



January 10, 2025

Erchonia Corporation
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K243811

Trade/Device Name: Erchonia Zerona® VZ8
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
Regulatory Class: Class II
Product Code: OLI
Dated: December 11, 2024
Received: December 11, 2024

Dear Prithul Bom:

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: 2025.01.10
12:00:56 -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)
K243811

Device Name
Erchonia Zerona® VZ8

Indications for Use (Describe)

The Erchonia Zerona® VZ8 is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K243811

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

11/01/2024

Device Information

Trade Name: Erchonia Zerona® VZ8
Model#: VZ8
Common Name: Fat Reducing Low Level Laser
Classification Name: Low level laser system for aesthetic use
Regulation Description: Low level laser energy for the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for noninvasive aesthetic use. (21 CFR 878.5400)
Classification: Class II
Panel: General & Plastic Surgery
Product Code: OLI

Predicate Device

Primary Predicate
Trade Name: Erchonia® Violet ZERONA® Z6 OTC
510K: K231474
Common Name: Fat Reducing Low Level Laser
Classification Name: Low level laser system for aesthetic use. (21 CFR 878.5400)
Product Code: OLI

Secondary Predicate

Trade Name: Erchonia® Emerald

510K: K192544

Common Name: Fat Reducing Low Level Laser

Classification Name: Low level laser system for aesthetic use. (21 CFR 878.5400)

Product Code: OLI

Device Description

The Zerona® VZ8 laser is designed for clients seeking noninvasive circumference reduction without invasive surgery. Zerona® VZ8 allows the patient to continue their daily activities without interruptions from surgery, pain, wounds or garments. The Zerona® VZ8 works by emulsifying adipose tissue which then releases into the interstitial space. Zerona VZ8 was built on the clinical foundation of its predecessors, Violet ZERONA® Z6 and ZERONA® Z6 OTC, which were proven through clinical studies to be safe and effective in the application of circumference reduction.

The Zerona® VZ8 is identical to the predecessor device, the Erchonia Violet ZERONA® Z6 OTC cleared under K231474, with the difference in the number of laser diodes (eight compared to six). The Installation and Proper Use Reference Guide for use for the Zerona® VZ8 is identical to the predecessor laser, the Erchonia® Violet ZERONA® Z6 OTC; consisting of the similar treatment set-up and same treatment protocol involving 6 treatments occurring over 2 weeks: 3 treatments per week; each treatment every other day.

The Zerona® VZ8 emits a 405-nanometer wavelength with a tolerance of ± 10 nanometer, from each of the eight specially created and patented electronic diodes. Laser devices are typically constructed to emit a "spot" of light. The Zerona® VZ8 laser utilizes internal mechanics that collects the light emitted from the laser diode and processes it through a proprietary patented lens, and then redirects the beam with a line refractor. The laser applicator heads, each produce an output power of 23mW (± 2 mW) measured. Laser diodes and adjustable laser arms are positioned no greater than 3-4 inches away from the client's target treatment areas.

The software incorporated into the operation of the Zerona® VZ8 complies with FDA and ISO Software Development and Validation regulations.

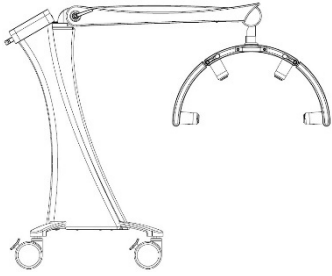
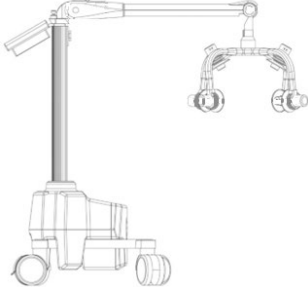
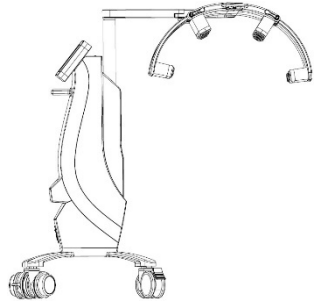
Intended Use

Zerona VZ8 is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference.

Zerona® VZ8 is intended to be distributed for Over-the-Counter (OTC) use.

Comparison of Technological Characteristics with the Predicate Device(s)

The Erchonia® Zerona® VZ8 is substantially equivalent to both its primary and secondary predicate devices. The primary predicate device, the Erchonia® Violet ZERONA® Z6 OTC (cleared under K231474), is the predecessor to the newly designed Zerona® VZ8 (subject device). Both devices share the same operational principles, including wavelength, power, energy source, and delivery method. The sole technological distinction between the subject and primary predicate device is the incorporation of two additional diode lasers, which does not compromise substantial equivalence, safety, or effectiveness, nor does it introduce new safety or effectiveness concerns. Additionally, the Erchonia® Zerona® VZ8 is substantially equivalent to the secondary predicate device, the Erchonia® Emerald. Both devices share an identical design, energy source, number of diodes, and total fluence.

Device	Erchonia Zerona® VZ8	Erchonia® Violet ZERONA® Z6 OTC	Erchonia® Emerald
510(k) #	Unknown	K231474	K192544
	Subject Device	Primary Predicate	Secondary Predicate
Manufacturer	Erchonia	Erchonia	Erchonia
Device Design			
Indication for Use	The Zerona® VZ8 is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference.	The Violet ZERONA Z6 OTC Laser is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference.	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/m2
Laser Power	23mW ± 2mW	23mW ± 2mW	16mW ± 1.25mW
Wavelength	400nm to 415nm	400nm to 415nm	522nm to 542 nm
Energy Source	Multi diode collected then line dispersed (coherent)	Multi diode collected then line dispersed (coherent)	Multi diode collected then line dispersed (coherent)
Number of Laser Diodes	8	6	10
Energy Delivery	Floor model device with probe head	Floor model device with probe head	Floor model device with probe head
Total Treatment Time Applied	20 minutes	20 minutes	30 minutes
Total Fluency	221 J	165 J	288 J
Target Size Per Diode	Line pattern, electronically scanned over area of treatment	Line pattern, electronically scanned over area of treatment	Line pattern, electronically scanned over area of treatment
User Interface	LCD Touchscreen	LCD Touchscreen	LCD Touchscreen
Principles of Operation	Mains power, converted to DC, powering semi-conductor diodes	Mains power, converted to DC, powering semi-conductor diodes	Mains power, converted to DC, powering semi-conductor diodes
Mechanism of Action	Low level light energy used as an adjunct to emulsify adipose tissue	Low level light energy used as an adjunct to emulsify adipose tissue	Low level light energy used as an adjunct to emulsify adipose tissue
Product Code	OLI	OLI	OLI

Performance Standards

The Erchonia® Zerona® VZ8 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 study results are being submitted as part of this submission

Risk Assessment

The Erchonia® Zerona® VZ8 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® Zerona® VZ8. The device complies with the IEC 60601-1, IEC 60601-1-2 and IEC 60825-1 standards.

Compliance with Voluntary Standards

The Erchonia® Zerona® VZ8 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 60825-1:2014 Edition 3.0

Substantially Equivalent Discussion

The Erchonia Zerona® VZ8 is substantially equivalent to its predecessor, the Erchonia® Violet ZERONA® Z6 OTC, cleared under K231474. Both devices share the same laser wavelength, power, energy source, and treatment duration. The sole technological distinction between the Zerona® VZ8 (subject device) and the Violet ZERONA® Z6 OTC (predicate device) is the incorporation of two additional laser diodes [8 vs 6], resulting in improved laser coverage of the treatment area. The safety and efficacy of employing additional laser diodes has been substantiated by the Erchonia Emerald (secondary predicate device), cleared under K192544. Sharing a comparable design with the subject device, the Erchonia Emerald was supported by safety and efficacy data from a full-scale controlled and powered clinical trial utilizing ten laser diodes compared to the subject device's eight. Moreover, the subject device's total fluence [221J] remains within the safety and efficacy parameters established by the secondary predicate [288J].

Conclusion

Any differences between the subject device and predicate do not render the device not substantially equivalent, do not affect safety or effectiveness, or raise different questions of safety and effectiveness. Therefore, the Erchonia Zerona® VZ8 (subject device) is substantially equivalent to the Erchonia® Violet ZERONA® Z6 OTC (predicate device), indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference.