July 21, 2023

Erchonia Corporation
Travis Sammons
Clinical Affairs Manager
650 Atlantis Rd.
Melbourne, Florida 32904

Re: K231474
Trade/Device Name: Erchonia Violet ZERONA® Z6 OTC
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
Regulatory Class: Class II
Product Code: OLI
Dated: May 18, 2023
Received: May 22, 2023

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 (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 postmarketing 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,

Jianting Wang -S

Jianting Wang
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231474

Device Name
Violet ZERONA® Z6 OTC

Indications for Use *(Describe)*
The Violet ZERONA® Z6 OTC 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.

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510(k) Summary

K231474

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

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Melbourne, FL 32904
Telephone: 321-473-1251
Fax: 321-473-1608

Establishment Registration Number

2032513

Name and Address of Official Correspondent

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Date Prepared

7/21/2023

Device Information

Trade Name: Erchonia Violet ZERONA® Z6 OTC
Model#: VZ6
Common Name: Fat Reducing Low Level Laser
Classification Name: 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

Erchonia ZERONA® Z6 OTC previously cleared under K162578.

Reference Device

Erchonia Zerona® Z6 OTC cleared under K143007.
The procedure administration protocol performed with the subject device, Erchonia Violet ZERONA® Z6 OTC, is identical to that evaluated in the comparative study which supported 510(k) clearance for K143007, with the difference in this current study being the use of a violet rather than red laser and a reduction in per-treatment treatment administration time from 40 minutes to 20 minutes. Both the subject and reference devices administered the same treatment protocol of 6 treatments occurring over 2 weeks.

Device Description

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

The Erchonia Violet ZERONA® Z6 OTC is identical to the predecessor device, the Erchonia ZERONA® Z6 OTC cleared under K162578, with the differences being light output (visible violet compared to visible red) and duration of treatment administrations (20 minutes compared to 40 minutes, which is automatically programmed into the device). The Installation and Proper Use Reference Guide for use for the Erchonia® Violet ZERONA® Z6 OTC are identical to those for use of the predecessor laser, the Erchonia® ZERONA® Z6 OTC; consisting of the same device set-up and same treatment protocol involving 6 treatments occurring over 2 weeks: 3 treatments per week; each treatment every other day.

The Violet ZERONA® Z6 OTC emits a 405-nanometer wavelength with a tolerance of ±10 nanometer, from each of the six specially created and patented electronic diodes. Laser devices are typically constructed to emit a "spot" of light. The Violet ZERONA® Z6 OTC 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 (± 2mW) 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 Violet ZERONA® Z6 OTC complies with FDA and ISO Software Development and Validation regulations.

Intended Use

The Violet ZERONA® Z6 OTC is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference.

Violet ZERONA® Z6 OTC is intended to be distributed for Over-the-Counter (OTC) use.

Comparison of Technological Characteristics with the Predicate Device

The following table compares the subject device (Erchonia Violet ZERONA® Z6 OTC) to the predicate device (Erchonia ZERONA® Z6 OTC). The comparison provides detailed information regarding the basis for the determination of substantial equivalence.

Device	Erchonia Violet ZERONA® Z6 OTC	Erchonia ZERONA® Z6 OTC	Differences
510(k) #	N/A	K162578	
	Subject Device	Predicate Device	
Device Design			None
Indication for Use	The Violet ZERONA Z6 OTC Laser is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference.	The ZERONA Z6 OTC Laser is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference.	None
Laser Power	23mW ± 2mW	17.25mW ± 1.25mW	Clinical study completed (refer to Performance Testing -Clinical)
Wavelength	Violet: 400nm- 415nm	Red: 630nm – 640nm	Clinical study completed (refer to Performance Testing -Clinical)
Energy Source	Multi diode collected then line dispersed (coherent)	Multi diode collected then line dispersed (coherent)	None
Number of Laser Diodes Applied Per Treatment Area	6	6	None
Energy Delivery	Floor model device with probe head	Floor model device with probe head	None
Total Treatment Time Applied	20 minutes	40 minutes	Clinical study completed (refer to Performance Testing -Clinical)
Treatment Frequency	3 x week, 2 weeks	3 x week, 2 weeks	None
Total Fluency	165 J	248 J	Clinical study completed (refer to Performance Testing -Clinical)
Target Size Per Diode	Line pattern, electronically scanned over area of treatment (516 cm^2)	Line pattern, electronically scanned over area of treatment (516 cm^2)	None
User Interface	LCD Touchscreen	LCD Touchscreen	None
Principles of Operation	Mains power, converted to DC, powering semi-conductor diodes	Mains power, converted to DC, powering semi-conductor diodes	None
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	None
Product Code	OLI	OLI	None

Performance Standards
The Erchonia Violet ZERONA® Z6 OTC complies with FDA's performance standards for light-emitting products (21CFR 1040.10 and 21 CFR 1040.11 by Laser Notice #50).

Risk Assessment
The Erchonia Violet ZERONA® Z6 OTC is acceptable in accordance with IEC 60601 edition 3.1, 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.

Electromagnetic Compatibility and Electrical Safety
The Erchonia Violet ZERONA® Z6 OTC utilizes the same components as the predicate device, Erchonia ZERONA® Z6 OTC, with the exception of the laser diode. The Erchonia Violet ZERONA® Z6 OTC emits violet light and the Erchonia ZERONA® Z6 OTC emits red light, the change does not alter the safety and EMC testing previously conducted on the Erchonia ZERONA® Z6 OTC. Therefore, the safety and EMC testing which was conducted on the Erchonia ZERONA® Z6 OTC device applies to the Erchonia Violet ZERONA® Z6 OTC. The device testing complies with the current IEC 60601-1, IEC 60601-2 and IEC 60825-1 standards.

Compliance with Voluntary Standards
The Erchonia Violet ZERONA® Z6 OTC complies with the following voluntary standards:
IEC 60601-1-2:2014 Edition 4.0
IEC 60601-1:2005 Edition 3.1
IEC 60825-1:2014 Edition 3.0

Performance Testing-Clinical
BACKGROUND: The purpose of this clinical study was to determine the effectiveness of the Erchonia Violet ZERONA® Z6 OTC laser device, in providing noninvasive body circumference reduction.

STUDY DESIGN: This clinical study was an open-label single-arm design to evaluate the efficacy of application of the Erchonia Violet ZERONA® Z6 OTC violet laser application to that of application of the Erchonia® ZERONA Z6 OTC red laser for the reduction of body circumference.

SUBJECTS: Twenty-five (25) subjects, 84% of whom were female completed the study. Mean subject age was 49.96 years, mean baseline body mass index (BMI) was 26.43kg/m², and mean baseline combined waist-hips-bilateral thighs circumference was 123.16.

STUDY PROCEDURES: Each subject received six (6) treatments with the Erchonia Violet ZERONA® Z6 OTC across a two-week period. The study procedure was identical to that evaluated in the comparative study, with the difference being evaluated in this study being use of a violet rather than red laser and a reduction in per-treatment administration time from 40 minutes to 20 minutes.

STUDY MEASURES: The study primary outcome measure of combined waist-hips-bilateral thighs circumference (inches) was measured at baseline and at completion of the two-week treatment phase (study endpoint).

STUDY RESULTS: Success for the current study group was pre-determined as mean change in combined circumference measurements of -3.72±5% inches (-3.53 to -3.91 inches). The mean change in total body circumference measurement at study endpoint relative to baseline was -3.91 inches, falling within the pre-specified maximally clinically acceptable difference range (-3.53 to -3.91 inches), and exceeding the pre-established lower boundary of -3.53 inches by -0.38 inches; thereby establishing study primary success.

SAFETY: No adverse events were reported or observed for any subject across study duration.

CONCLUSION: The study results demonstrate that application of the Erchonia Violet ZERONA® Z6 OTC violet laser is as effective in providing clinically meaningful circumference reduction as the Erchonia ZERONA® Z6 OTC red laser, with half the required per-treatment administration time (from 40 to 20 minutes), which is a significant time savings to the patient.

Substantially Equivalent Discussion

The Erchonia Violet ZERONA® Z6 OTC is substantially equivalent to the predicate device, the Erchonia ZERONA® Z6 OTC previously submitted under K162578. Both the subject device and the predicate device have identical device design, number of diodes, energy delivery, treatment frequency, and mechanism of action. The differences in laser diodes (wavelength and laser power) and treatment time applied per area, is justified in the outcome of the clinical study that demonstrates the difference does not render the device not substantially equivalent, does not affect the safety or effectiveness, or raise different questions of safety and effectiveness.

The clinical data provided in this submission demonstrates that the application of the Erchonia Violet ZERONA® Z6 OTC (violet laser) maintains the same safety profile and is as effective in providing clinically meaningful circumference reduction as the Erchonia ZERONA® Z6 OTC (red laser), with half the required per-treatment administration time, which is a significant time savings to the patient. (See Table 1)

Table 1: Combined Circumference Reduction Across Study Duration by Device

	Erchonia Violet ZERONA® Z6 OTC	**Erchonia ZERONA® Z6 OTC**
Laser Diode	Violet	Red
n	25	22
Total Treatment Time Applied	20 minutes	40 minutes
Combined Circumference Reduction (inches)	**3.91 (95% CI: 3.26 – 4.56)**	**3.72 (95% CI: 2.78 – 4.66)**
Side Effects	None	None

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 Violet ZERONA® Z6 OTC (subject device) is substantially equivalent to the Erchonia ZERONA® Z6 OTC (predicate device), indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference.