March 24, 2022

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

Re: K220519
Trade/Device Name: Erchonia Zerona Z-Bed
Regulation Number: 21 CFR 878.5400
Regulation Name: Low level laser system for aesthetic use
878.5650
Regulatory Class: Class II
Product Code: OLI
Dated: February 22, 2022
Received: February 23, 2022

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 (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,

Purva Pandya, D.Eng.
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)*
K220519

Device Name
Zerona® Z-Bed

Indications for Use *(Describe)*
The Zerona® Z-Bed Laser 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.

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510(k) Summary

K220519

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
650 Atlantis Rd.
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

01/10/2022

Device Information

Trade Name: Erchonia Zerona® Z-Bed
Model#: JZB
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

Trade Name: Zerona® Z6 OTC
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)
Product Code: OLI

Device Description

The Zerona® Z-Bed laser is specially designed for non-invasive fat loss. Zerona® Z-Bed is a new body-sculpting procedure designed for client's seeking noninvasive fat loss without invasive surgery. Zerona® Z-Bed allows the individual to continue their daily activities without interruptions from surgery, pain, wounds or garments. The Zerona® Z-Bed works by utilizing proven low level laser technology to emulsify adipose tissue (defined as leakage of the fat out of the cell) which then releases into the interstitial space. The excess fat is passed through the body during its normal course of detoxification. The Zerona® Z-Bed was built on the clinical foundation of its predecessors, Zerona® Z6 OTC, Zerona® and Zerona®-AD which were proven through a double-blind, randomized, multi-site, and placebo controlled studies to be safe and effective in the application of circumference reduction and noninvasive fat loss.

The Zerona® Z-Bed emits a 635 nanometer wavelength with a tolerance of ±10 nanometer, from each of the twelve specially created and patented electronic diodes. Laser devices are typically constructed to emit a "spot" of light. The Zerona® Z-Bed 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 17.5mW (± 1.25mW) measured, per non-convergent beams. Laser diodes and adjustable laser arms are positioned no greater than 3-4 inches away from the client's target treatment areas. In this position the diode emits a line width of 3mm and a mean length of 3.5in. (8.9cm), each line emits approximately (.0002 joules per cm^2 / minute) per area at 3inches and approximately (.0001 joules per cm^2 / minute) per area at 4inches. The treatment time of 20 minutes would be approximately .004 j/cm^2 at 3 inches and approximately .002 j/cm^2 at 4 inches away from the skin.

The Zerona® Z-Bed laser device has been classified by the FDA/EC as a Class II/IIa device and a Class II/2 Laser. This designation represents a current standard for use in order to ensure the safety of the individual. A Class II/IIa Laser is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging.

The Zerona® Z-Bed laser device has been classified by the FDA Class II device and a Class 2 laser in accordance IEC 60825-1 (Complies with 21CFR 1040.10 and 21 CFR 1040.11 by Laser Notice #50). The performance parameters and intended use of the Erchonia® Zerona® Z-Bed are compliant to the internationally recognized safety testing standards for medical devices. The testing of the Zerona® Z-Bed device includes functional performance, electrical, safety and component verification, in accordance with the FDA QS requirement, validated annually through ISO 13485 audits. The software incorporated into the operation of the Zerona® Z-Bed complies with FDA and ISO Software Development and Validation regulations.

The Zerona® Z-Bed laser package is comprised of (1) Zerona® Z-Bed Laser Device, (1) Laser Safety Glasses, (1) Power Cord, (1) Power Supply, (1) Tape Measure, (1) Pack of Lucasol Disinfectant Wipes, and (1) Operation & Maintenance Manual. This following information is included to familiarize you with the components of the device.

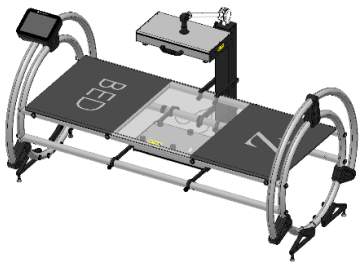
Indication for Use

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

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

Design Change

The principles of operation of the Erchonia® Zerona® Z-Bed (Model# JZB) are identical to the predicate device, Erchonia® Zerona® Z6 OTC (Model# SHR), with the exception of a design change. Below is a table that details the design changes of the technology between the Zerona® Z-Bed (subject device) and the Zerona® Z6 OTC (predicate device).

Erchonia® Zerona® Z6 OTC (Model# SHR)	**Erchonia® Zerona® Z-BED (Model# JZB)**	**Reason for Change**
		Updated Appearance
Standalone laser platform to be positioned over standard treatment table *(not included)*	Incorporates a built-in user laying surface	Eliminates the need for independent treatment table
Device Total Laser Diodes: 6 laser diodes located in the main head assembly. The main head assembly with six laser diodes is applied to the anterior, and once treatment is complete, the individual rotates over, and the main head assembly is applied to the posterior.	Device Total Laser Diodes: 12 Six laser diodes located in the top head assembly applied to the anterior and six laser diodes located underneath user laying surface applied to the posterior.	The addition of six diodes located underneath the user laying surface allows for the anterior and posterior of the individual to be treated simultaneously; and eliminates the two-step treatment process, involving the individual treating anterior and then rotating over for treatment of posterior.
Erchonia® Zerona Z6 OTC (Model# SHR)	**Erchonia® Zerona® Z-BED (Model# JZB)**	**Areas Left Unchanged**
Six laser diodes are applied to each treatment surface area. *(anterior/ posterior)*	Six laser diodes are applied to each treatment surface area. *(anterior/ posterior)*	The number of diodes applied per treatment area (anterior/ posterior) remains at 6 diodes.
20-minute treatment time per surface area. *(anterior/ posterior)*	20-minute treatment time per surface area. *(anterior/ posterior)*	Treatment time per surface area remains at 20 minutes. *(anterior/ posterior)*
Laser applicator heads: Line pattern, electronically scanned over area of treatment (516 cm^2)	Laser applicator heads: Line pattern, electronically scanned over area of treatment (516 cm^2)	Laser applicator heads remains a line pattern, electronically scanned over area of treatment (516 cm^2)
The main arm adjustment is designed using spring tension. The adjustment of the main arm is by manual movement from the end user. This allows the end user to lower and raise for proper positioning to individual for accurate treatment distance.	The top head assembly adjustment is designed using spring tension. The adjustment of the top head assembly is by manual movement from the end user. This allows the end user to lower and raise for proper positioning to individual for accurate treatment distance.	The top head assembly adjustment remains the use of spring tension for manual movement from the end user.

Performance Data

Compliance with Voluntary Standards

The Erchonia® Zerona® Z-Bed complies with the following voluntary standards:
IEC 60601-1-2:2014 Edition 4.0
IEC 60601-1:2005, AMD1:2012
IEC 60825-1:2014 Edition 3.0

Performance Standards

The Erchonia® XLR8 Laser complies with FDA's performance standards for light-emitting products (21CFR 1040.10 and 21 CFR 1040.11 by Laser Notice #50).

Software

Software verification and validation testing was conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "minor" level of concern.

Risk Assessment

The Erchonia® Zerona® Z-Bed, Model#: JZB 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

Safety and EMC testing was conducted on the Erchonia® Zerona® Z-Bed, Model#: JZB device. The device complies with the IEC 60601-1, IEC 60601-2 and IEC 60825-1 standards.

Performance Testing-Animal

No animal testing conducted

Performance Testing-Clinical

No clinical study results are being submitted as part of this submission.

Comparison of Technological Characteristics with the Predicate Device

The Erchonia® Zerona® Z-Bed (Model# JZB) is substantially equivalent to the predicate device, the Erchonia® Zerona® Z6 OTC (Model# SHR) previously cleared under K162578. The Zerona® Z6 OTC is the predecessor to the newly designed Zerona® Z-Bed (subject device), both devices have same the principles of operation, including wavelengths, power, energy source, and energy delivery.

Device	**Erchonia® Zerona® Z-Bed**	**Erchonia Zerona® Z6 OTC**
Ref. 510(k)	Subject Device	K162578
Indication for Use	The Erchonia® Z-BED Laser is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference. Erchonia® Z-BED is intended to be distributed for Over-the-Counter (OTC) use.	The ZERONA Z6 OTC Laser is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference. Zerona® Z6 OTC is intended to be distributed for Over-the-Counter (OTC) use.
Laser Power	17.25mW ± 1.25mW	17.25mW ± 1.25mW
Wavelength	Red 630 nm – 640 nm	Red 630 nm – 640 nm
Waveform	Constant Wave	Constant Wave
Energy Source	Multi diode collected then line dispersed (coherent)	Multi diode collected then line dispersed (coherent)
Power Supply	100 – 240V~ 1.5-.5A, 50-60 Hz electrical outlet	100 – 240V~ 1.5-.5A, 50-60 Hz electrical outlet
Number of Laser Diodes Applied Per Treatment Area	6	6
Energy Delivery	Floor model device with probe head	Floor model device with probe head
Treatment Time Applied Per Area	20 minutes	20 minutes
Treatment Frequency	3 x week, 2 weeks	3 x week, 2 weeks
Total Fluency	248 J	248 J
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)
User Interface	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
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
Product Code	OLI	OLI

Conclusion

The Erchonia® Zerona® Z-BED (Model# JZB) is substantially equivalent to the predecessor device, the Erchonia® Zerona® Z6 OTC (Model# SHR), cleared under K162578. The design change does not render the device not substantially equivalent, does not affect the safety or effectiveness, or raise different questions of safety and effectiveness.

The only technological difference between the Zerona® Z-BED (subject device) and Zerona® Z6 OTC (predecessor device) is the addition of six laser diodes, which provides the means to administer the treatment to the anterior and posterior of the individual simultaneously and therefore eliminating the two-step treatment process, involving the individual treating anterior and then rotating over for treatment of posterior. This change does not affect the safety or effectiveness due to the fact the Zerona® Z-BED (subject device) and Zerona® Z6 OTC (predecessor device) deliver the same number of diodes (6), laser power (17.25mW) and treatment time (20 minutes) to each treatment area (anterior/ posterior). Furthermore, both the subject device and predecessor deliver the same amount of total light energy (248 J).

Therefore, we conclude that the Erchonia® Zerona® Z-BED redesign (subject device) is substantially equivalent to the predecessor, Erchonia Zerona® Z6 OTC (predicate device), indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference