Received: June 16, 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

TANISHA
L. HITHE -S

Digitally signed by
TANISHA L. HITHE -S
Date: 2025.09.12
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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)

K251843

Device Name

Erchonia EVRL

Indications for Use (Describe)

The Erchonia EVRL is intended to emit energy in the red and blue region of the spectrum, and is specifically indicated to treat mild to moderate acne.

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
K251843**

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: 888-242-0571
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
Telephone: 888-242-0571
Fax: 321-473-1608
Email: tsammons@erchonia.com

Date Prepared

09/08/2025

Device Information

Trade Name: Erchonia EVRL
Model#: EVRL
Common Name: Over-the-counter powered light based laser for acne
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification: Class II
Panel: General & Plastic Surgery
Product Code: OLP

Predicate Device

Primary Predicate
Trade Name: The Luminance RED Acne Device
510(k) Number: K220729
Product Code: OLP

Secondary Predicate

Trade Name: Acne Light Therapy Wand
510(k) Number: K160691
Product Code: OLP

Device Description

The Erchonia EVRL is a compact, handheld device designed to reduce the appearance of mild to moderate acne. It emits visible blue light at a 405nm wavelength and red light at 640nm, both with a ± 10 nm tolerance.

The EVRL device provides a non-thermal and non-contact treatment, designed for use approximately one to three inches from the skin without direct contact. It features an intuitive touchscreen interface with a preset acne treatment protocol, activated by a press-to-start button for ease of operation. A built-in visual countdown timer and audible treatment indicator “beep” assist the user during treatment, and the device automatically powers off upon completion of the treatment cycle. The wavelength and power settings are factory-set and cannot be modified by the user.

The Erchonia EVRL has been classified by the FDA as a Class II device. The testing of the Erchonia EVRL device includes functional performance, electrical, safety and component verification, in accordance with the FDA QS requirement. The software incorporated into the operation of the Erchonia EVRL complies with FDA and ISO Software Development and Validation regulations.

Intended Use

The Erchonia EVRL is intended to emit energy in the red and blue region of the spectrum, and is specifically indicated to treat mild to moderate acne

Comparison of Technological Characteristics with the Predicate Device(s)

The Erchonia EVRL is substantially equivalent to the primary and secondary predicate devices. It shares the same indications for use as the primary predicate device, the Luminance RED Acne Device. The EVRL incorporates technological characteristics that are identical or similar to those of the predicate devices, including handheld form, wavelength specifications, energy output (joules), light emission, light aperture size, and power source. There are no differences in technological characteristics that raise new questions of safety or effectiveness.

Table - Comparison of Technological Characteristics with the Predicate Device

Device	Erchonia EVRL (Model# EVRL)	The Luminance RED Acne Device	Acne Light Therapy Wand	Substantial Equivalence Remarks
510(k) #	K251843	K220729	K160691	N/A
Product Code	OLP	OLP	OLP	Same
OTC	Yes	Yes	Yes	Same
Handheld	Yes	Yes	Yes	Same
Wavelength	Blue: 405nm (+/- 10 nm) Red: 640nm (+/- 10 nm)	Blue: 415 nm (+/- 10 nm) Red: 660 nm (+/- 10 nm)	Blue: 442 +/- 4 nm Red: 633 nm +/- 4 nm	Similar to both the primary and secondary predicate. <i>See Note 1</i>
Treatment Dose (Joules)	9 (4.5 Joules of each wavelength)	9 (4.5 Joules of each wavelength)	19.4468	Same as the Primary Predicate
Light Emission	A combination of blue light and red light is emitted	Treat with blue light followed by red light	A combination of blue light and red light is emitted	Same as the Secondary Predicate
IEC 60601 Compliant	Yes	Yes	Yes	Same
Power Source	Lithium-ion battery	Lithium-ion battery	Alkaline Battery	Same as the Primary Predicate
Light Aperture Size (cm ²)	0.5 – 3.048 cm ² line	0.2 – 3.1 cm ² circle	Unknown	Similar to the Primary Predicate <i>See Note 2.</i>
Power Density (mW/cm ²)	15 mW/cm ² for each wavelength (red and blue)	50 mW/cm ² for each wavelength (red and blue)	Blue: 26.5 mW/cm ² Red 7.5 mW/cm ²	Similar to both the primary and secondary predicate
Fluence (J/cm ²)	1.46 – 9 J/cm ²	1.45 – 22.5 J/cm ²	Unknown	Similar to the Primary Predicate
Treatment Regimen	2 times per day, morning and night	2 times per day, morning and night	Unknown	Same as the Primary Predicate
Indications for Use	The Erchonia EVRL is intended to emit energy in the red and blue region of the spectrum, and is specifically indicated to treat mild to moderate acne.	The Luminance RED acne Device is intended to emit energy in the red and blue region of the spectrum, and is specifically indicated to treat mild to moderate acne.	The Acne Light Therapy Wand is indicated to treat mild to moderate inflammatory acne.	Same as the Primary Predicate

Note 1: The wavelength equivalency tables below illustrate the wavelength equivalency between the Erchonia EVRL and the Predicate devices.

Blue Wavelength	
Erchonia EVRL	395 nm to 415 nm
The Luminance RED Acne Device	405 nm to 425 nm
Wavelength Equivalency	405 nm to 415 nm

Red Wavelength	
Erchonia EVRL	630 nm to 650 nm
Acne Light Therapy Wand	629 nm to 637 nm
Wavelength Equivalency	630 nm to 637 nm

Note 2: The light aperture size, measured in cm², is identical to the primary predicate device. The difference in applying the treatment in a line or circular pattern does not impact safety or effectiveness.

Performance Standards

The Erchonia EVRL 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

No clinical testing was required as the subject device is technologically equivalent to legally marketed predicate devices with the same intended use and similar technical characteristics.

Usability Testing

Usability testing was conducted on the Erchonia EVRL, which complies with IEC 62366-1 and IEC 60601-1-6.

Biocompatibility

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

Risk Assessment

The Erchonia EVRL 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 EMC testing was conducted on the Erchonia EVRL. The device complies with the IEC 60601-1, IEC 60601-1-2 and IEC 60825-1 standards.

Compliance with Voluntary Standards

The Erchonia EVRL 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

The Erchonia® EVRL is substantially equivalent to the identified primary and secondary predicate devices. The subject device shares key technological characteristics with the predicate devices, including handheld configuration, wavelength specifications, energy output, light emission profile, aperture size, and internal power source. Any minor differences between the subject device and predicate device does not affect safety or effectiveness, nor raise different questions of safety and effectiveness. The Erchonia EVRL device, as designed and manufactured, has been found to be substantially equivalent to the predicate devices.