U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(smw)
FOLDER:	K121695 - 123 pages
COMPANY:	ERCHONIA CORPORATION (ERCHONIA)
PRODUCT:	FAT REDUCING LOW LEVEL LASER (OLI)
SUMMARY:	Product: ERCHONIA ZERONA
DATE REQUESTED:	Oct 19, 2015
DATE PRINTED:	Oct 19, 2015
Note:	Printed

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Erchonia Corporation
% Regulatory Insight, Incorporated
Mr. Kevin Walls
Principal Consultant
5401 South Cottonwood Court
Greenwood Village, Colorado 80121

AUG 23 2012

Re: K121695
Trade/Device Name: Erchonia Zerona
Regulation Number: 21 CFR 878.5400
Regulation Name: Low level laser system for aesthetic use
Regulatory Class: Class II
Product Code: OLI
Dated: July 20, 2012
Received: July 24, 2012

Dear Mr. Walls:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121695

Device Name: Erchonia Zerona

Indications for Use: The Erchonia Zerona is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121695

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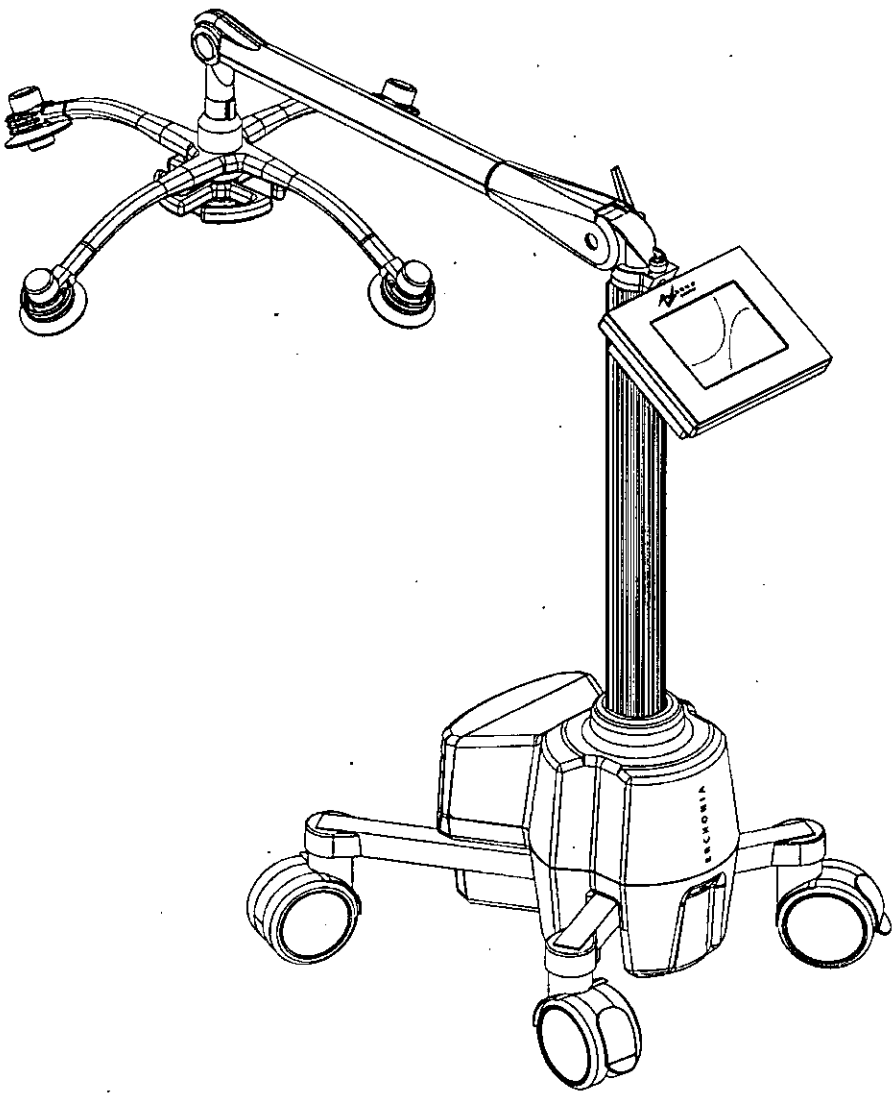
510(k) Number K121695



Erchonia Zerona

Operation & Maintenance Manual

Acknowledgements and Accreditations

We at Erchonia® Corporation would like to thank you for purchasing the Erchonia Zerona.

Erchonia® Corporation is an ISO certified company and undergoes periodic audits by external governing agencies, including the FDA, in order to ensure compliance to the highest quality standards. Our company is run in accordance to and our devices are manufactured in accordance with:

- FDA Good Manufacturing Practices
- ISO 9001:2000 - Quality
- ISO 13485:2003 - Medical
- ISO 60825-1 - Laser Safety
- FDA Laser Class 2
- IEC Laser Class 2
- MDD 93/42/EEC
- EN/IEC 60601-1-2 EMC
- EN/IEC EN60601-1-1 Safety

Legend:

FDA - US Food &Drug Administration, which includes the CDRH (Center for Device Radiological Health)
ISO - International Standards, Harmonized with US, Canadian, European and Asian standards
MDD - Medical Device Directive

Doc No.	Issue Date	Rev. Level	Rev. Date
O&M-MLS	7/12/07	1B	8/12/08
O&M-MLS	7/12/07	1C	5/27/10
O&M-Zerona	6/5/12	1D	6/5/12
O&M-Zerona	7/31/12	1E	7/31/12

Legend:
The following symbols are throughout the text of this manual to identify areas of concern. For your safety, the safety of your patients and the care of the device, please heed.

WARNING: Failure to heed this warning can result in harm to the patient and / or damage to equipment.

CAUTION: Failure to heed this caution can result in a malfunction of the equipment.

Erchonia® Corporation
2021 Commerce Drive McKinney, TX 75069
Phone 214.544.2227 • Fax 214.544.2228
www.erchonia.com

Table of Contents

Erchonia Zerona Components

The Erchonia Zerona model has been shipped to you with some assembly required. This section is included for you to familiarize yourself with the components of the unit ensuring the remainder of this manual is clearly communicated.

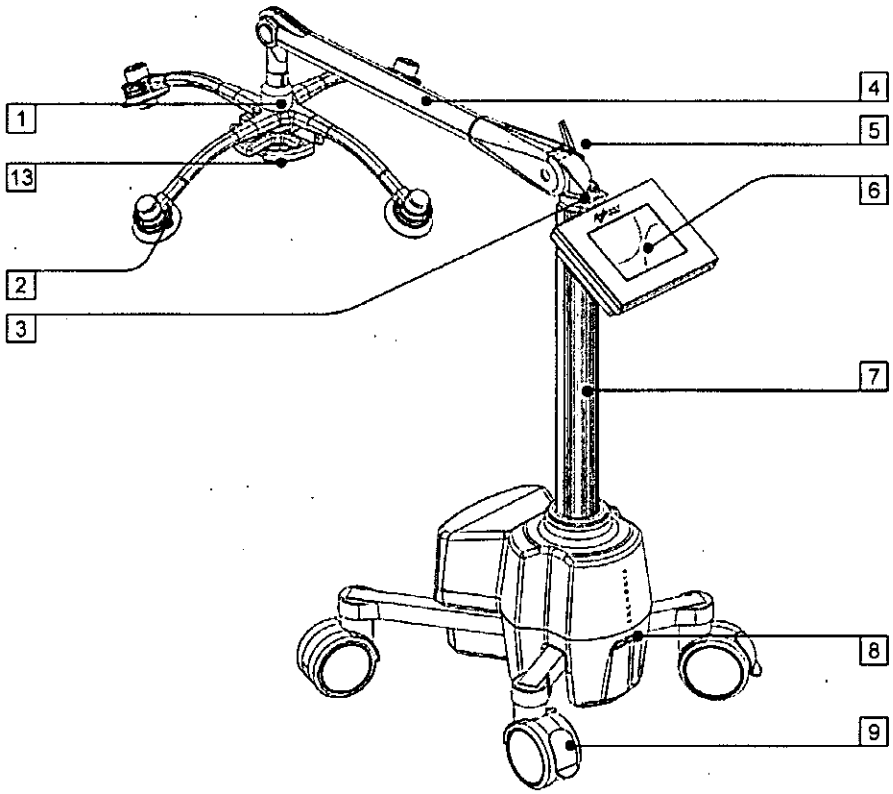


Fig 1

1. Laser Head Assembly
2. Laser Output Head
3. Power Safety Lockout Key
4. Laser Arm
5. Arm Lock
6. Touchscreen Control Surface
7. Main Upright of Base
8. Power Inlet
9. Rear Wheel Lock
10. Power Cord (Fig 2)
11. Locking Nut (Fig 2)
12. Electrical Connector (Fig 3)
13. Handle

Assembly Instructions

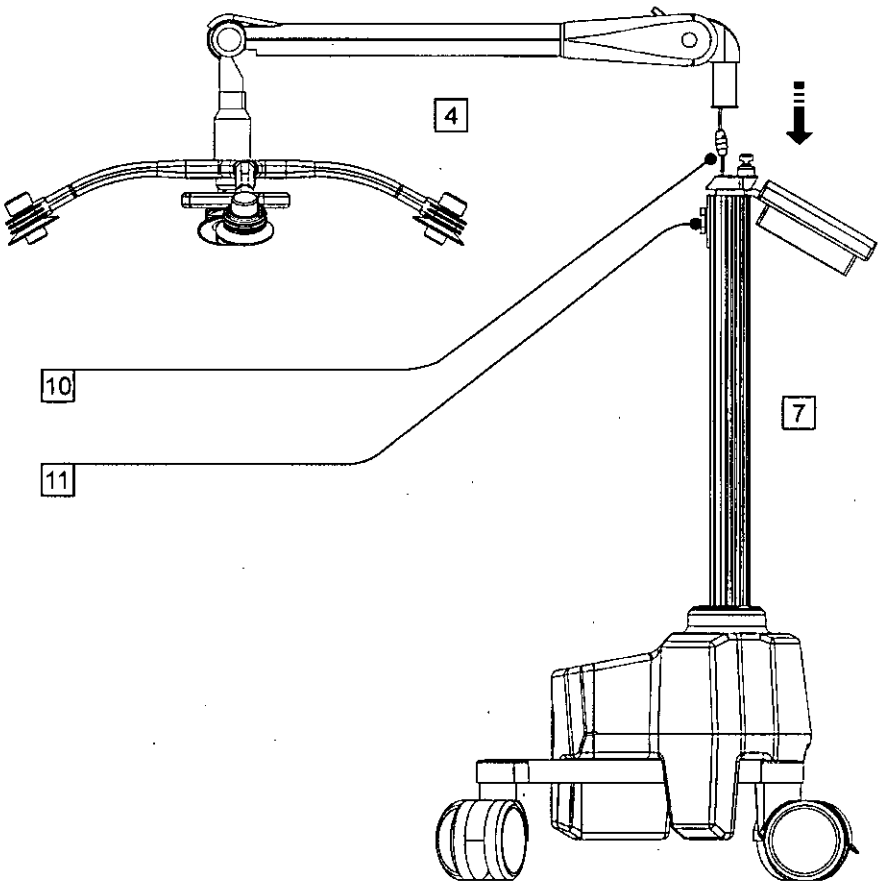


Fig. 2

Step 1:
The electrical connection [12] from the base to the arm must be connected as shown in fig 3.

Simply insert the 2 halves of the electrical connection (Fig 3) together slightly pushing the outlet into the inlet. Twist until secure. (The connector can only be connected one way)

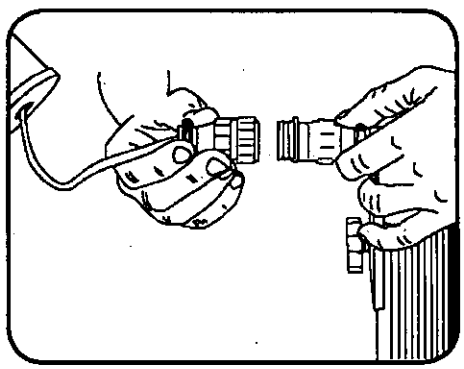


Fig. 3

After insertion, hold the female connector secure while gently twisting the locking collar until it locks **and can no longer be twisted.** This is important so the two halves do not separate over time.

Step 2:
Remove or loosen the locking nut [11] as shown in figure 4.

Step 3:
Gently feed the connector and cable into the base main upright [7] as shown in figure 5. It must be pushed into the hole.

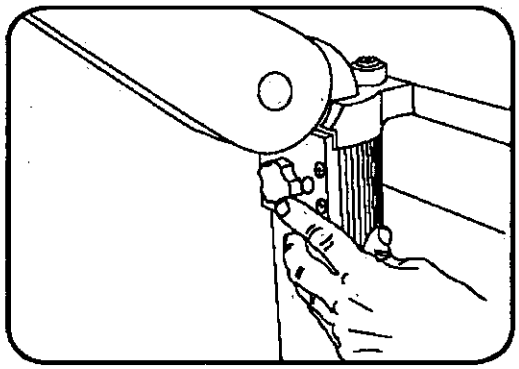


Fig. 4

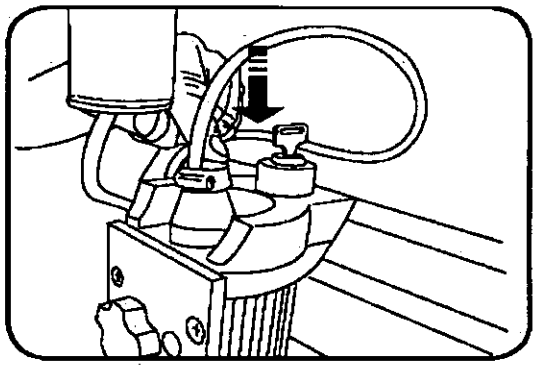


Fig. 5

Step 4:
After the wire and connector have been fed into the hole insert the arm tube into the base main upright [7] as shown in figure 6. Insertion is easier with a helper. Also make sure the tube is aligned with the hole.

After the tube is inserted and pushed down to the bottom of its slot, carefully screw in the locking nut [11] (as shown in figure 7) into the treaded opening in the arm tube and tighten. This will keep the main head assembly from unwanted rotation during use. Your Zerona is now ready for use.

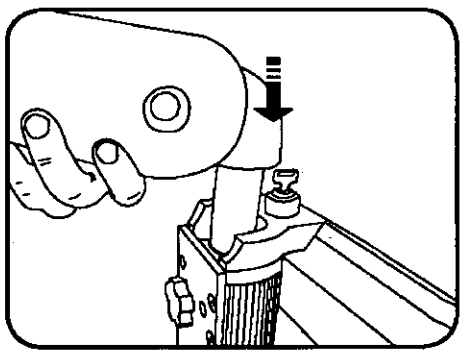


Fig. 6

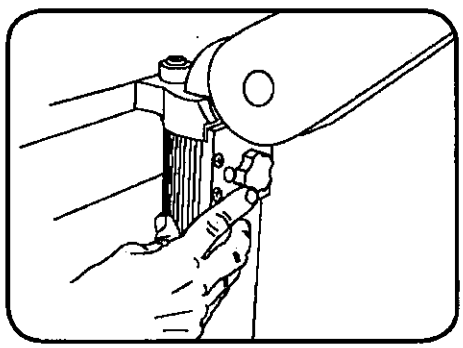


Fig. 7

Additional Information

The arm tension can be adjusted or locked into position with lever [5] as shown in figure 8.

To activate your Zerona, the safety key [3] must be inserted into its socket located on the top of the base upright as shown in figure 9. After insertion turn it to the right to turn on. Because the Zerona has 2 computers when you first turn it on it will take a few moments to warm up before use.

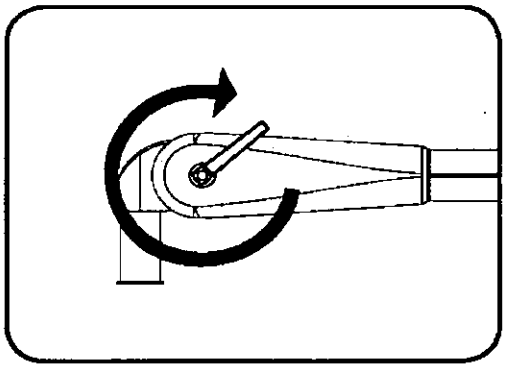


Fig. 8

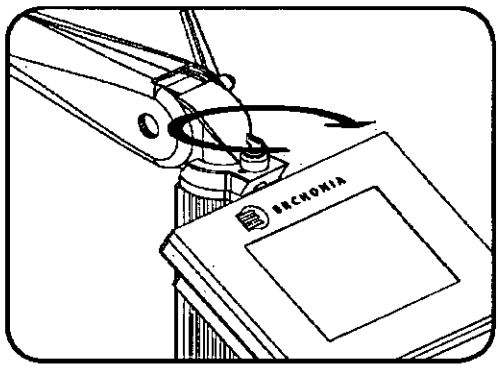


Fig. 9

If you are having problems pushing the wire harness and wires into the column, or if you have dropped the unconnected end in the column and need to retrieve it for connection, the front panel can be slid down as shown. This exposes the wires in the column.

If you need to go further down the column to retrieve.the connector the panel can be pulled out to allow more access to the column, see figures 10, 11.

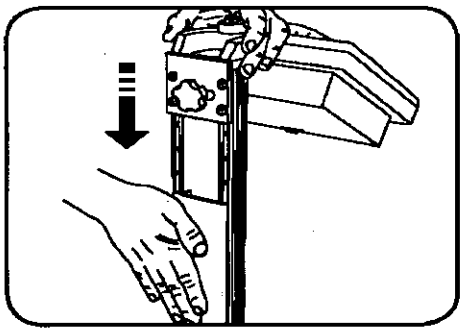


Fig. 10

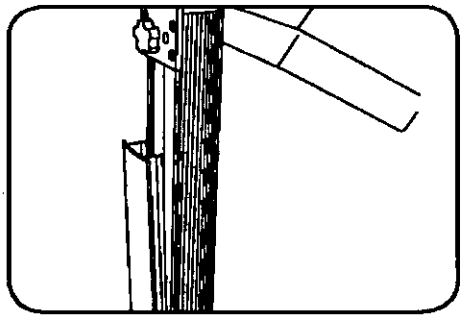


Fig. 11

Introduction to Contents

The Erchonia Zerona package is comprised of (1) Erchonia Zerona, (1) pair of patient protective eyewear, (1) power cord, this user guide and a warranty card. The components of this package are detailed below.

Erchonia Zerona

The Erchonia Zerona is made up of five independent 635 nanometer diodes, each with variable frequency. The variable frequency feature of the Erchonia Zerona is a pulsed wave, defined as containing a selected series of breaks, variances that are pre-programmed. Clinical studies have shown that pulse wave is the most effective method of laser use.

Laser devices are typically constructed to emit a "spot" of light. The Erchonia Zerona utilizes internal mechanics that collects the light emitted from the diode and processes through a proprietary patented lens which redirects the beam with a line refractor. The lines generated by each head are rotated via a patented rotation device that operates independent of each other to ensure thorough coverage. The target area is approximately 8" x 10" inches or 80 square inches, approximately 516 square centimeters.

Power

The mains power switch is the key on top of the touch screen, ref Item 3, FIG 1. The unit will not operate unless the key is in the ON position. Turning the key to the OFF position satisfies the FDA requirement for mechanical lock out, ensuring the safety of non-authorized users.

The mains power switch has a fail safe system which ensures the 110/240 voltage from a wall socket can never come in contact with the user. The system uses a 2 amp fuse, which will only require replacement if there is an issue. To replace, locate fuse holder in back of base unit, pull fuse holder out of enclosure, replace fuses and reinsert.

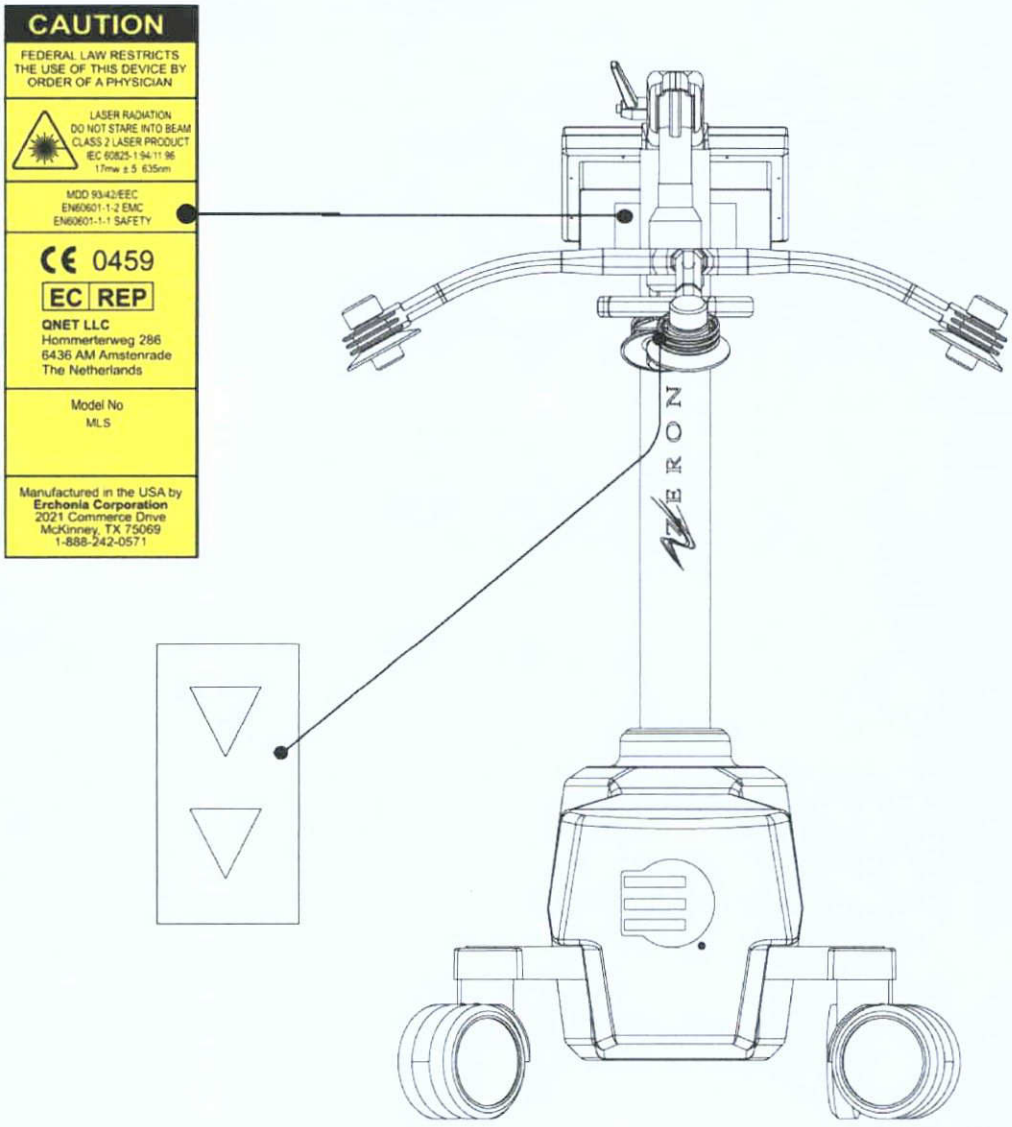
Protective Eyewear

The Erchonia Zerona is classified by the FDA as a Class 2 Laser Product. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 hazard class device 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. To ensure there is no possible instance of residual effect, we have included a pair of specialty patient glasses for use by the patient during treatment.

Labeling

The Erchonia Zerona is manufactured in accordance to the Good Manufacturing Procedures set forth by the FDA, ISO Standards (International) and CE (Certified European) standards and testing results per Article 9, the device is a Class I Shock Protection and a Class II Medical device. Each of these governing agencies requires specific labeling. All required labels affixed according to the relevant codes. Each label is pictured and described in this section. Additionally, the placement of each label on the Erchonia Zerona is communicated.

The diagram below shows the compliance labels and their placement. The large black background label is this primary label and is compliant to FDA and ISO standards, the left side of the image captures the FDA code regulated classifications and the right side of the label covers International criteria, each of the laser diodes (5) have a label affixed that show the direction of the laser beam output.



Manufacturer and Distributor Information

Manufacturer's Information
Erchonia Corporation
2021 Commerce Dr.
McKinney, TX 75069
214.544.2227

Distributor Information
Erchonia Corporation
2021 Commerce Dr
McKinney, TX 75069
214.544.2227

Indications for Use

The Erchonia Zerona is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

Histological evidence has identified that following exposure to Erchonia Zerona at 635nm wavelength of light, a transitory pore is established within the protective membrane of adipocytes, providing a means for the stored fatty material to exit the cell entering the interstitial space. This response is secondary to the absorption of light by photoabsorbing complexes positioned within the cell that modulates the cell bioenergetics. Release of intracellular fat promotes cellular collapse of the adipocyte significantly reducing cell volume. The material enters the interstitial space which is regulated by an anastomosing network of lymphatic vessels that funnel towards lymph nodes transporting fluids including the fatty material released via laser therapy. Flow of lymph which originates in connective tissue eventually is deposited into the circulatory system primarily through the thoracic duct which empties into the subclavian vein. As the fluid passes through the lymph nodes the extraneous materials are filtered out via macrophages, which contain enzymes capable of degrading triglycerides and cholesterol. The administration of the Erchonia Zerona has been proven to induce transitory pore formation, liberating accumulated fatty material, which is absorbed degraded by the lymphatic system and removed from the treated region, producing a slimming outcome based upon the volume reduction of cells.

References: Niera, R., Arroyave, Ramirez, H., et al. Fat liquefication: Effect of low-level laser energy on adipose tissue. *Plast. Reconstr. Surg.* (2002): 110; 912-22.

Instructions for Use

Setting Up the Unit
To turn the unit ON, place the key in the key lock and turn to the ON position. NOTE: The unit requires a minimum of 30-45 seconds to launch the programming contained with the internal computers. Once the device is ready for use, the touch screen will display the non-invasive body contouring screen.

When you press the start button it will launch the non-invasive protocol. If for any reason you need to pause, press the pause button. To restart, press pause again. The "treatment time in minutes" field shows the elapsed time. The protocol is 20 minutes

long and will stop automatically when complete. When done, return the key to the off position.

Front of the Body

1. The patient lies comfortably flat on his or her back on the table such that the front area of the patient's body encompassing the region spanning from the patient's stomach (abdomen) down through the hips and frontal aspect of both thighs, is facing upwards.
2. The center diode of the Erchonia Zerona is positioned at a distance of 6.00 inches above the patient, centered along the body's midline (the "line" that vertically "dissects" the body into two equal halves).
3. The Erchonia Zerona is activated for 20 minutes. Each scanner emits to the patient a laser beam of approximately 17mW with a wavelength of 635 nm, and creates a spiraling circle pattern that is totally random and independent from the others. These patterns overlap each other to guarantee total coverage within the target area of approximately 516 square centimeters.

Back of the Body

1. The patient turns over to lie flat on his or her stomach such that the back area of the patient's body encompassing the region spanning from the patient's back down through the hips and back aspect of both thighs is facing upwards.
2. The center diode of the Erchonia Zerona is positioned at a distance of 6.00 inches above the patient, centered along the body's midline (the "line" that vertically "dissects" the body into two equal halves).
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Application / Administration

The Erchonia Zerona is intended for use by health care professionals as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. The treatment protocol that is hard coded into the device has been developed in conjunction with Medical Doctors, Erchonia Medical Researchers and IRB advisors (see clinical trial summary). Medical professionals in receipt of this device are to use the preset as their medical training and experience dictate.

Clinical Trial Summary

A DOUBLE-BLIND, PLACEBO-CONTROLLED RANDOMIZED EVALUATION OF THE EFFECT OF THE ERCHONIA ZERONA ON BODY CONTOURING OF THE WAIST, HIPS AND THIGHS.
Erchonia Medical. Inc.

BACKGROUND: The purpose of this clinical study was to determine the effectiveness of the Erchonia Zerona for non-invasive body contouring of the waist, hips and thighs by applying the Erchonia Zerona around the waist, hips and thighs six times across two weeks.

STUDY DESIGN: The study was a placebo-controlled, randomized, double-blind parallel group design conducted across three independent test sites.

SUBJECTS: Sixty seven (67) subjects completed this study. Of the 67 participating subjects, 35 were randomized to the active procedure group and 32 were randomized to the placebo group.

Subjects were those aged 18 to 65 years with a Body Mass Index (BMI) of less than 30 kg/m^2 who were deemed suitable for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that had failed to respond to diet and exercise; specifically for the indication of body contouring in the areas of the waist, hips and bilateral thighs, as per the American Academy of Cosmetic Surgery's 2006 Guidelines for Liposuction Surgery developed by a joint Ad Hoc Committee of the American Society of Liposuction Surgery (ASLSS) and the American Academy of Cosmetic Surgery (AACS).

The majority of study subjects were Caucasian females, as illustrated in Table 1 below.

Table 1: Table of Subject Demographics

Gender	**Female**		**Male**	
n=67	*number*	*%*	*number*	*%*
	64	96%	3	4%
Ethnicity	**Caucasian**		**Caucasian/African American**	
n=67	*number*	*%*	*number*	*%*
	66	99%	1	1%

STUDY MEASURES: Circumference measurements for the hips, waist and bilateral thighs, and body mass index (BMI) were recorded at baseline, study mid-point (week 1), study endpoint (week 2), and study follow-up two weeks later. Subject satisfaction with the procedure outcome was recorded at study endpoint.

BASELINE MEASUREMENTS: Table 2 below contains the mean baseline circumference and BMI measurements.

Table 2: Mean Baseline measurements

	Test Group n=35	Placebo Group n=32	All Subjects Combined n=67
Body Mass Index (BMI)	25.74	26.05	25.89
Waist circumference (ins.)	33.94	34.85	34.37
Hip circumference (ins.)	38.99	39.88	39.41
Right thigh (ins.)	23.80	24.12	23.95
Left thigh (ins.)	23.59	24.14	23.85
Total circumference (ins.)	**120.31**	**122.99**	**121.59**

A series of t-tests for independent samples found there was no statistically significant difference in any of the above baseline measurements between subject procedure groups ($p>0.05$).

STUDY PROCEDURE: Subjects received six procedure administrations with the Erchonia Zerona to the front and back areas of the waist, hips and bilateral thighs, across a consecutive two-week period: three procedures per week, each procedure two to three days apart.

STUDY RESULTS

(i) Total Circumference Measurements: Individual circumference measurements for each of a subject's waist, hips and right and left thighs was combined to attain the study primary outcome measure of a combined total circumference measurement.

It was pre-determined that a subject would be considered a study success if he or she attained a 3.0 inch or greater reduction in total circumference measurement from baseline to study endpoint (after completion of the two-week procedure phase).

60.00% of subjects who received the study procedures with the actual Erchonia Zerona attained a decrease in total circumference measurement of 3.0 inches or greater compared with 6.25% of subjects who received the study procedures with a 'fake' (placebo) laser device. A Fischer's Exact Test for two independent proportions found this difference of 53.75% to be statistically significant at $p<0.00001$.

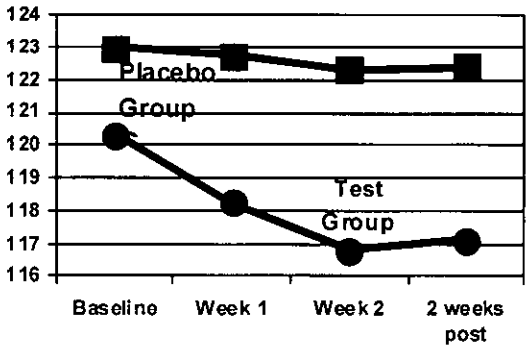
The magnitude of the mean change in total circumference measurement was a decrease of 3.521 inches for subjects who received the study procedures with the actual Erchonia Zerona and a decrease of 0.684 inches for subjects who received the study procedures with a 'fake' (placebo) laser device. A t-test for independent samples found the difference of 2.8378 inches in mean total circumference change between procedure groups to be statistically significant ($t=-7.30$; $df=65$; $p(\text{two-tailed})<0.0001$). In confirmation, a One-Way ANOVA for 2 Independent Samples also found this mean difference between procedure groups in combined inches lost to be statistically significant ($F=53.3623$, $p<0.0001$).

Table 3 and Chart 1 below show the mean change in total circumference measurements across the four study measurement time points.

Table 3: Mean total circumference measurement (ins.) across evaluation points

	Test Group	Placebo Group
Baseline	120.31	122.99
Midpoint (week 1)	118.25	122.73
Endpoint (week 2)	116.79	122.31
Follow-up (week 4)	117.09	122.37

Chart 1: Mean total circumference measurement (ins.) across evaluation points



For test group subjects, total circumference measurements decreased progressively from baseline across the procedure administration phase, indicating a progressive and cumulative treatment effect of the laser.

Total circumference measurements stabilized across the subsequent 2-week follow-up assessment period during which time no laser procedures were administered, indicating duration of the treatment effect up to at least 2 weeks following the end of laser procedure administration. For placebo group subjects, there were no notable changes in total circumference measurements across or between any of the assessment points.

(ii) <u>Individual Area Circumference Measurements</u>: Table 4 below shows the mean circumference measurements for individual body areas.

Table 4: Mean individual body area circumference measurements.

	Test Group n=35				Placebo Group			
inches	**Waist**	**Hips**	**Right thigh**	**Left thigh**	**Waist**	**Hips**	**Right thigh**	**Left thigh**
Baseline	33.94	38.99	23.80	23.59	34.85	39.88	24.12	24.14
Week 1	33.38	38.26	23.31	23.30	34.85	39.80	24.10	23.98
Week 2	32.96	37.94	22.95	22.94	34.60	39.67	24.07	23.97
2 weeks post	32.86	38.29	23.02	22.92	34.53	39.66	24.16	24.02

As with total circumference measurements, individual area circumference measurements decreased progressively from baseline across the procedure administration phase for test group subjects, indicating a progressive and cumulative treatment effect of the laser. Individual body area circumference measurements then stabilized across the subsequent 2-week follow-up assessment period during which time no laser procedures were administered, indicating duration of the treatment effect up to at least 2 weeks. For placebo group subjects, there were no notable changes in individual body area circumference measurements across or between any of the measurement points.

(iii) Change in weight in pounds and change in body mass index (BMI): Neither weight measurements nor body mass index (BMI) changed notably across or between any of the four study measurement points for either test or placebo subject groups.

However, individual body area and combined total circumference measurements did change notably across and between measurement points for test group subjects but not for placebo group subjects. This combined finding further supports the effectiveness of the Erchonia Zerona as it demonstrates that the change in body shape (statistically significant reduction in combined inches at the waist, hip and thighs) attained for test group subjects resulted from the Erchonia Zerona application and not from incidental weight loss or change in body mass index as a result of incidental weight loss.

(iv) Study outcome satisfaction ratings: At completion of the study procedure administration phase, the subject was asked to rate how satisfied he or she was with any overall change in body shape attained using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied.

70% of test group subjects reported being 'Satisfied' (Very or Somewhat Satisfied) with the outcome of the study procedures compared with 26% of placebo subjects. Conversely, 36% of placebo group subjects reported being 'Dissatisfied' (Not very satisfied or Not at all satisfied) compared with 3% of test group subjects.

(v) Adverse events: There was no adverse event for any subject throughout the duration of the clinical study. There was no change in skin markers in the treated body areas, and no notable deviation from baseline diet, exercise or concomitant medication use for any study subject.

CONCLUSION: The Erchonia Zerona is an effective tool for body contouring, significantly reducing circumference measurements when applied to the hips, stomach and bilateral thighs over a 2-week period.

Warnings / Cautions / Maintenance

Warnings

1. The long term effects of prolonged use of non-thermal laser exposure are unknown.
2. Laser treatment should not be applied over, or in proximity to, cancerous lesions as conclusive tests have not been conducted.
3. To eliminate any possible danger to the eyes safety glasses must be worn by the patient during treatment.

Cautions

1. Safety of non-thermal lasers for use during pregnancy has not been established.
2. Caution should be used over areas of skin that lack normal sensation.
3. Use only with accessories recommended by manufacturer.
4. Avoid the ingress of any liquid.

Maintenance and Cleaning

The Erchonia Zerona, if used according to the instructions contained within this manual will operate efficiently for years. To ensure proper care, it is advisable for the end-user to perform:

1. Regular visual inspection to make sure there is no external damage other than normal wear and tear. If during these inspections you identify an area of concern, please contact the manufacturer.
2. If you notice a change in the performance of the device while in the ON position, please contact the manufacturer.
3. The internal components should not require any maintenance, however if an issue arises, which will show itself in the form of altered performance, the device must be sent to the manufacturer.
4. Since the device contains a touchscreen interface, periodic cleaning of the touchscreen will be necessary. To clean the touchscreen, use warm soapy water only, applied with a clean cloth that has been wrung out to ensure there is NOT an excess of fluid.
5. The touchscreen back up battery must be replaced every five years. This must be done by manufacturer.
6. The unit must be stored, shipped and used at temperatures not to exceed 41C/105.8°F.

Disposal

The Erchonia Zerona is a self-contained unit that emits light energy and as such creates no by-product that requires disposal; however, the unit itself, when spent and beyond repair or functional use, should be sent back to the manufacturer for disposal. This process ensures the proper separation and handling of all the internal parts and reduces any risk to the patient and/or environment.

Warranty Information

Limited Warranty
The Erchonia Zerona is warranted to be free from defect in material and workmanship for a period of TWO YEARS from the date of purchase. For warranty to be valid, it is critical that the end-user complete and return the enclosed warranty card. Failure to return warranty card may adversely impact warranty processing and/or void warranty.

Terms and Conditions
• This product contains a 30 day money back guarantee, which covers purchase price only. If for any reason, the end-user is unsatisfied with the product and/or its performance, it can be returned for full refund of purchase price.

• Shipping required facilitating warranty repair and or maintenance issues within the first 90 days will be paid by the manufacturer.

• Shipping required facilitating warranty repair and or maintenance issues after 90 days is the financial responsibility of the end-user.

• Warranty DOES NOT cover instances involving or damages resulting from:
- Accident, misuse or abuse
- Lack of responsible care
- Alteration or disassembly
- Loss of parts
- Exposure to the elements
- Ingress of liquid

• Warranty is NON-TRANSFERABLE. If device is sold to another party, by any one other than an approved Erchonia distributor, the warranty is VOID.

Point of Contact
If for any reason you are dissatisfied with this product, have warranty concerns or questions regarding proper operation of the device; please call 214.544.2227 for immediate assistance.

Warranty Card
Please remove warranty card from packaging, complete and mail within 90 days of purchase. Failure to do so may adversely impact manufacturer's ability to successfully administer warranty.

ERCHONIA

World Leader in Low Level Laser Technology™

Erchonia Corporation
2021 Commerce Drive McKinney, TX 75069
1-888-242-0571 or 214-544-2227

K121695

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 22, 2012

ERCHONIA CORPORATION
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT.
GREENWOOD VILLAGE, COLORADO 80121
ATTN: KEVIN WALLS

510k Number: K121695
Product: ERCHONIA ZERONA
On Hold As of 6/21/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act requires that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

* * * COMMUNICATION RESULT REPORT (JUN. 22. 2012 12:23PM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : JUN. 22. 2012 12:15PM

FILE	MODE	OPTION	ADDRESS	RESULT	PAGE
6822	MEMORY TX		917209625413	E-3) 3)	0/2

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES — **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 22, 2012

ERCHONIA CORPORATION
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT.
GREENWOOD VILLAGE, COLORADO 80121
ATTN: KEVIN WALLS

510k Number: K121695
Product: ERCHONIA ZERONA
On Hold As of 6/21/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

* * * COMMUNICATION RESULT REPORT (JUN. 22. 2012 11:22AM) * * *

FAX HEADER 1:
FAX HEADER 2:

T 'SMITTED/STORED : JUN. 22. 2012 11:10AM F MODE	OPTION	ADDRESS	RESULT	PAGE
6810 MEMORY TX		917209625413	E-3) 3)	0/2

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 22, 2012

ERCHONIA CORPORATION
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT.
GREENWOOD VILLAGE, COLORADO 80121
ATTN: KEVIN WALLS

510k Number: K121695
Product: ERCHONIA ZERONA
On Hold As of 6/21/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

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DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 11, 2012

ERCHONIA CORPORATION
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT.
GREENWOOD VILLAGE, COLORADO 80121
ATTN: KEVIN WALLS

510k Number: K121695

Received: 6/7/2012

Product: ERCHONIA ZERONA

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Williams, Michael *

From: Microsoft Outlook
To: 'kevin@reginsight.com'
Sent: Monday, June 11, 2012 11:47 AM
Subject: Relayed: Ack Letter for K121695

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'kevin@reginsight.com'

Subject: Ack Letter for K121695

Sent by Microsoft Exchange Server 2007

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

June 07, 2012

USER FEE HOLD LETTER - HAVE NOT RECEIVED PAYM

ERCHONIA CORPORATION
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT.
GREENWOOD VILLAGE, COLORADO 80121
ATTN: KEVIN WALLS

510k Number: K121695
Received: 6/7/2012
User Fee ID Number: 6062166
Product: ERCHONIA ZERONA

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to mail a check, please send a check to one of the addresses listed below:

By Regular Mail
Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

By Private Courier(e.g.,Fed Ex, UPS, etc.)
U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301)847-8120 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/cdrh/mdufma/fy09userfee.html. In addition, the 510k Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm.

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In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)796-7100 or its toll-fee number (800)638-2041, or contact them at their Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Edwena Jones at Edwena.Jones@fda.hhs.gov or directly at (301)796-7200. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Edwena Jones
Consumer Safety Technician
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Mcdonald, Lisa *

From: Microsoft Outlook
To: 'kevin@reginsight.com'
nt: Thursday, June 07, 2012 3:36 PM
bject: Relayed: K121695 ACK Letter

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'kevin@reginsight.com'

Subject: K121695 ACK Letter

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88

K121695
SU/OSORO

Regulatory Insight, Inc.

Worldwide Medical Device Submissions and Quality Systems

FDA/CDRH/DCC
JUN 7 2012
RECEIVED

June 6, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: 510(k) Notification for the Erchonia Zerona

Dear Sir or Madam:

Please find enclosed a 510(k) premarket notification for the Erchonia Zerona manufactured by Erchonia Corporation. The Erchonia Zerona is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. There are no changes in technology between the Erchonia Zerona and the Erchonia ML Scanner (MLS), which was cleared under 510(k) #K082609. The sole purpose of this 510(k) is to change the name of the device from Erchonia ML Scanner (MLS) to Erchonia Zerona.

An electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission. If you have any questions or concerns regarding the information enclosed, please contact me at the phone, fax or email address below.

Sincerely,

Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.

5401 S. Cottonwood Court • Greenwood Village, Colorado 80121 • U.S.A.
Phone: (720) 962-5412 • Fax: (720) 962-5413
Email: info@regInsight.com • Web: www.reginsight.com

Form Approved: OMB No 0910-511 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) [redacted] Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
REGULATORY INSIGHT INC 5401 S. Cottonwood Ct. Greenwood Village CO 80121 US	Kevin Walls 2.1 E-MAIL ADDRESS kevin@reginsight.com 2.2 TELEPHONE NUMBER (include Area code) 720-9625412
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) [redacted] 06-Jun-2012

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Regulatory Insight, Inc.

Worldwide Medical Device Submissions and Quality Systems

June 6, 2012

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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Phone: (720) 962-5412 • Fax: (720) 962-5413
E-mail: info@reginsight.com • Web: www.reginsight.com

Erchonia Zerona 510(k)
Table of Contents

Name and Address of Sponsor

Erchonia Corporation
2021 Commerce Dr.
McKinney, TX 75069
Phone: 214-544-2227
Fax: 214-544-2228

Name and Address of Manufacturer

Erchonia Corporation
2021 Commerce Dr.
McKinney, TX 75069
Phone: 214-544-2227
Fax: 214-544-2228

Establishment Registration Number

2032513

Name and Address of Official Correspondent

Regulatory Insight, Inc.
5401 S. Cottonwood Ct.
Greenwood Village, Colorado 80121
Contact: Mr. Kevin Walls, RAC
Telephone: 720-962-5412
Fax: 720-962-5413
Email: kevin@reginsight.com

CDRH Premarket Review Submission Cover Sheet

Please refer to the completed Form FDA 3514 contained in **Appendix A**.

Truthful and Accuracy Statement

See **Appendix B**.

510(k) Statement

See **Appendix C**.

Device Name

Trade Name: Erchonia Zerona
Common Name: Fat reducing low level laser
Classification Name: Low level laser system for aesthetic use

Classification, Panel and Product Code

Class II, General & Plastic Surgery, OLI

Previous Submission

This same device was submitted and subsequently cleared under 510(k) # K082609 for the same indications for use.

Indications for Use

The Erchonia Zerona is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.

Refer to **Appendix D** for the Indications for Use contained on a separate page per CDRH instructions.

Device Description

The Erchonia Zerona is exactly the same device as the Erchonia ML Scanner (MLS). The only change to the device is the device name from Erchonia ML Scanner (MLS) to Erchonia Zerona. Please refer to 510(k) # K082609 for the complete device description.

Labeling

Please refer to **Appendix E** for a copy of the Erchonia Zerona Operation and Maintenance Manual.

Performance Standards

The Erchonia Zerona complies with FDA's performance standards for light-emitting products (21 CFR Part 1040).

Substantial Equivalence

Comparison of the New and Predicate Devices

Device	Erchonia ML Scanner (MLS)	Erchonia Zerona
510(k)	K082609	N/A
Indications for Use	The Erchonia ML Scanner (MLS) is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs	The Erchonia Zerona is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs
Power	17 mw	17 mw
Wavelength	Red 630 nm – 640 nm (near infrared)	Red 630 nm – 640 nm (near infrared)
Waveform	Pulsed	Pulsed
Energy Source	Five diodes, each collected then line dispersed and rotated	Five diodes, each collected then line dispersed and rotated

Power Supply	AC	AC
Energy Delivery	Machine mounted probe	Machine mounted probe
Treatment Time	20 minutes	20 minutes
Target Size	Line pattern, mechanically rotated to form circles and scanned over treatment area.	Line pattern, mechanically rotated to form circles and scanned over treatment area.
Target Population	Individuals intending to undergo liposuction procedure.	Individuals intending to undergo liposuction procedure.
Locations for Use	Hospital, health care provider office.	Hospital, health care provider office.

Clinical Study Results

The Erchonia Zerona is exactly the same device as the Erchonia ML Scanner (MLS). The only change to the device is the device name from Erchonia ML Scanner (MLS) to Erchonia Zerona. Please refer to 510(k) # K082609 for the clinical study results.

Software

The Erchonia Zerona is exactly the same device as the Erchonia ML Scanner (MLS). The only change to the device is the device name from Erchonia ML Scanner (MLS) to Erchonia Zerona. Please refer to 510(k) # K082609 for the software documentation.

Risk Assessment

The Erchonia Zerona is exactly the same device as the Erchonia ML Scanner (MLS). The only change to the device is the device name from Erchonia ML Scanner (MLS) to Erchonia Zerona. Please refer to 510(k) # K082609 for the risk assessment.

Biocompatibility

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

Compliance with Voluntary Standards

The Erchonia Zerona complies with the following voluntary standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.

- EN 60601-1-2:2001; Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standard: Electromagnetic compatibility for Class A equipment

- IEC 60825-1 (Second edition - 2007), Safety of laser products - Part 1: Equipment classification and requirements CORRIGENDUM 1

The Erchonia Zerona is exactly the same device as the Erchonia ML Scanner (MLS). The only change to the device is the device name from Erchonia ML Scanner (MLS) to Erchonia Zerona. Please refer to 510(k) # K082609 for the test reports and the Forms FDA 3654.

Error - Couldn't merge file with following reason - PdfReader not opened with owner password
090026218105e951.pdf
System attempted to attach the file. Please look at attachments to open this file manually.

Truthful and Accuracy Statement

I believe to the best of my knowledge, in my capacity as President of Erchonia Corporation, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Steven Shanks
President
Erchonia Corporation

6-4-12
Date

510(k) Statement

I certify that, in my capacity as President of Erchonia Corporation, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

6-4-12

Steven Shanks
President
Erchonia Corporation

Date

Indications for Use

510(k) Number (if known): _____

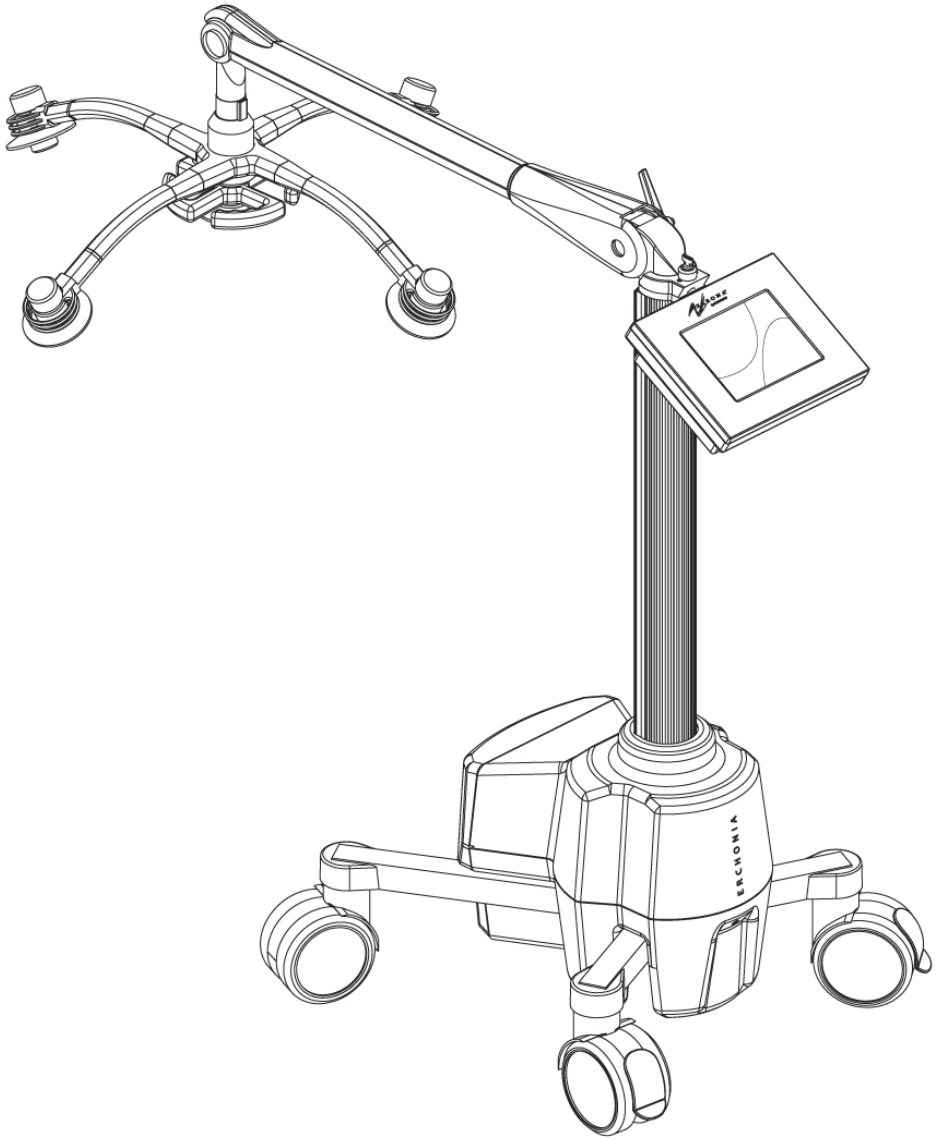
Device Name: Erchonia Zerona

Indications for Use: The Erchonia Zerona is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Erchonia Zerona

Operation & Maintenance Manual

Acknowledgements and Accreditations

We at Erchonia® Corporation would like to thank you for purchasing the Erchonia Zerona.

Erchonia® Corporation is an ISO certified company and undergoes periodic audits by external governing agencies, including the FDA, in order to ensure compliance to the highest quality standards. Our company is run in accordance to and our devices are manufactured in accordance with:

- FDA Good Manufacturing Practices
- ISO 9001:2000 - Quality
- ISO 13485:2003 - Medical
- ISO 60825-1 - Laser Safety
- FDA Laser Class 2
- IEC Laser Class 2
- MDD 93/42/EEC
- EN/IEC 60601-1-2 EMC
- EN/IEC EN60601-1-1 Safety

Legend:

FDA - US Food &Drug Administration, which includes the CDRH (Center for Device Radiological Health)
ISO - International Standards, Harmonized with US, Canadian, European and Asian standards
MDD - Medical Device Directive

Doc No.	Issue Date	Rev. Level	Rev. Date
O&M-MLS	7/12/07	1B	8/12/08
O&M-MLS	7/12/07	1C	5/27/10
O&M-Zerona	6/5/12	1D	6/5/12

Legend:
The following symbols are throughout the text of this manual to identify areas of concern. For your safety, the safety of your patients and the care of the device, please heed.

WARNING: Failure to heed this warning can result in harm to the patient and / or damage to equipment.

CAUTION: Failure to heed this caution can result in a malfunction of the equipment.

Erchonia® Corporation
2021 Commerce Drive McKinney, TX 75069
Phone 214.544.2227 • Fax 214.544.2228
www.erchonia.com

Table of Contents

Erchonia Zerona Components

The Erchonia Zerona model has been shipped to you with some assembly required. This section is included for you to familiarize yourself with the components of the unit ensuring the remainder of this manual is clearly communicated.

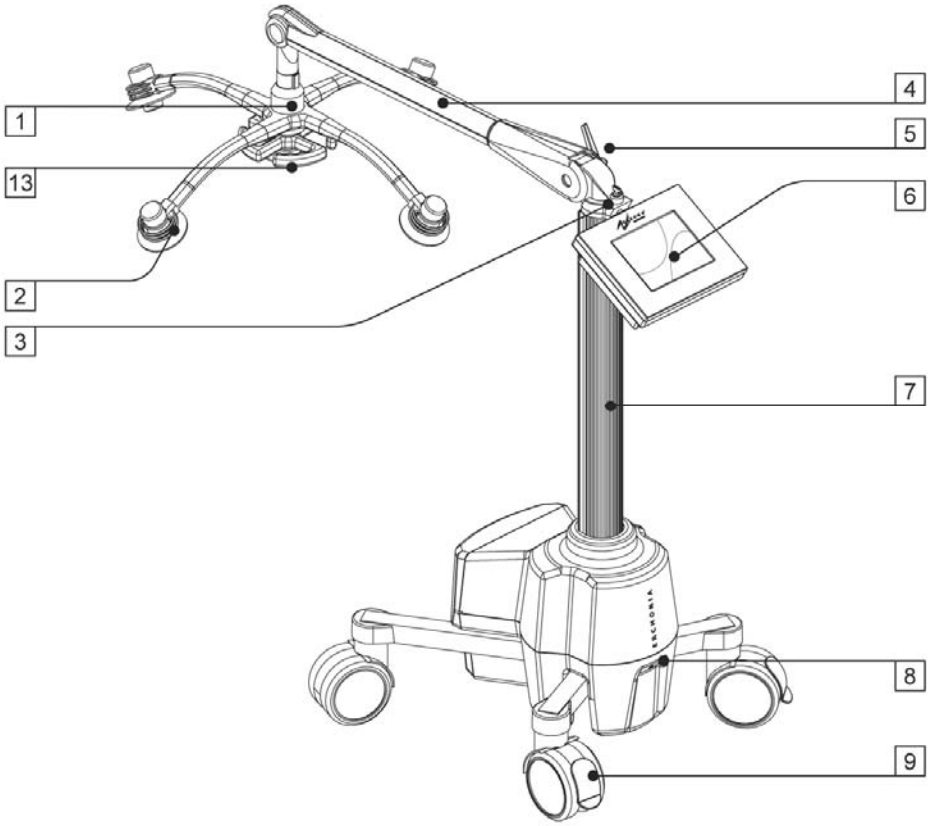


Fig 1

1. Laser Head Assembly
2. Laser Output Head
3. Power Safety Lockout Key
4. Laser Arm
5. Arm Lock
6. Touchscreen Control Surface
7. Main Upright of Base
8. Power Inlet
9. Rear Wheel Lock
10. Power Cord (Fig 2)
11. Locking Nut (Fig 2)
12. Electrical Connector (Fig 3)
13. Handle

Assembly Instructions

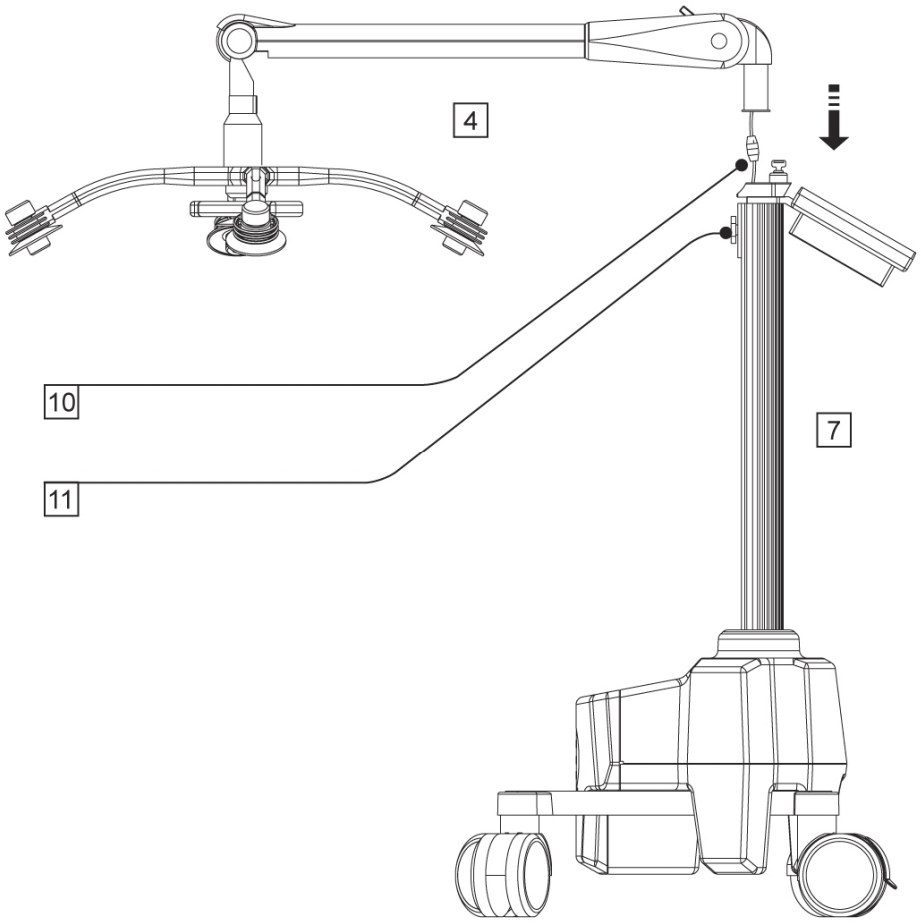


Fig. 2

Step 1:
The electrical connection [12] from the base to the arm must be connected as shown in fig 3.

Simply insert the 2 halves of the electrical connection (Fig 3) together slightly pushing the outlet into the inlet. Twist until secure. (The connector can only be connected one way)

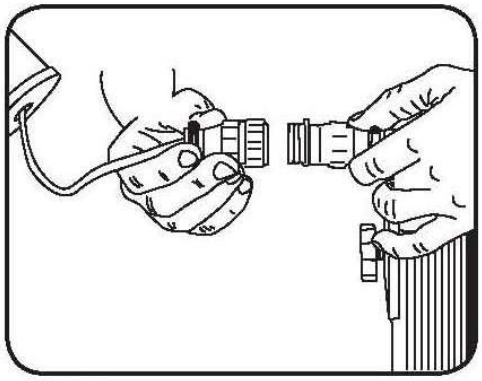


Fig. 3

After insertion, hold the female connector secure while gently twisting the locking collar until it locks **and can no longer be twisted.** This is important so the two halves do not separate over time.

Step 2:
Remove or loosen the locking nut [11] as shown in figure 4.

Step 3:
Gently feed the connector and cable into the base main upright [7] as shown in figure 5. It must be pushed into the hole.

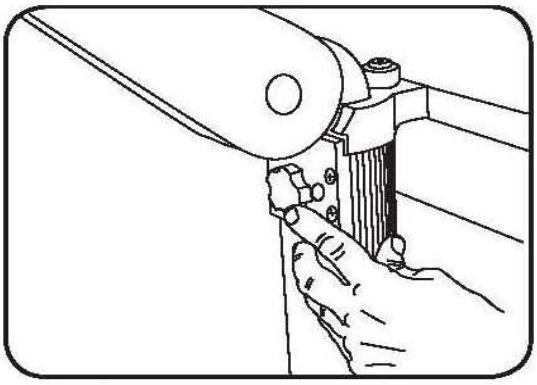


Fig. 4

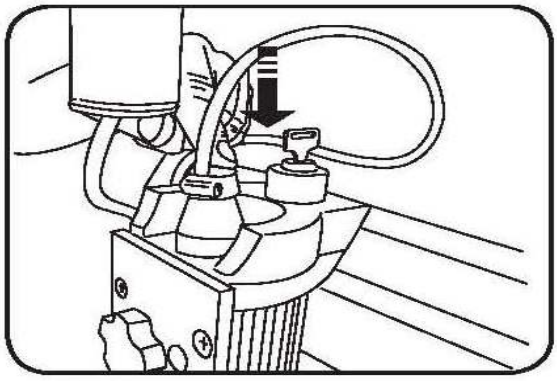


Fig. 5

Step 4:
After the wire and connector have been fed into the hole insert the arm tube into the base main upright [7] as shown in figure 6. Insertion is easier with a helper. Also make sure the tube is aligned with the hole.

After the tube is inserted and pushed down to the bottom of its slot, carefully screw in the locking nut [11] (as shown in figure 7) into the treaded opening in the arm tube and tighten. This will keep the main head assembly from unwanted rotation during use. Your Zerona is now ready for use.

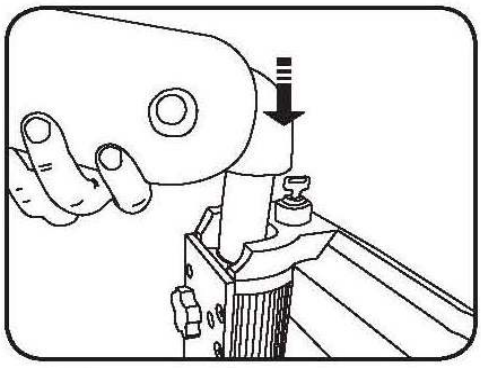


Fig. 6

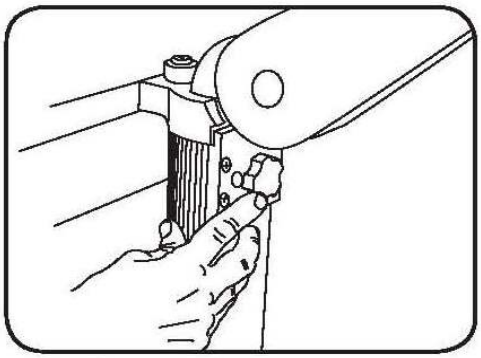


Fig. 7

Additional Information

The arm tension can be adjusted or locked into position with lever [5] as shown in figure 8.

To activate your Zerona, the safety key [3] must be inserted into its socket located on the top of the base upright as shown in figure 9. After insertion turn it to the right to turn on. Because the Zerona has 2 computers when you first turn it on it will take a few moments to warm up before use.

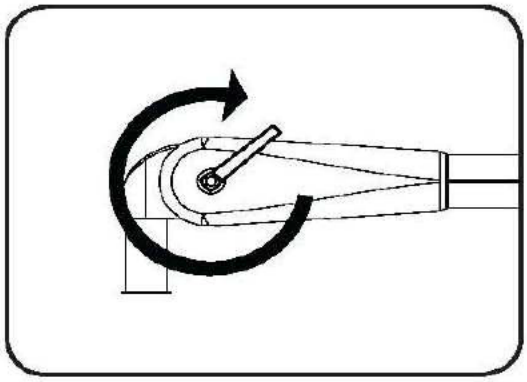


Fig. 8

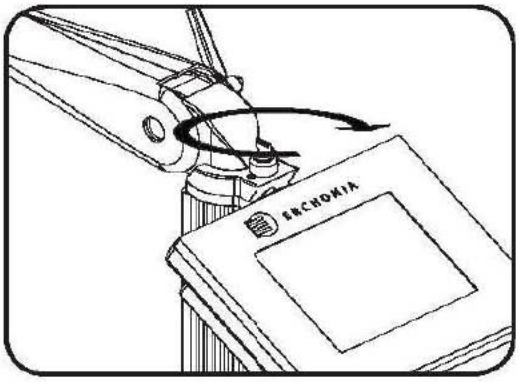


Fig. 9

If you are having problems pushing the wire harness and wires into the column, or if you have dropped the unconnected end in the column and need to retrieve it for connection, the front panel can be slid down as shown. This exposes the wires in the column.

If you need to go further down the column to retrieve the connector the panel can be pulled out to allow more access to the column, see figures 10, 11.

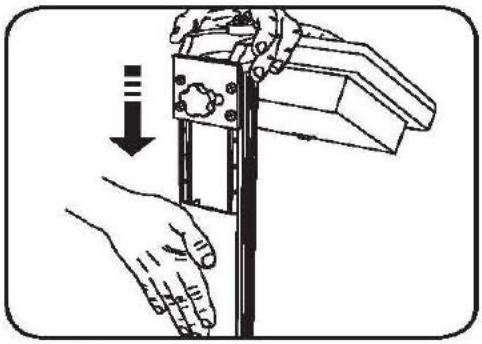


Fig. 10

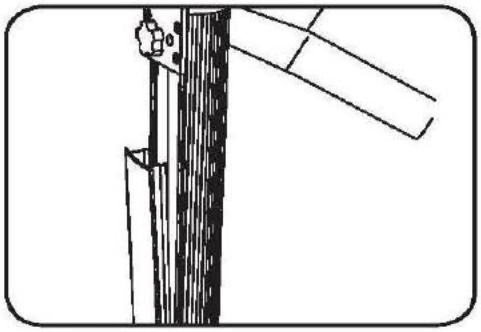


Fig. 11

Introduction to Contents

The Erchonia Zerona package is comprised of (1) Erchonia Zerona, (1) pair of patient protective eyewear, (1) power cord, this user guide and a warranty card. The components of this package are detailed below.

Erchonia Zerona

The Erchonia Zerona is made up of five independent 635 nanometer diodes, each with variable frequency. The variable frequency feature of the Erchonia Zerona is a pulsed wave, defined as containing a selected series of breaks, variances that are pre-programmed. Clinical studies have shown that pulse wave is the most effective method of laser use.

Laser devices are typically constructed to emit a "spot" of light. The Erchonia Zerona utilizes internal mechanics that collects the light emitted from the diode and processes through a proprietary patented lens which redirects the beam with a line refractor. The lines generated by each head are rotated via a patented rotation device that operates independent of each other to ensure thorough coverage. The target area is approximately 8" x 10" inches or 80 square inches, approximately 516 square centimeters.

Power

The mains power switch is the key on top of the touch screen, ref Item 3, FIG 1. The unit will not operate unless the key is in the ON position. Turning the key to the OFF position satisfies the FDA requirement for mechanical lock out, ensuring the safety of non-authorized users.

The mains power switch has a fail safe system which ensures the 110/240 voltage from a wall socket can never come in contact with the user. The system uses a 2 amp fuse, which will only require replacement if there is an issue. To replace, locate fuse holder in back of base unit, pull fuse holder out of enclosure, replace fuses and reinsert.

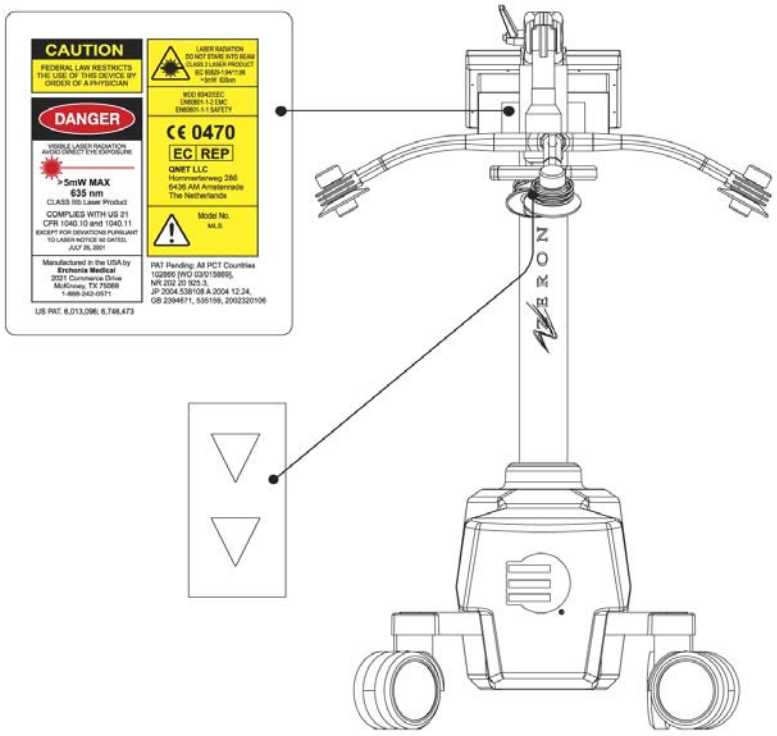
Protective Eyewear

The Erchonia Zerona is classified by the FDA as a Class 2 Laser Product. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 hazard class device 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. To ensure there is no possible instance of residual effect, we have included a pair of specialty patient glasses for use by the patient during treatment.

Labeling

The Erchonia Zerona is manufactured in accordance to the Good Manufacturing Procedures set forth by the FDA, ISO Standards (International) and CE (Certified European) standards and testing results per Article 9, the device is a Class I Shock Protection and a Class II Medical device. Each of these governing agencies requires specific labeling. All required labels affixed according to the relevant codes. Each label is pictured and described in this section. Additionally, the placement of each label on the Erchonia Zerona is communicated.

The diagram below shows the compliance labels and their placement. The large black background label is this primary label and is compliant to FDA and ISO standards, the left side of the image captures the FDA code regulated classifications and the right side of the label covers International criteria, each of the laser diodes (5) have a label affixed that show the direction of the laser beam output.



Manufacturer and Distributor Information

Manufacturer's Information
Erchonia Corporation
2021 Commerce Dr.
McKinney, TX 75069
214.544.2227

Distributor Information
Erchonia Corporation
2021 Commerce Dr
McKinney, TX 75069
214.544.2227

Indications for Use

The Erchonia Zerona is indicated for non-invasive body contouring of the waist, hips and thighs.

Histological evidence has identified that following exposure to Erchonia Zerona at 635nm wavelength of light, a transitory pore is established within the protective membrane of adipocytes, providing a means for the stored fatty material to exit the cell entering the interstitial space. This response is secondary to the absorption of light by photoabsorbing complexes positioned within the cell that modulates the cell bioenergetics. Release of intracellular fat promotes cellular collapse of the adipocyte significantly reducing cell volume. The material enters the interstitial space which is regulated by an anastomosing network of lymphatic vessels that funnel towards lymph nodes transporting fluids including the fatty material released via laser therapy. Flow of lymph which originates in connective tissue eventually is deposited into the circulatory system primarily through the thoracic duct which empties into the subclavian vein. As the fluid passes through the lymph nodes the extraneous materials are filtered out via macrophages, which contain enzymes capable of degrading triglycerides and cholesterol. The administration of the Erchonia Zerona has been proven to induce transitory pore formation, liberating accumulated fatty material, which is absorbed degraded by the lymphatic system and removed from the treated region, producing a slimming outcome based upon the volume reduction of cells.

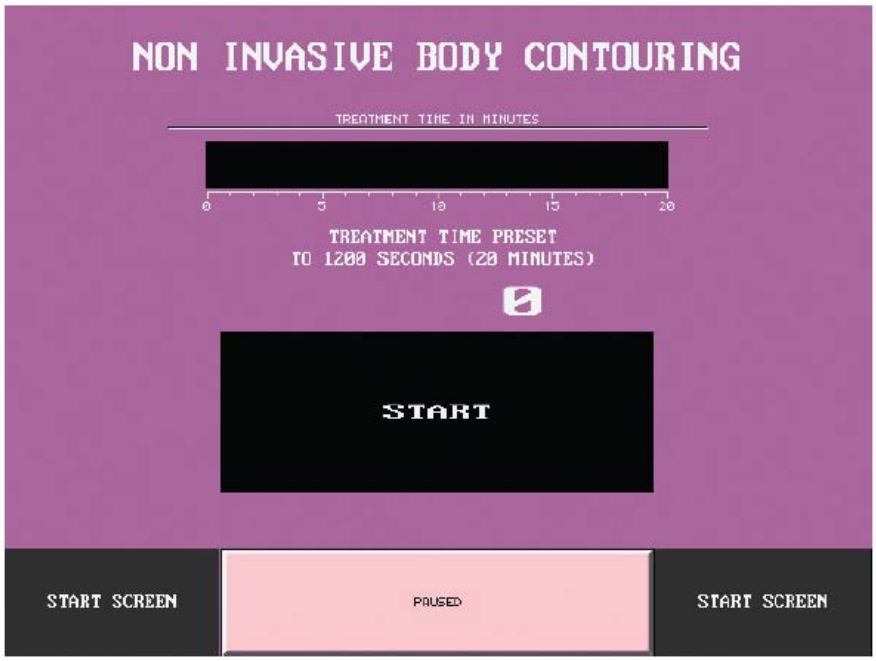
References: Niera, R., Arroyave, Ramirez, H., et al. Fat liquefication: Effect of low-level laser energy on adipose tissue. *Plast. Reconstr. Surg.* (2002): 110; 912-22.

Instructions for Use

Setting Up the Unit

To turn the unit ON, place the key in the key lock and turn to the ON position. NOTE: The unit requires a minimum of 30-45 seconds to launch the programming contained with the internal computers. Once the device is ready for use, the touch screen will display the non-invasive body contouring screen.

When you press the start button it will launch the non-invasive protocol. If for any reason you need to pause, press the pause button. To restart, press pause again. The “treatment time in minutes” field shows the elapsed time. The protocol is 20 minutes long and will stop automatically when complete. When done, return the key to the off position.



Front of the Body

1. The patient lies comfortably flat on his or her back on the table such that the front area of the patient's body encompassing the region spanning from the patient's stomach (abdomen) down through the hips and frontal aspect of both thighs, is facing upwards.
2. The center diode of the Erchonia Zerona is positioned at a distance of 6.00 inches above the patient, centered along the body's midline (the "line" that vertically "dissects" the body into two equal halves).
3. The Erchonia Zerona is activated for 20 minutes. Each scanner emits to the patient a laser beam of approximately 17mW with a wavelength of 635 nm, and creates a spiraling circle pattern that is totally random and independent from the others. These patterns overlap each other to guarantee total coverage within the target area of approximately 516 square centimeters.

Back of the Body

1. The patient turns over to lie flat on his or her stomach such that the back area of the patient's body encompassing the region spanning from the patient's back down through the hips and back aspect of both thighs is facing upwards.
2. The center diode of the Erchonia Zerona is positioned at a distance of 6.00 inches above the patient, centered along the body's midline (the "line" that vertically "dissects" the body into two equal halves).
3. The Erchonia Zerona is activated for 20 minutes. Each scanner emits to the patient a laser beam of approximately 17mW with a wavelength of 635 nm, and creates a spiraling circle pattern that is totally random and independent from the others. These patterns overlap each other to guarantee total coverage within the target area of approximately 516 square centimeters.

Application / Administration

The Erchonia Zerona is intended for use by health care professionals for non-invasive body contouring of the waist, hips, and thighs. The treatment protocol that is hard coded into the device has been developed in conjunction with Medical Doctors, Erchonia Medical Researchers and IRB advisors (see clinical trial summary). Medical professionals in receipt of this device are to use the preset as their medical training and experience dictate.

Clinical Trial Summary

A DOUBLE-BLIND, PLACEBO-CONTROLLED RANDOMIZED EVALUATION OF THE EFFECT OF THE ERCHONIA ZERONA ON BODY CONTOURING OF THE WAIST, HIPS AND THIGHS.
Erchonia Medical. Inc.

BACKGROUND: The purpose of this clinical study was to determine the effectiveness of the Erchonia Zerona for non-invasive body contouring of the waist, hips and thighs by applying the Erchonia Zerona around the waist, hips and thighs six times across two weeks.

STUDY DESIGN: The study was a placebo-controlled, randomized, double-blind parallel group design conducted across three independent test sites.

SUBJECTS: Sixty seven (67) subjects completed this study. Of the 67 participating subjects, 35 were randomized to the active procedure group and 32 were randomized to the placebo group.

Subjects were those aged 18 to 65 years with a Body Mass Index (BMI) of less than 30 kg/m² who were deemed suitable for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that had failed to respond to diet and exercise; specifically for the indication of body contouring in the areas of the waist, hips and bilateral thighs, as per the American Academy of Cosmetic Surgery's 2006 Guidelines for Liposuction Surgery developed by a joint Ad Hoc Committee of the American Society of Liposuction Surgery (ASLSS) and the American Academy of Cosmetic Surgery (AACS).

The majority of study subjects were Caucasian females, as illustrated in Table 1 below.

Table 1: Table of Subject Demographics

Gender	**Female**		**Male**	
n=67	*number*	*%*	*number*	*%*
	64	96%	3	4%
Ethnicity	**Caucasian**		**Caucasian/African American**	
n=67	*number*	*%*	*number*	*%*
	66	99%	1	1%

STUDY MEASURES: Circumference measurements for the hips, waist and bilateral thighs, and body mass index (BMI) were recorded at baseline, study mid-point (week 1), study endpoint (week 2), and study follow-up two weeks later. Subject satisfaction with the procedure outcome was recorded at study endpoint.

BASELINE MEASUREMENTS: Table 2 below contains the mean baseline circumference and BMI measurements.

Table 2: Mean Baseline measurements

	Test Group n=35	**Placebo Group n=32**	**All Subjects Combined n=67**
Body Mass Index (BMI)	25.74	26.05	25.89
Waist circumference (ins.)	33.94	34.85	34.37
Hip circumference (ins.)	38.99	39.88	39.41
Right thigh (ins.)	23.80	24.12	23.95
Left thigh (ins.)	23.59	24.14	23.85
Total circumference (ins.)	**120.31**	**122.99**	**121.59**

A series of t-tests for independent samples found there was no statistically significant difference in any of the above baseline measurements between subject procedure groups ($p>0.05$).

STUDY PROCEDURE: Subjects received six procedure administrations with the Erchonia Zerona to the front and back areas of the waist, hips and bilateral thighs, across a consecutive two-week period: three procedures per week, each procedure two to three days apart.

STUDY RESULTS

(i) Total Circumference Measurements: Individual circumference measurements for each of a subject's waist, hips and right and left thighs was combined to attain the study primary outcome measure of a combined total circumference measurement.

It was pre-determined that a subject would be considered a study success if he or she attained a 3.0 inch or greater reduction in total circumference measurement from baseline to study endpoint (after completion of the two-week procedure phase).

60.00% of subjects who received the study procedures with the actual Erchonia Zerona attained a decrease in total circumference measurement of 3.0 inches or greater compared with 6.25% of subjects who received the study procedures with a 'fake' (placebo) laser device. A Fischer's Exact Test for two independent proportions found this difference of 53.75% to be statistically significant at $p<0.00001$.

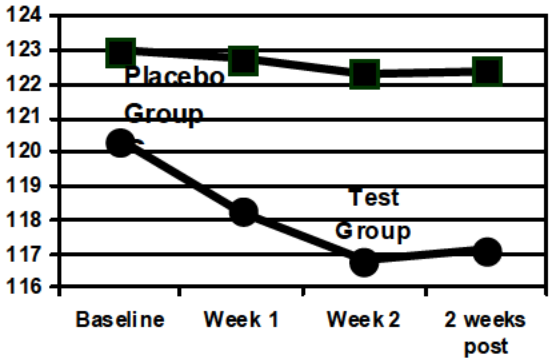
The magnitude of the mean change in total circumference measurement was a decrease of 3.521 inches for subjects who received the study procedures with the actual Erchonia Zerona and a decrease of 0.684 inches for subjects who received the study procedures with a 'fake' (placebo) laser device. A t-test for independent samples found the difference of 2.8378 inches in mean total circumference change between procedure groups to be statistically significant (t=-7.30; df=65; p(two-tailed)<0.0001). In confirmation, a One-Way ANOVA for 2 Independent Samples also found this mean difference between procedure groups in combined inches lost to be statistically significant (F=53.3623, p<0.0001).

Table 3 and Chart 1 below show the mean change in total circumference measurements across the four study measurement time points.

Table 3: Mean total circumference measurement (ins.) across evaluation points

	Test Group	Placebo Group
Baseline	120.31	122.99
Midpoint (week 1)	118.25	122.73
Endpoint (week 2)	116.79	122.31
Follow-up (week 4)	117.09	122.37

Chart 1: Mean total circumference measurement (ins.) across evaluation points



For test group subjects, total circumference measurements decreased progressively from baseline across the procedure administration phase, indicating a progressive and cumulative treatment effect of the laser.

Total circumference measurements stabilized across the subsequent 2-week follow-up assessment period during which time no laser procedures were administered, indicating duration of the treatment effect up to at least 2 weeks following the end of laser procedure administration. For placebo group subjects, there were no notable changes in total circumference measurements across or between any of the assessment points.

(ii) <u>Individual Area Circumference Measurements</u>: Table 4 below shows the mean circumference measurements for individual body areas.

Table 4: Mean individual body area circumference measurements.

	Test Group n=35				Placebo Group			
inches	**Waist**	**Hips**	**Right thigh**	**Left thigh**	**Waist**	**Hips**	**Right thigh**	**Left thigh**
Baseline	33.94	38.99	23.80	23.59	34.85	39.88	24.12	24.14
Week 1	33.38	38.26	23.31	23.30	34.85	39.80	24.10	23.98
Week 2	32.96	37.94	22.95	22.94	34.60	39.67	24.07	23.97
2 weeks post	32.86	38.29	23.02	22.92	34.53	39.66	24.16	24.02

As with total circumference measurements, individual area circumference measurements decreased progressively from baseline across the procedure administration phase for test group subjects, indicating a progressive and cumulative treatment effect of the laser. Individual body area circumference measurements then stabilized across the subsequent 2-week follow-up assessment period during which time no laser procedures were administered, indicating duration of the treatment effect up to at least 2 weeks. For placebo group subjects, there were no notable changes in individual body area circumference measurements across or between any of the measurement points.

(iii) Change in weight in pounds and change in body mass index (BMI): Neither weight measurements nor body mass index (BMI) changed notably across or between any of the four study measurement points for either test or placebo subject groups. However, individual body area and combined total circumference measurements did change notably across and between measurement points for test group subjects but not for placebo group subjects. This combined finding further supports the effectiveness of the Erchonia Zerona as it demonstrates that the change in body shape (statistically significant reduction in combined inches at the waist, hip and thighs) attained for test group subjects resulted from the Erchonia Zerona application and not from incidental weight loss or change in body mass index as a result of incidental weight loss.

(iv) Study outcome satisfaction ratings: At completion of the study procedure administration phase, the subject was asked to rate how satisfied he or she was with any overall change in body shape attained using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied.

70% of test group subjects reported being ‘Satisfied’ (Very or Somewhat Satisfied) with the outcome of the study procedures compared with 26% of placebo subjects. Conversely, 36% of placebo group subjects reported being ‘Dissatisfied’ (Not very satisfied or Not at all satisfied) compared with 3% of test group subjects.

(v) Adverse events: There was no adverse event for any subject throughout the duration of the clinical study. There was no change in skin markers in the treated body areas, and no notable deviation from baseline diet, exercise or concomitant medication use for any study subject.

CONCLUSION: The Erchonia Zerona is an effective tool for body contouring, significantly reducing circumference measurements when applied to the hips, stomach and bilateral thighs over a 2-week period.

Warnings / Cautions / Maintenance

Warnings

1. The long term effects of prolonged use of non-thermal laser exposure are unknown.
2. Laser treatment should not be applied over, or in proximity to, cancerous lesions as conclusive tests have not been conducted.
3. To eliminate any possible danger to the eyes safety glasses must be worn by the patient during treatment.

Cautions

1. Safety of non-thermal lasers for use during pregnancy has not been established.
2. Caution should be used over areas of skin that lack normal sensation.
3. Use only with accessories recommended by manufacturer.
4. Avoid the ingress of any liquid.

Maintenance and Cleaning

The Erchonia Zerona, if used according to the instructions contained within this manual will operate efficiently for years. To ensure proper care, it is advisable for the end-user to perform:

1. Regular visual inspection to make sure there is no external damage other than normal wear and tear. If during these inspections you identify an area of concern, please contact the manufacturer.
2. If you notice a change in the performance of the device while in the ON position, please contact the manufacturer.
3. The internal components should not require any maintenance, however if an issue arises, which will show itself in the form of altered performance, the device must be sent to the manufacturer.
4. Since the device contains a touchscreen interface, periodic cleaning of the touchscreen will be necessary. To clean the touchscreen, use warm soapy water only, applied with a clean cloth that has been wrung out to ensure there is NOT an excess of fluid.
5. The touchscreen back up battery must be replaced every five years. This must be done by manufacturer.
6. The unit must be stored, shipped and used at temperatures not to exceed 41C/105.8ºF.

Disposal

The Erchonia Zerona is a self-contained unit that emits light energy and as such creates no by-product that requires disposal; however, the unit itself, when spent and beyond repair or functional use, should be sent back to the manufacturer for disposal. This process ensures the proper separation and handling of all the internal parts and reduces any risk to the patient and/or environment.

Warranty Information

Limited Warranty
The Erchonia Zerona is warranted to be free from defect in material and workmanship for a period of TWO YEARS from the date of purchase. For warranty to be valid, it is critical that the end-user complete and return the enclosed warranty card. Failure to return warranty card may adversely impact warranty processing and/or void warranty.

Terms and Conditions
• This product contains a 30 day money back guarantee, which covers purchase price only. If for any reason, the end-user is unsatisfied with the product and/or its performance, it can be returned for full refund of purchase price.

• Shipping required facilitating warranty repair and or maintenance issues within the first 90 days will be paid by the manufacturer.

• Shipping required facilitating warranty repair and or maintenance issues after 90 days is the financial responsibility of the end-user.

• Warranty DOES NOT cover instances involving or damages resulting from:
- Accident, misuse or abuse
- Lack of responsible care
- Alteration or disassembly
- Loss of parts
- Exposure to the elements
- Ingress of liquid

• Warranty is NON-TRANSFERABLE. If device is sold to another party, by any one other than an approved Erchonia distributor, the warranty is VOID.

Point of Contact
If for any reason you are dissatisfied with this product, have warranty concerns or questions regarding proper operation of the device; please call 214.544.2227 for immediate assistance.

Warranty Card
Please remove warranty card from packaging, complete and mail within 90 days of purchase. Failure to do so may adversely impact manufacturer's ability to successfully administer warranty.

ERCHONIA

World Leader in Low Level Laser Technology™

Erchonia Corporation
2021 Commerce Drive McKinney, TX 75069
1-888-242-0571 or 214-544-2227

COVER SHEET MEMORANDUM

From: Reviewer Name Richard P. Fallen

Subject: 510(k) Number K121695 S1

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			N/A
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			N/A
Is clinical data necessary to support the review of this 510(k)?			X
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			X

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	**Class***	**Product Code**
878.5400	II	OLI

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: [signature] (Branch Chief) GSDB (Branch Code) 8/22/12 (Date)

Final Review: [signature] (Division Director) 8/23/12 (Date)

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K121695/S1____

Date: August 21, 2012
To: The Record
From: Richard P. Felten

Office: ODE
Division: DSORD

510(k) Holder: Regulatory Insight, Inc
Device Name: Erchonia Zerona
Contact: Kevin Walls, Principal Consultant
Phone: 720-962-5412
Fax: 720-962-5413
Email: kevin@reginsight.com

Agree pDF 8/23/12

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Erchonia Zerona into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form			X

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

The Erchonia Zerona is the identical device previously granted marketing permission through the granting of a reclassification petition under the de Novo reclassification regulation. There have been no changes to the indication for use, technology, risk assessment, or software design. A modification has been made

to the indication for use, not to the essential use of reduction in circumference of waist, hips, and thighs, but to specifying the target population by adding to the indication the specific population the device is intended to treat. This change is to include in the indication for use the phrase "adjunct for individuals intending to undergo liposuction procedures.

IV. Indications for Use

The Erchonia Zerona is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

V. Predicate Device Comparison

This device is identical to the device previously granted marketing through K082609. There have been no changes to the device. This application is limited to a change in device Trade Name.

VI. Labeling

The User Manual is essentially identical to the originally cleared manual under K082609. Review of this manual has identified several editorial issues that the company will be asked to revise. The major issue in the manual is the use of the term "body contouring" which implies uses beyond the limit specific indications granted for waist, hip, and thigh circumference reduction.

The company has deleted reference to "body contouring" and "non-invasive body contouring" that were used in the indication for use, in the application section, and as part of the computer screen.

The company has also provided a completely revised User Manual which contains the revised indication for use, the revised and clearer laser warning label which now includes the 17 mW output value and revised applications and screen labeling that no longer includes use of the phrase "body contouring".

VII. Sterilization/Shelf Life/Reuse

N/A

VIII. Biocompatibility

N/A

IX. Software

There is no change to the software for this application. This 510(k) is limited to a Trade Name change.

Version:		
Level of Concern:		
	Yes	**No**
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Provided in K082609

8

XI. Performance Testing – Bench

N/A

XII. Performance Testing – Animal

N/A

XIII. Performance Testing – Clinical

N/A

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	X		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

XV. Deficiencies

XVI. Contact History

Mr. Kevin Walls was contacted by electronic mail on August 20, 2012 and requested to provide the revised page 1 having the revised Common Name information. This was received by electronic mail on August 20, 2012.

XVII. Recommendation SE

Regulation Number: 21 CFR 878.5400
Regulation Name: Low level laser for aesthetic use.
Regulatory Class: Class II
Product Code: OLI

Richard P. Fellen
Reviewer

Aug 21, 2012
Date

I concur with name change - SE.
Branch Chief

8/22/12
Date

August 21, 2012

Review of K121695/S1

Submitted by Regulatory Insight, Inc.
for Erchonia Corporation

Reviewed by Richard P. Felten, DSORD, GSDB

Richard P. Felten

This supplement is the company's response to our request for additional information forwarded to the company by electronic mail on June 20, 2012. This application was submitted solely to change the name of the device from Erchonia ML Scanner to Erchonia Zerona. The company has stated that there are no changes in indications for use, device design, or software.

Review of the original submission identified a number of issues that needed to be addressed. The company has provided the following responses:

1. The company has corrected several locations where the original device name of ML Scanner was still used and the company has provided revised pages correcting this problem.

2. The company has provided a revised laser warning label.

3. The company has deleted reference to "body contouring" and "non-invasive body contouring" that were used in indication for use statement, was part of the application for use section, and was on the computer screen.

4. In responding to our issue of identifying their device as a fat reducing low level laser the company pointed out that this was based on the identifier used in our Product Code data base. The company was informed that product codes are for internal tracking purposes only and were not intended as regulatory definition of marketed devices. The company agreed to change the Common Name of their device to Low Level Laser and provided this change by electronic mail dated August 20, 2012.

5. The company pointed out in response to our issue of patient identification that the term identifying patients as those intended to have liposuction procedures had been part of prior Erchonia submittals, specifically K041139. Review of the history of the Erchonia low level lasers for body circumference reduction and for localize pair relief did show that this patient identifier had been commonly used in company comparison tables. It was therefore decided that in keeping with the prior clearance for K41139 we would request that the company specifically include in the indication for use statement the patient identifier by adding the phrase "adjunct for individuals intending to undergo

liposuction procedures". The company has agreed to this change and has provided the revised stand alone indications for use page.

Besides making the above changes, Erchonia has included in this response a revised FDA Form 3514 which now contains the revised indications for use statement. The company has also provided a completely revised User Manual which contains the revised indication for use, the revised and clearer laser warning label which now includes the 17 mW output value and revised applications and screen labeling that no longer includes use of the phrase "body contouring".

At this time all of the deficiencies identified in our original review have been adequately addressed. This application does include the required Truthful and Accurate Statement. The company has decided not to provide a 510(k) Summary but instead has provided the 510(k) Statement.

This application was submitted solely for a name change to the device. There have been no changes in indication in terms of the specific indication of reduction in circumference of waist, hips, and thighs and not changes to the device or its software.

I recommend that this application be determined to be Substantially Equivalent to the predicate cleared under K082609.

Felten, Richard P.

From: Kevin Walls [kevin@reginsight.com]
Sent: Tuesday, July 31, 2012 3:44 PM
To: Felten, Richard P.
Cc: Ogden, Neil; Steve Shanks; Debra Engolia
Subject: RE: Erchonia K120690 and K120695
Attachments: 001_OM Manual_Zerona_7_31_2012.pdf; 002_Form 3514_Zerona.pdf; 003_Indications for Use Statement_Zerona.pdf; 004_Comparison Table_Zerona.pdf; 001_OM-Zerona-AD_7_31_2012.pdf; 002_Form 3514_Zerona-AD.pdf; 003_Indications for Use Statement_Zerona-AD.pdf; 004_Comparison Table_Zerona-AD.pdf

Dear Mr. Felten,

The Sponsor of 510(k)s K120690 and K120695 agrees to all of your proposed changes. Please refer to the attached revised O&M Manuals, Forms 3514, Indications for Use Statements and Comparison Tables, which address the following:

a) replaced the labels to show a laser output of 17 mW
b) replaced the Common Name "Fat reducing low level laser" with "Low level laser"
c) replaced the indications for use with the statements you listed below.

Please let me know whether you have any additional questions or concerns of if there is any additional information we can provide to you in order for FDA to find both the Zerona-AD (K120690) and the Zerona (K120695) substantially equivalent.

Best regards,
Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.
Phone: +1-720-962-5412
Fax: +1-720-962-5413
Email: kevin@reginsight.com
Web: www.reginsight.com
Public Profile: http://www.linkedin.com/in/kevinwalls

From: Felten, Richard P. [mailto:Richard.Felten@fda.hhs.gov]
Sent: Tuesday, July 31, 2012 8:39 AM
To: Kevin Walls (kevin@reginsight.com)
Cc: Ogden, Neil
Subject: Erchonia K120690 and K120695

Kevin:

I have completed the review of these two applications and have discussed them with Neil Ogden. There are two areas that we do not agree with your responses.

(b)(4)

[redacted]

(b)(4)

[redacted]

Plese make the requested changes to these applications. The revised sections of the applications can be sent to me by electronic mail.

Richard P. Felten
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Surgical, Orthopedic, and Restorative Devices
General Surgery Devices Branch

E-mail: Richard.Felten@fda.hhs.gov
Phone: (301) 796-6392

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
06/06/2012	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Erchonia Corporation	2032513		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	214-544-2227		
Street Address	**FAX Number *(including area code)***		
2021 Commerce Dr.	214-544-2228		
City	**State / Province**	**ZIP/Postal Code**	**Country**
McKinney	TX	75069	USA
Contact Name			
Steven Shanks			
Contact Title	**Contact E-mail Address**		
President	SShanks@erchonia.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Regulatory Insight, Inc.			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	720-962-5412		
Street Address	**FAX Number *(including area code)***		
5401 S. Cottonwood Ct.	720-962-5413		
City	**State / Province**	**ZIP Code**	**Country**
Greenwood Village	CO	80121	USA
Contact Name			
Kevin Walls			
Contact Title	**Contact E-mail Address**		
Principal Consultant	kevin@reginsight.com		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☒ Other Reason *(specify)*:

Change in name only. There are no changes made in the technology or the indications for use.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	OLI	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached
☒ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K082609	ERCHONIA ML SCANNER (MLS)	Erchonia Corporation
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Low Level Laser

	Trade or Proprietary or Model Name for This Device	Model Number
1	Erchonia Zerona	
2		
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	K082609	2	3	4	5	6
7		8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
OLI	878.5400	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
General & Plastic Surgery		

Indications *(from labeling)*

The Erchonia Zerona is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Erchonia Corporation		Establishment Registration Number: 2032513	
Division Name *(if applicable)*		Phone Number *(including area code)*: 214-544-2227	
Street Address: 2021 Commerce Dr.		FAX Number *(including area code)*: 214-544-2228	
City: McKinney		State / Province: TX	ZIP Code: 75069 / Country: USA
Contact Name: Steven Shanks	Contact Title: President	Contact E-mail Address: SShanks@erchonia.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	IEC	Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.		10/31/2005
2	60601-1-2	AAMI / ANSI / IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests		09/09/2008
3	60825-1	IEC	Safety of laser products - Part 1: Equipment classification and requirements CORRIGENDUM 1		03/18/2011
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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 control number.

Indications for Use

510(k) Number (if known): K121695

Device Name: Erchonia Zerona

Indications for Use: The Erchonia Zerona is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Comparison of the New and Predicate Devices

Device	Erchonia ML Scanner (MLS)	Erchonia Zerona
510(k)	K082609	120695
Indications for Use	The Erchonia ML Scanner (MLS) is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs	The Erchonia Zerona is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.
Power	17 mw	17 mw
Wavelength	Red 630 nm – 640 nm (near infrared)	Red 630 nm – 640 nm (near infrared)
Waveform	Pulsed	Pulsed
Energy Source	Five diodes, each collected then line dispersed and rotated	Five diodes, each collected then line dispersed and rotated
Power Supply	AC	AC
Energy Delivery	Machine mounted probe	Machine mounted probe
Treatment Time	20 minutes	20 minutes
Target Size	Line pattern, mechanically rotated to form circles and scanned over treatment area.	Line pattern, mechanically rotated to form circles and scanned over treatment area.
Target Population	Individuals intending to undergo liposuction procedure.	Individuals intending to undergo liposuction procedure.
Locations for Use	Hospital, health care provider office.	Hospital, health care provider office.

Felten, Richard P.

From: Kevin Walls [kevin@reginsight.com]
Sent: Monday, August 20, 2012 12:29 PM
To: Felten, Richard P.
Cc: Steve Shanks; Debra Engolia
Subject: RE: Erchonia
Attachments: Zerona 510(k) Page 1.pdf; Zerona-AD 510(k) Page 1.pdf

Dear Mr. Felten

Please refer to the revised Page 1 of both 510(k)s.

Best regards,
Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.
Phone: +1-720-962-5412
Fax: +1-720-962-5413
Email: kevin@reginsight.com
Web: www.reginsight.com
Public Profile: http://www.linkedin.com/in/kevinwalls

From: Felten, Richard P. [mailto:Richard.Felten@fda.hhs.gov]
Sent: Monday, August 20, 2012 9:56 AM
To: Kevin Walls (kevin@reginsight.com)
Subject: Erchonia

Kevin:

I apologize but just realized I also do not seem to have the revised page one with the Common Name changed to Low Level Laser. I need this for both applications.

Thanks

Richard

Name and Address of Sponsor

Erchonia Corporation
2021 Commerce Dr.
McKinney, TX 75069
Phone: 214-544-2227
Fax: 214-544-2228

Name and Address of Manufacturer

Erchonia Corporation
2021 Commerce Dr.
McKinney, TX 75069
Phone: 214-544-2227
Fax: 214-544-2228

Establishment Registration Number

2032513

Name and Address of Official Correspondent

Regulatory Insight, Inc.
5401 S. Cottonwood Ct.
Greenwood Village, Colorado 80121
Contact: Mr. Kevin Walls, RAC
Telephone: 720-962-5412
Fax: 720-962-5413
Email: kevin@reginsight.com

CDRH Premarket Review Submission Cover Sheet

Please refer to the completed Form FDA 3514 contained in **Appendix A**.

Truthful and Accuracy Statement

See **Appendix B**.

510(k) Statement

See **Appendix C**.

Device Name

Trade Name: Erchonia Zerona
Common Name: Low level laser
Classification Name: Low level laser system for aesthetic use

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Richard P. Fe Iten

Subject: 510(k) Number K121695

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold). Electronic Mail 6-20-2012

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number	**Class***	**Product Code**
878.5400	II	OLI

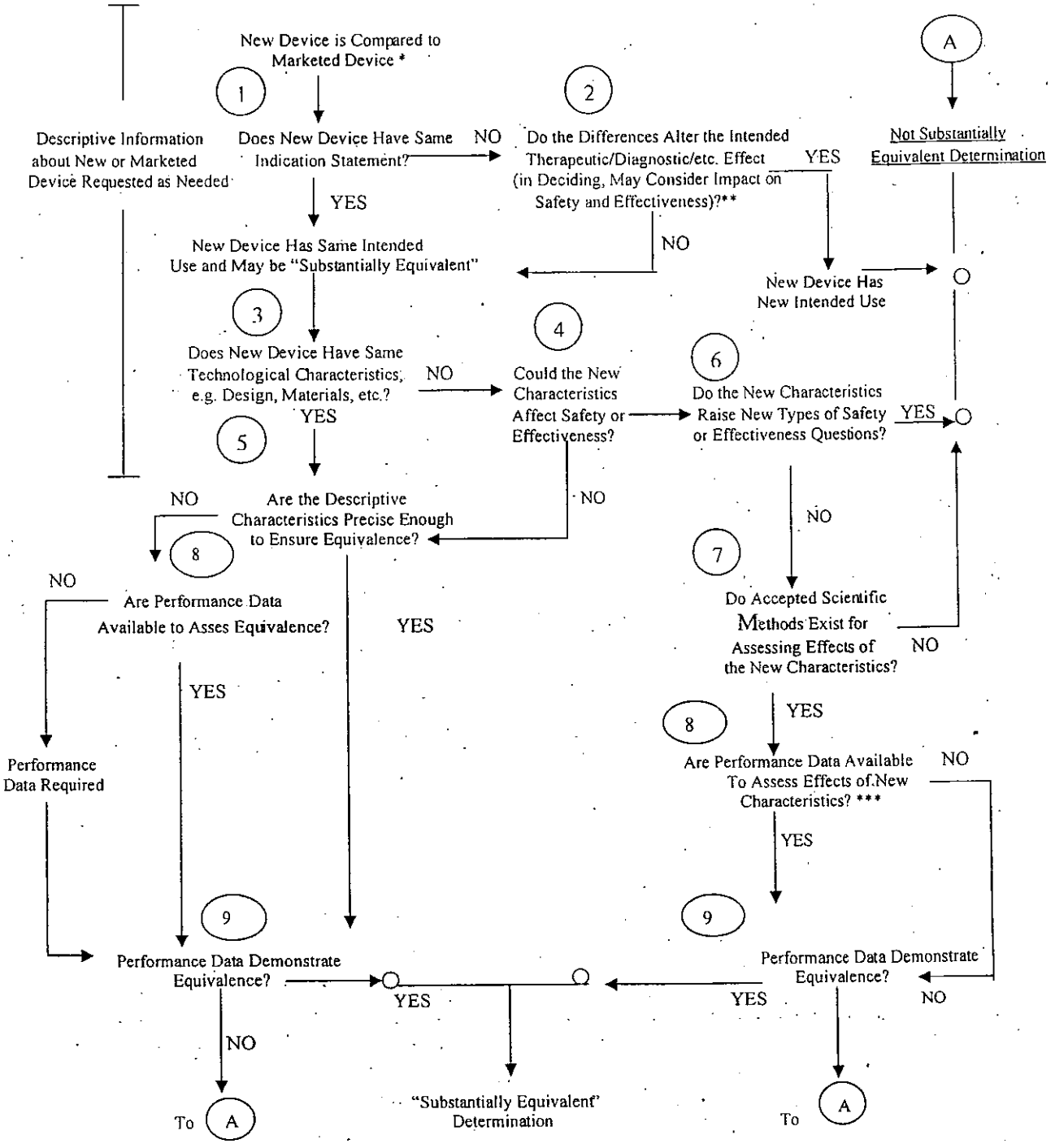
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Neil R P Ogden (Branch Chief) GSDB (Branch Code) 6/20/12 (Date)

Final Review: (Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K121695

Date: June 18, 2012
To: The Record
From: Richard P. Felten

Office: ODE
Division: DSORD

510(k) Holder: Regulatory Insight, Inc
Device Name: Erchonia Zerona
Contact: Kevin Walls, Principal Consultant
Phone: 720-962-5412
Fax: 720-962-5413
Email: kevin@reginsight.com

I. Purpose and Submission Summary

The 510(k) holder would like to introduce the Erchonia Zerona into interstate commerce.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form			X

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

(b)(4) [redacted]

IV. Indications for Use

The Erchonia Zerona is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.

V. Predicate Device Comparison

This device is identical to the device previously granted marketing through K082609. There have been no changes to the device. This application is limited to a change in device Trade Name.

(b)(4) [redacted]

VII. Sterilization/Shelf Life/Reuse

N/A

VIII. Biocompatibility

N/A

IX. Software

There is no change to the software for this application. This 510(k) is limited to a Trade Name change.

Version:		
Level of Concern:		
	Yes	**No**
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies:		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Provided in K082609

XI. Performance Testing – Bench

N/A

XII. Performance Testing – Animal

N/A

XIII. Performance Testing – Clinical

N/A

XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?			If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?			If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

XV. Deficiencies

(b)(4)

[redacted]

75

(b)(4)

[redacted]

XVI. Contact History

(b)(4)

[redacted]

XVII. Recommendation HOLD
Regulation Number: 21 CFR 878.5400
Regulation Name: Low level laser for aesthetic use.
Regulatory Class: Class II
Product Code: OLI

Richard P. Felton
Reviewer

June 18, 2012
Date

[signature] I concur with AI issues.
Branch Chief

6/20/12
Date

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June 18, 2012

Review of K121695

Submitted by Regulatory Insight, Inc.
for Erchonia Corporation

Reviewed by Richard P. Felten, DSORD, GSDB

Richard P. Felten

(b)(4)

[redacted]

(b)(4)

[redacted]

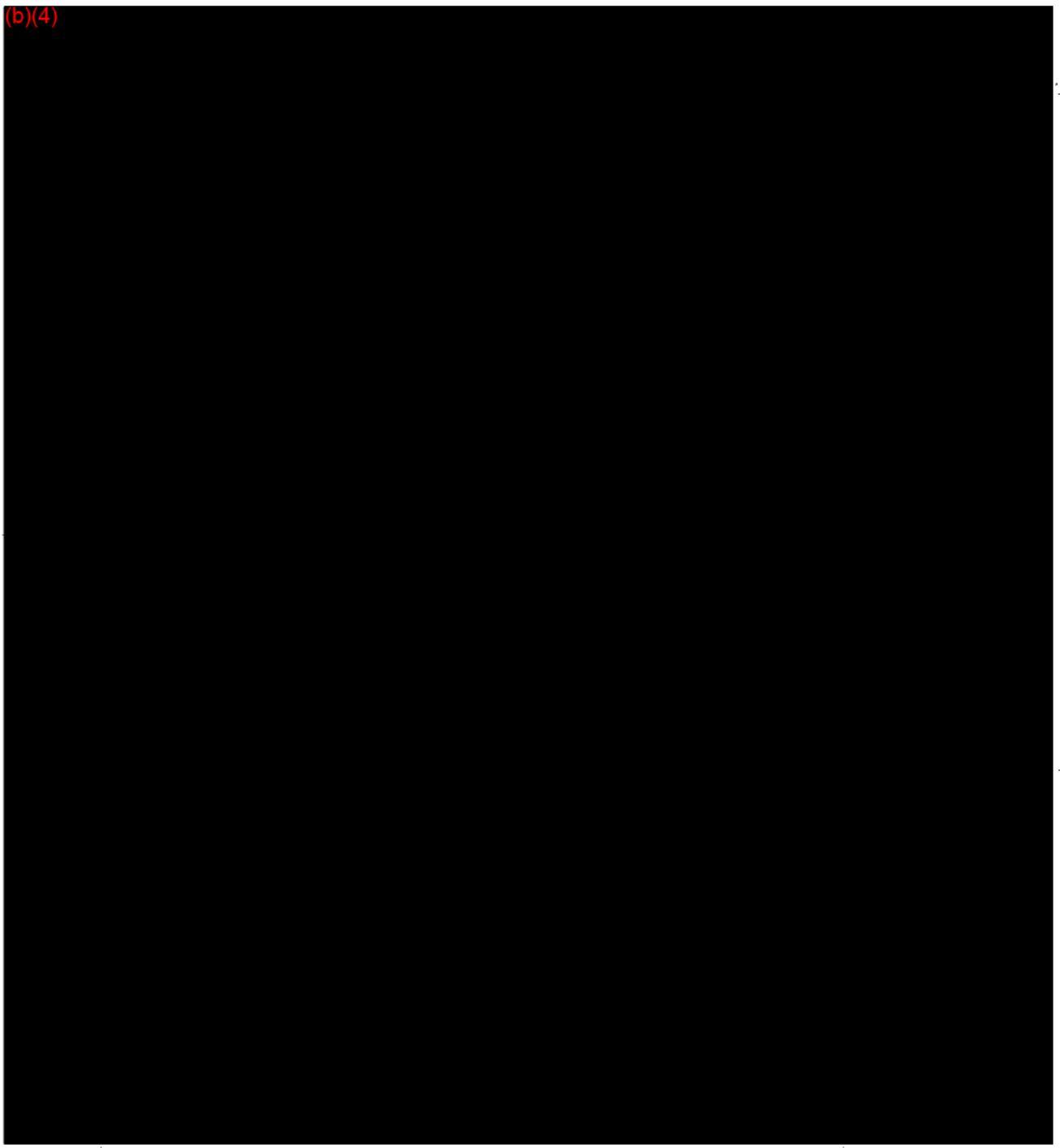
June 18, 2012

K121695

Erchonia Zerona Deficiencies

Richard P. Felten, DSORD, GSDB

(b)(4)



(b)(4)

[redacted]

I concur.

6/20/12

Felten, Richard P.

From: Tylka, Corinne S.
Sent: Friday, June 15, 2012 3:23 PM
To: Felten, Richard P.
Subject: RE: Laser Labeling

Hi Richard,

(b)(4) [redacted]

Does that make sense?

Cory

From: Felten, Richard P.
Sent: Friday, June 15, 2012 3:07 PM
To: Tylka, Corinne S.
Subject: Laser Labeling

Cory:

(b)(4) [redacted]

Thanks

Richard

81

Felten, Richard P.

ɔm: Felten, Richard P.
nt: Wednesday, June 20, 2012 9:52 AM
To: Kevin Walls (kevin@reginsight.com)
Subject: Erchonia Name Changes

Attachments: Erchonia Zerona-AD Name Change Deficiencies K121690.doc; Erchonia Zerona Name Change Deficiencies K121695.doc

Kevin:

(b)(4)

[redacted]

Erchonia Zerona-AD Name Change...

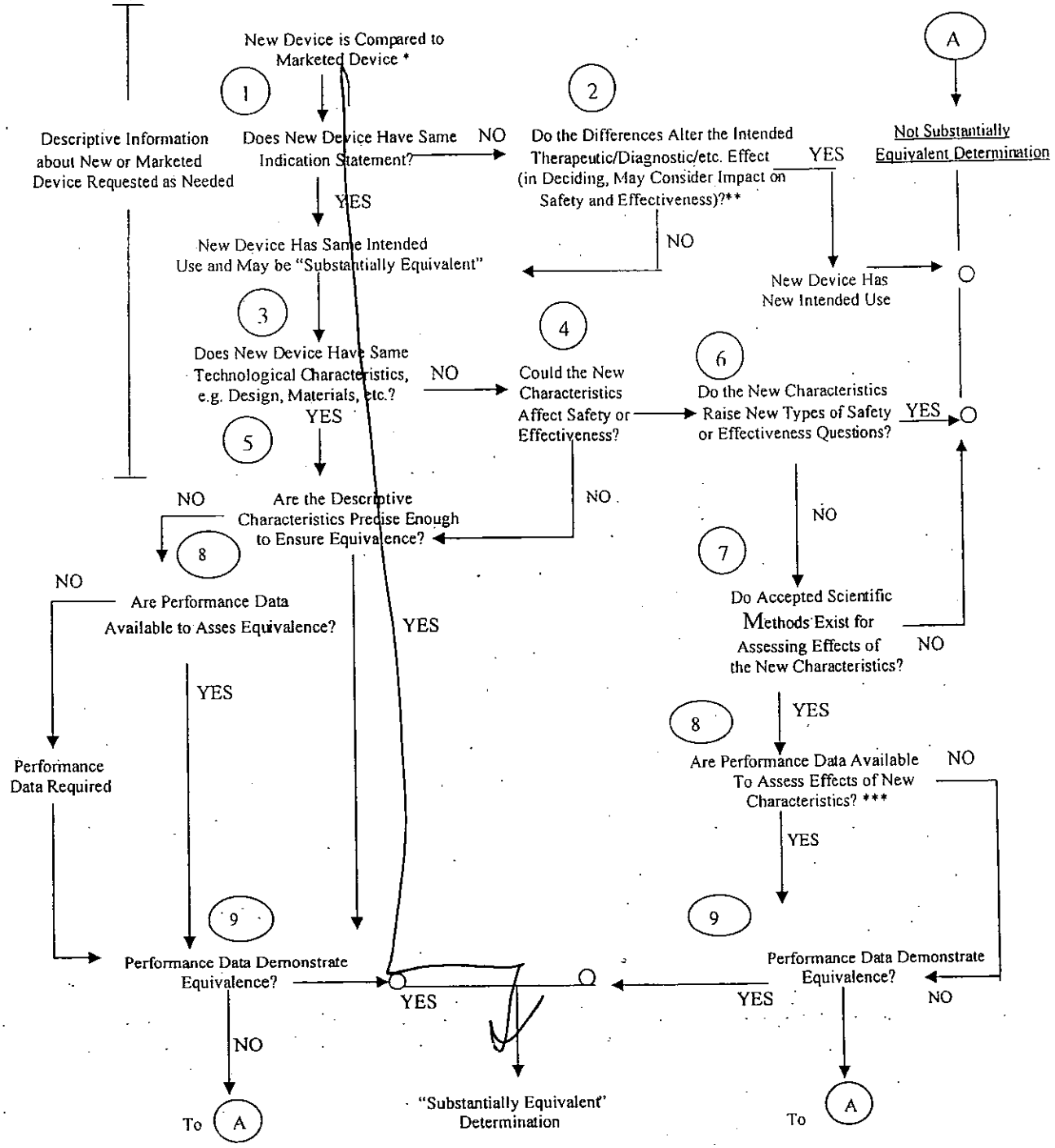
Erchonia Zerona Name Change De...

Richard P. Felten
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Surgical, Orthopedic, and Restorative Devices
General Surgery Devices Branch

E-mail: Richard.Felten@fda.hhs.gov
Phone: (301) 796-6392

82

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 24, 2012

ERCHONIA CORPORATION
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT.
GREENWOOD VILLAGE, COLORADO 80121
ATTN: KEVIN WALLS

510k Number: K121695

Product: ERCHONIA ZERONA

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

Grayson, Giovanna *

From: Microsoft Outlook
To: 'kevin@reginsight.com'
Sent: Tuesday, July 24, 2012 1:27 PM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'kevin@reginsight.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

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Regulatory Insight, Inc.
Worldwide Medical Device Submissions and Quality Systems

K121695 | 87

FDA/CDRH/DCC

JUL 24 2012

RECEIVED

July 20, 2012

Mr. Richard Felten
U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: FDA's Request for Additional Information for 510(k) K121695 for the Erchonia Zerona

Dear Mr. Felten:

The following is Erchonia Corporation's response to FDA's request for additional information for

(b)(4)

[redacted]

33 Golden Eagle Lane • Littleton, Colorado 80127 • U.S.A.
Phone: (720) 962-5412 • Fax: (720) 962-5413
E-mail: info@reginsight.com • Web: www.reginsight.com

Device	Erchonia MLS Laser (New)	Erchonia EML Laser (Predicate)
510(k)	N/A	K041139
Indications for Use	The Erchonia® ML Scanner (MLS) is indicated for non-invasive body contouring of the waist, hips and thighs	The Erchonia EML is indicated as an adjunct to liposuction procedures of the thighs, hips and stomach for reduction of pain associated with the recovery process.
Power	1 mw	1 mw
Wavelength	Red 630 nm – 640 nm (near infrared)	Red 630 nm – 640 nm (near Infrared)
Waveform	Pulsed	Pulsed
Energy Source	Five diodes, each collected then line dispersed and rotated	Dual diode collected then line dispersed (coherent)
Power Supply	AC	115/220 V ac 50/60 Hz electrical outlet, rechargeable batteries
Energy Delivery	Machine mounted probe	Handheld treatment probe
Treatment Time	0 – 9.9 minutes	0 – 9.9 minutes
Target Size	Line pattern, mechanically rotated to form circles and scanned over treatment area.	Line pattern, manually scanned over area of treatment
Target Population	Individuals intending to undergo liposuction procedure.	Individuals undergoing liposuction procedure.
Locations for Use	Hospital, health care provider office.	Hospital, health care provider office.

3. *On page ii of Appendix E, the term MLS Components is still in the Contents List.*

   Response: The Operation and Maintenance Manual was corrected to state, "Erchonia Zerona Components". Please refer to the new Manual contained in **Appendix A**.

4. *On page 7 of Appendix E, the laser warning label can not be read. This label should be of adequate size that the reader of the User Manual can clearly read the contents of the Laser Label.*

   Response: The label contained on Page 7 of the Operation and Maintenance Manual was enlarged so it can be read. Please refer to the new Manual contained in **Appendix A**.

(b)(4)

[redacted]

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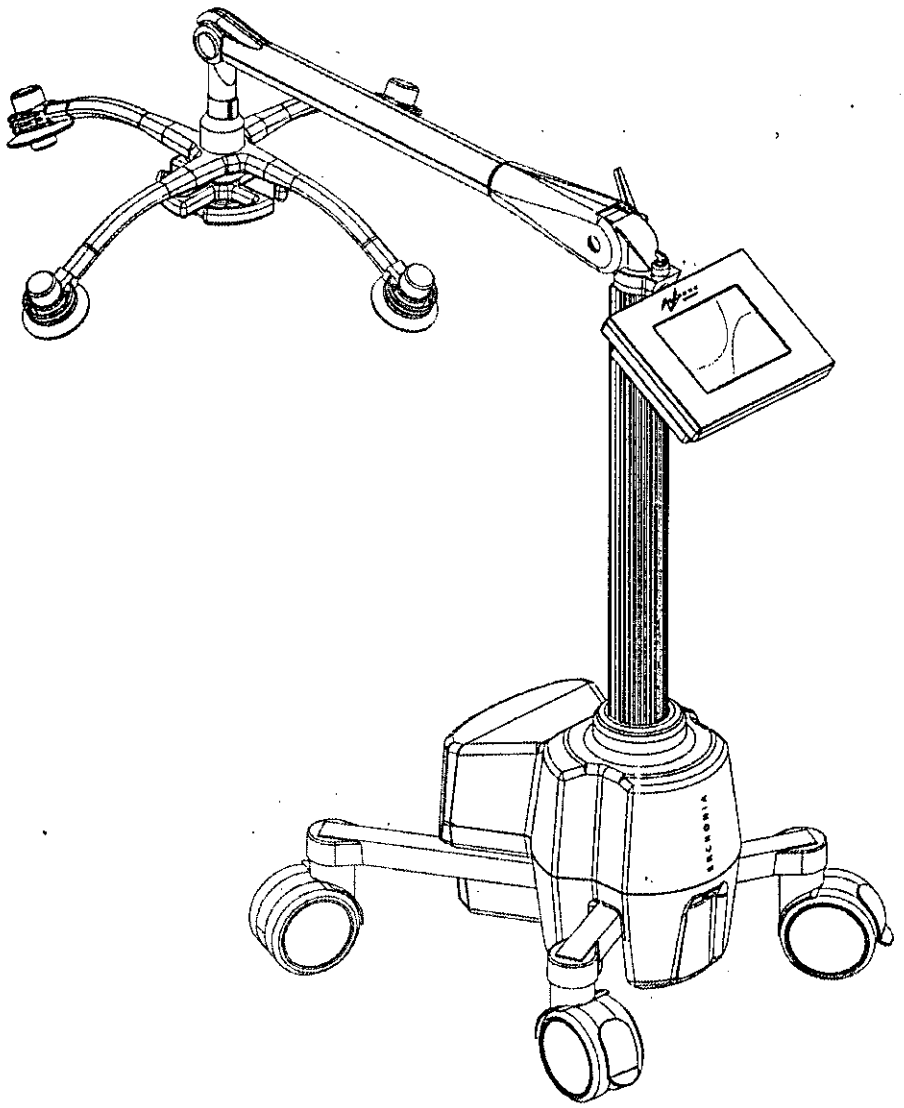
(b)(4)

[redacted]

Respectfully yours,

Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.



Erchonia Zerona

Operation & Maintenance Manual

Acknowledgements and Accreditations

We at Erchonia® Corporation would like to thank you for purchasing the Erchonia Zerona.

Erchonia® Corporation is an ISO certified company and undergoes periodic audits by external governing agencies, including the FDA, in order to ensure compliance to the highest quality standards. Our company is run in accordance to and our devices are manufactured in accordance with:

- FDA Good Manufacturing Practices
- ISO 9001:2000 - Quality
- ISO 13485:2003 - Medical
- ISO 60825-1 - Laser Safety
- FDA Laser Class 2
- IEC Laser Class 2
- MDD 93/42/EEC
- EN/IEC 60601-1-2 EMC
- EN/IEC EN60601-1-1 Safety

Legend:

FDA - US Food &Drug Administration, which includes the CDRH (Center for Device Radiological Health)
ISO - International Standards, Harmonized with US, Canadian, European and Asian standards
MDD - Medical Device Directive

Doc No.	Issue Date	Rev. Level	Rev. Date
O&M-MLS	7/12/07	1B	8/12/08
O&M-MLS	7/12/07	1C	5/27/10
O&M-Zerona	6/5/12	1D	6/5/12

Legend:
The following symbols are throughout the text of this manual to identify areas of concern. For your safety, the safety of your patients and the care of the device, please heed.

WARNING: Failure to heed this warning can result in harm to the patient and / or damage to equipment.

CAUTION: Failure to heed this caution can result in a malfunction of the equipment.

Erchonia® Corporation
2021 Commerce Drive McKinney, TX 75069
Phone 214.544.2227 • Fax 214.544.2228
www.erchonia.com

Table of Contents

Erchonia Zerona Components

The Erchonia Zerona model has been shipped to you with some assembly required. This section is included for you to familiarize yourself with the components of the unit ensuring the remainder of this manual is clearly communicated.

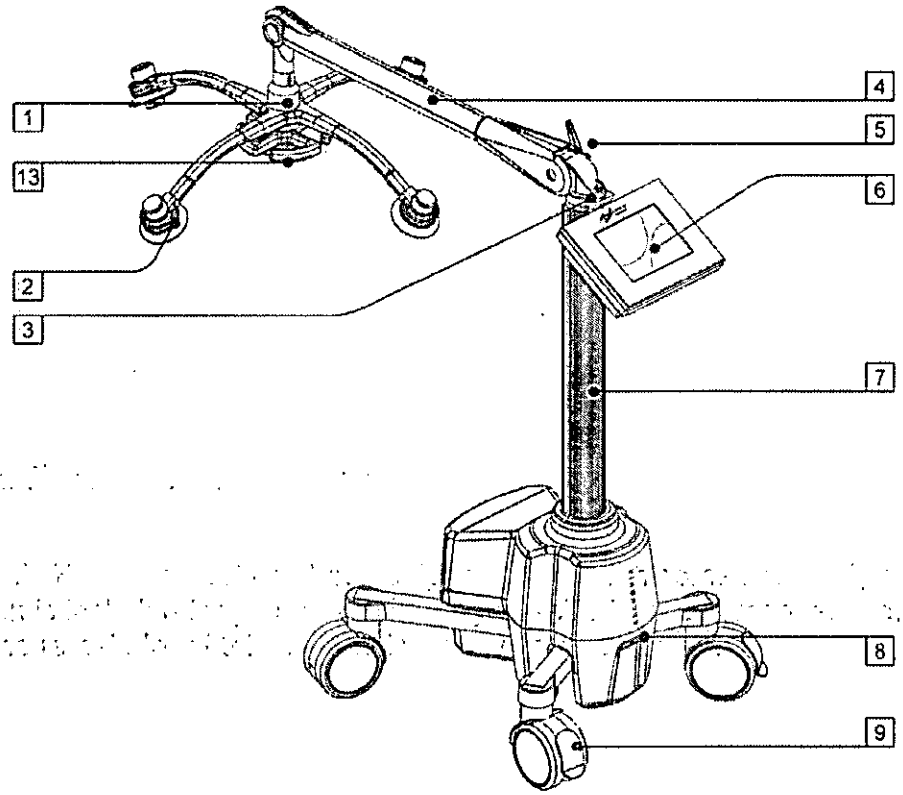


Fig 1

1. Laser Head Assembly
2. Laser Output Head
3. Power Safety Lockout Key
4. Laser Arm
5. Arm Lock
6. Touchscreen Control Surface
7. Main Upright of Base
8. Power Inlet
9. Rear Wheel Lock
10. Power Cord (Fig 2)
11. Locking Nut (Fig 2)
12. Electrical Connector (Fig 3)
13. Handle

Assembly Instructions

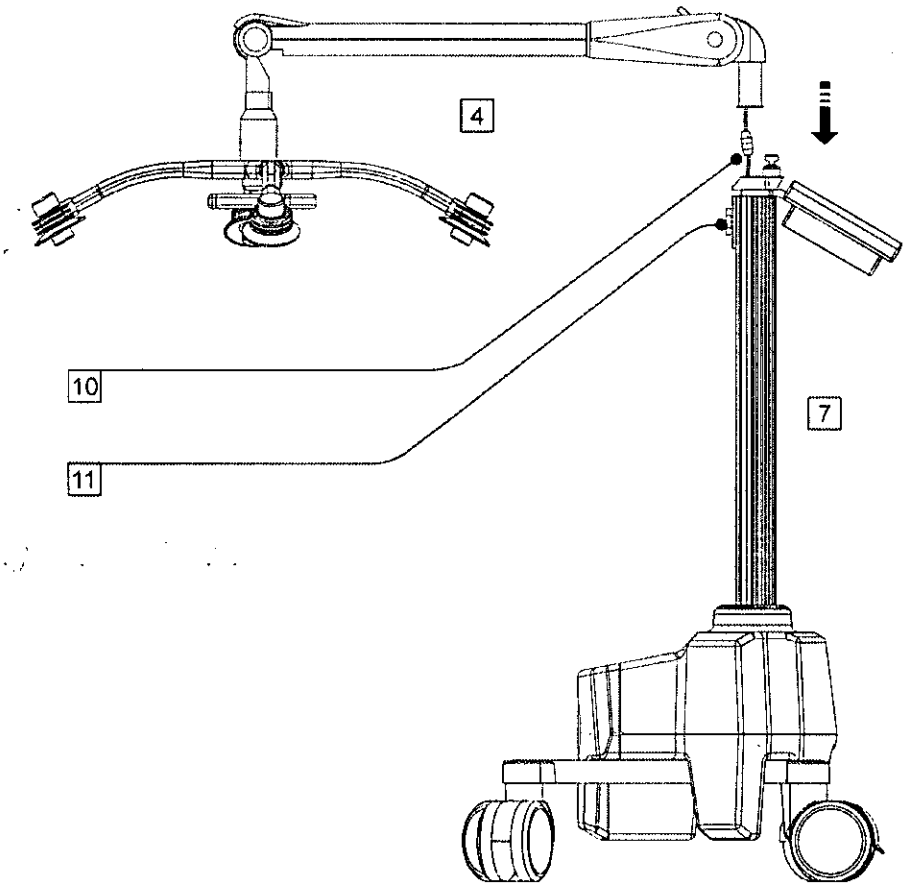


Fig. 2

Step 1:
The electrical connection [12] from the base to the arm must be connected as shown in fig 3.

Simply insert the 2 halves of the electrical connection (Fig 3) together slightly pushing the outlet into the inlet. Twist until secure. (The connector can only be connected one way)

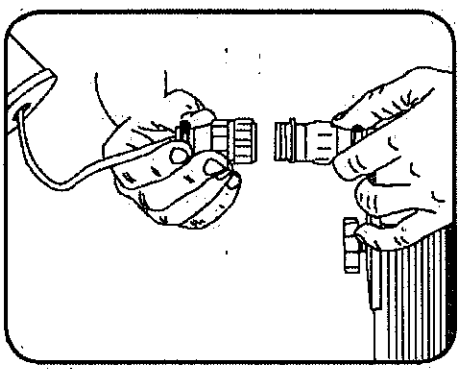


Fig. 3

After insertion, hold the female connector secure while gently twisting the locking collar until it locks **and can no longer be twisted.** This is important so the two halves do not separate over time.

Step 2:
Remove or loosen the locking nut [11] as shown in figure 4.

Step 3:
Gently feed the connector and cable into the base main upright [7] as shown in figure 5. It must be pushed into the hole.

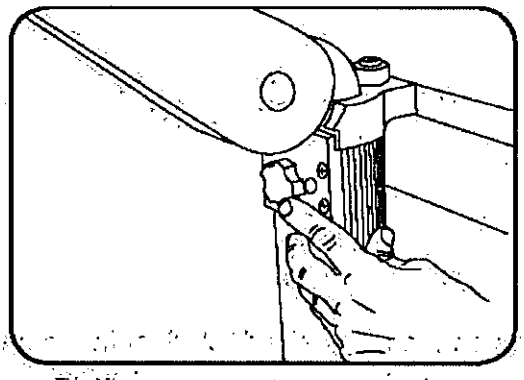


Fig. 4

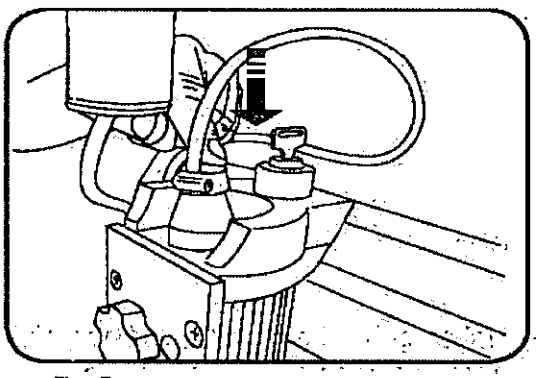


Fig. 5

Step 4:
After the wire and connector have been fed into the hole insert the arm tube into the base main upright [7] as shown in figure 6. Insertion is easier with a helper. Also make sure the tube is aligned with the hole.

After the tube is inserted and pushed down to the bottom of its slot, carefully screw in the locking nut [11] (as shown in figure 7) into the treaded opening in the arm tube and tighten. This will keep the main head assembly from unwanted rotation during use. Your Zerona is now ready for use.

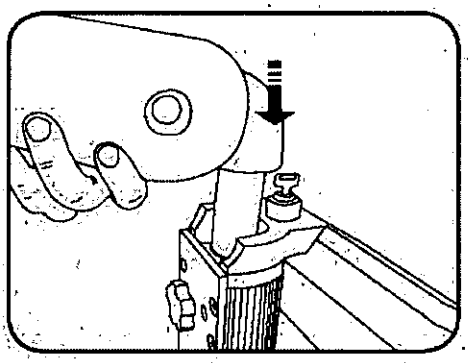


Fig. 6

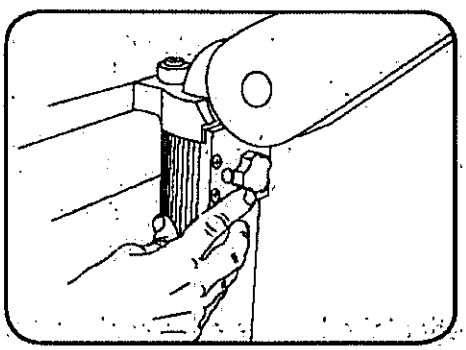


Fig. 7

Additional Information

The arm tension can be adjusted or locked into position with lever [5] as shown in figure 8.

To activate your Zerona, the safety key [3] must be inserted into its socket located on the top of the base upright as shown in figure 9. After insertion turn it to the right to turn on. Because the Zerona has 2 computers when you first turn it on it will take a few moments to warm up before use.

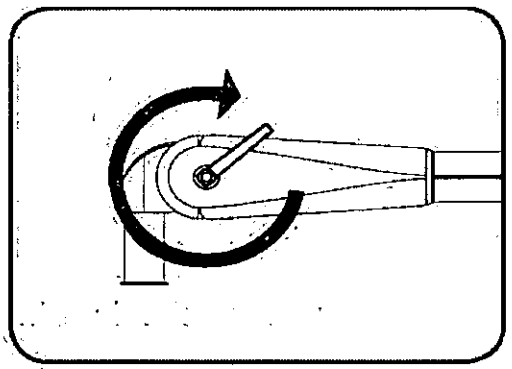


Fig. 8

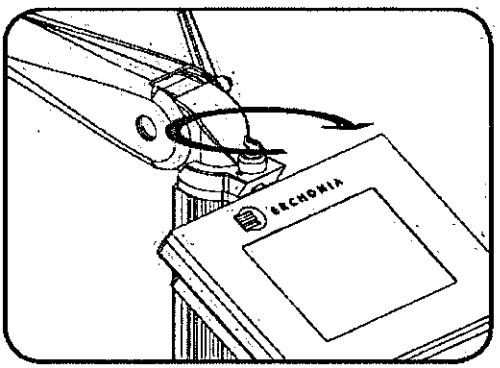


Fig. 9

If you are having problems pushing the wire harness and wires into the column, or if you have dropped the unconnected end in the column and need to retrieve it for connection, the front panel can be slid down as shown. This exposes the wires in the column.

If you need to go further down the column to retrieve the connector the panel can be pulled out to allow more access to the column, see figures 10, 11.

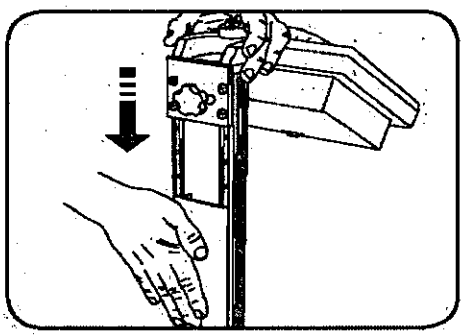


Fig. 10

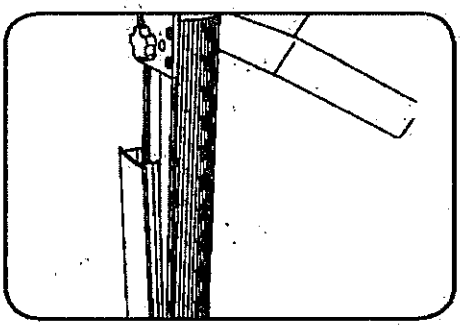


Fig. 11

Introduction to Contents

The Erchonia Zerona package is comprised of (1) Erchonia Zerona, (1) pair of patient protective eyewear, (1) power cord, this user guide and a warranty card. The components of this package are detailed below.

Erchonia Zerona

The Erchonia Zerona is made up of five independent 635 nanometer diodes, each with variable frequency. The variable frequency feature of the Erchonia Zerona is a pulsed wave, defined as containing a selected series of breaks, variances that are pre-programmed. Clinical studies have shown that pulse wave is the most effective method of laser use.

Laser devices are typically constructed to emit a "spot" of light. The Erchonia Zerona utilizes internal mechanics that collects the light emitted from the diode and processes through a proprietary patented lens which redirects the beam with a line refractor. The lines generated by each head are rotated via a patented rotation device that operates independent of each other to ensure thorough coverage. The target area is approximately 8" x 10" inches or 80 square inches, approximately 516 square centimeters.

Power

The mains power switch is the key on top of the touch screen, ref Item 3, FIG 1. The unit will not operate unless the key is in the ON position. Turning the key to the OFF position satisfies the FDA requirement for mechanical lock out, ensuring the safety of non-authorized users.

The mains power switch has a fail safe system which ensures the 110/240 voltage from a wall socket can never come in contact with the user. The system uses a 2 amp fuse, which will only require replacement if there is an issue. To replace, locate fuse holder in back of base unit, pull fuse holder out of enclosure, replace fuses and reinsert.

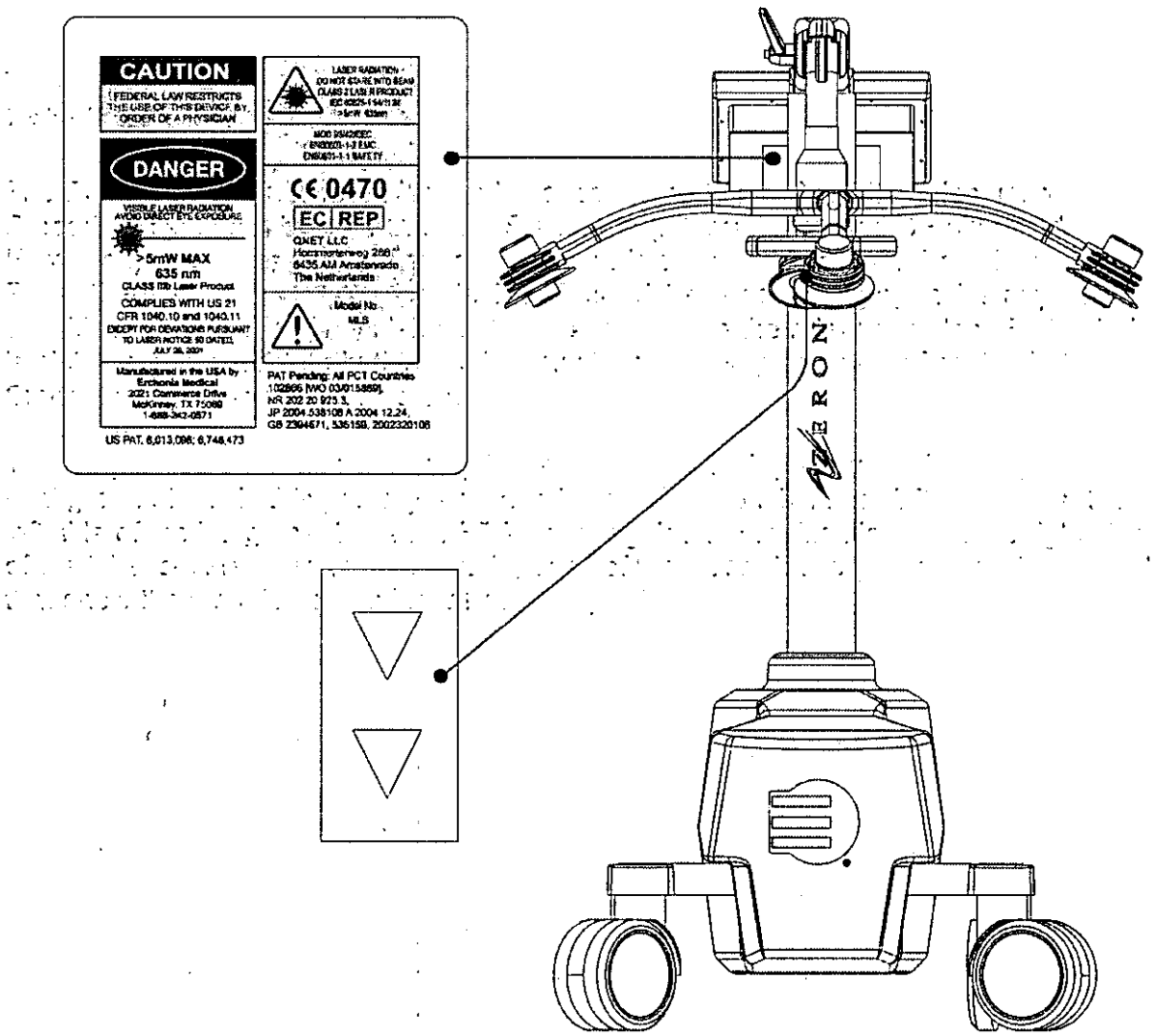
Protective Eyewear

The Erchonia Zerona is classified by the FDA as a Class 2 Laser Product. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 hazard class device 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. To ensure there is no possible instance of residual effect, we have included a pair of specialty patient glasses for use by the patient during treatment.

Labeling

The Erchonia Zerona is manufactured in accordance to the Good Manufacturing Procedures set forth by the FDA, ISO Standards (International) and CE (Certified European) standards and testing results per Article 9, the device is a Class I Shock Protection and a Class II Medical device. Each of these governing agencies requires specific labeling. All required labels affixed according to the relevant codes. Each label is pictured and described in this section. Additionally, the placement of each label on the Erchonia Zerona is communicated.

The diagram below shows the compliance labels and their placement. The large black background label is this primary label and is compliant to FDA and ISO standards, the left side of the image captures the FDA code regulated classifications and the right side of the label covers International criteria, each of the laser diodes (5) have a label affixed that show the direction of the laser beam output.



Manufacturer and Distributor Information

Manufacturer's Information
Erchonia Corporation
2021 Commerce Dr.
McKinney, TX 75069
214.544.2227

Distributor Information
Erchonia Corporation
2021 Commerce Dr
McKinney, TX 75069
214.544.2227

Indications for Use

The Erchonia Zerona is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.

Histological evidence has identified that following exposure to Erchonia Zerona at 635nm wavelength of light, a transitory pore is established within the protective membrane of adipocytes, providing a means for the stored fatty material to exit the cell entering the interstitial space. This response is secondary to the absorption of light by photoabsorbing complexes positioned within the cell that modulates the cell bioenergetics. Release of intracellular fat promotes cellular collapse of the adipocyte significantly reducing cell volume. The material enters the interstitial space which is regulated by an anastomosing network of lymphatic vessels that funnel towards lymph nodes transporting fluids including the fatty material released via laser therapy. Flow of lymph which originates in connective tissue eventually is deposited into the circulatory system primarily through the thoracic duct which empties into the subclavian vein. As the fluid passes through the lymph nodes the extraneous materials are filtered out via macrophages, which contain enzymes capable of degrading triglycerides and cholesterol. The administration of the Erchonia Zerona has been proven to induce transitory pore formation, liberating accumulated fatty material, which is absorbed degraded by the lymphatic system and removed from the treated region, producing a slimming outcome based upon the volume reduction of cells.

References: Niera, R., Arroyave, Ramirez, H., et al. Fat liquefication: Effect of low-level laser energy on adipose tissue. *Plast. Reconstr. Surg.* (2002): 110; 912-22.

Instructions for Use

Setting Up the Unit
To turn the unit ON, place the key in the key lock and turn to the ON position. NOTE: The unit requires a minimum of 30-45 seconds to launch the programming contained with the internal computers. Once the device is ready for use, the touch screen will display the non-invasive body contouring screen.

When you press the start button it will launch the non-invasive protocol. If for any reason you need to pause, press the pause button. To restart, press pause again. The "treatment time in minutes" field shows the elapsed time. The protocol is 20 minutes

long and will stop automatically when complete. When done, return the key to the off position.

Front of the Body

1. The patient lies comfortably flat on his or her back on the table such that the front area of the patient's body encompassing the region spanning from the patient's stomach (abdomen) down through the hips and frontal aspect of both thighs, is facing upwards.
2. The center diode of the Erchonia Zerona is positioned at a distance of 6.00 inches above the patient, centered along the body's midline (the "line" that vertically "dissects" the body into two equal halves).
3. The Erchonia Zerona is activated for 20 minutes. Each scanner emits to the patient a laser beam of approximately 17mW with a wavelength of 635 nm, and creates a spiraling circle pattern that is totally random and independent from the others. These patterns overlap each other to guarantee total coverage within the target area of approximately 516 square centimeters.

Back of the Body

1. The patient turns over to lie flat on his or her stomach such that the back area of the patient's body encompassing the region spanning from the patient's back down through the hips and back aspect of both thighs is facing upwards.
2. The center diode of the Erchonia Zerona is positioned at a distance of 6.00 inches above the patient, centered along the body's midline (the "line" that vertically "dissects" the body into two equal halves).
3. The Erchonia Zerona is activated for 20 minutes. Each scanner emits to the patient a laser beam of approximately 17mW with a wavelength of 635 nm, and creates a spiraling circle pattern that is totally random and independent from the others. These patterns overlap each other to guarantee total coverage within the target area of approximately 516 square centimeters.

Application / Administration

The Erchonia Zerona is intended for use by health care professionals as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. The treatment protocol that is hard coded into the device has been developed in conjunction with Medical Doctors, Erchonia Medical Researchers and IRB advisors (see clinical trial summary). Medical professionals in receipt of this device are to use the preset as their medical training and experience dictate.

Clinical Trial Summary

A DOUBLE-BLIND, PLACEBO-CONTROLLED RANDOMIZED EVALUATION OF THE EFFECT OF THE ERCHONIA ZERONA ON BODY CONTOURING OF THE WAIST, HIPS AND THIGHS.
Erchonia Medical. Inc.

BACKGROUND: The purpose of this clinical study was to determine the effectiveness of the Erchonia Zerona for non-invasive body contouring of the waist, hips and thighs by applying the Erchonia Zerona around the waist, hips and thighs six times across two weeks.

STUDY DESIGN: The study was a placebo-controlled, randomized, double-blind parallel group design conducted across three independent test sites.

SUBJECTS: Sixty seven (67) subjects completed this study. Of the 67 participating subjects, 35 were randomized to the active procedure group and 32 were randomized to the placebo group.

Subjects were those aged 18 to 65 years with a Body Mass Index (BMI) of less than 30 kg/m² who were deemed suitable for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that had failed to respond to diet and exercise; specifically for the indication of body contouring in the areas of the waist, hips and bilateral thighs, as per the American Academy of Cosmetic Surgery's 2006 Guidelines for Liposuction Surgery developed by a joint Ad Hoc Committee of the American Society of Liposuction Surgery (ASLSS) and the American Academy of Cosmetic Surgery (AACS).

The majority of study subjects were Caucasian females, as illustrated in Table 1 below.

Table 1: Table of Subject Demographics

Gender	**Female**		**Male**	
n=67	*number*	*%*	*number*	*%*
	64	96%	3	4%
Ethnicity	**Caucasian**		**Caucasian/African American**	
n=67	*number*	*%*	*number*	*%*
	66	99%	1	1%

STUDY MEASURES: Circumference measurements for the hips, waist and bilateral thighs, and body mass index (BMI) were recorded at baseline, study mid-point (week 1), study endpoint (week 2), and study follow-up two weeks later. Subject satisfaction with the procedure outcome was recorded at study endpoint.

BASELINE MEASUREMENTS: Table 2 below contains the mean baseline circumference and BMI measurements.

Table 2: Mean Baseline measurements

	Test Group n=35	Placebo Group n=32	All Subjects Combined n=67
Body Mass Index (BMI)	25.74	26.05	25.89
Waist circumference (ins.)	33.94	34.85	34.37
Hip circumference (ins.)	38.99	39.88	39.41
Right thigh (ins.)	23.80	24.12	23.95
Left thigh (ins.)	23.59	24.14	23.85
Total circumference (ins.)	**120.31**	**122.99**	**121.59**

A series of t-tests for independent samples found there was no statistically significant difference in any of the above baseline measurements between subject procedure groups ($p>0.05$).

STUDY PROCEDURE: Subjects received six procedure administrations with the Erchonia Zerona to the front and back areas of the waist, hips and bilateral thighs, across a consecutive two-week period: three procedures per week, each procedure two to three days apart.

STUDY RESULTS

(i) Total Circumference Measurements: Individual circumference measurements for each of a subject's waist, hips and right and left thighs was combined to attain the study primary outcome measure of a combined total circumference measurement.

It was pre-determined that a subject would be considered a study success if he or she attained a 3.0 inch or greater reduction in total circumference measurement from baseline to study endpoint (after completion of the two-week procedure phase).

60.00% of subjects who received the study procedures with the actual Erchonia Zerona attained a decrease in total circumference measurement of 3.0 inches or greater compared with 6.25% of subjects who received the study procedures with a 'fake' (placebo) laser device. A Fischer's Exact Test for two independent proportions found this difference of 53.75% to be statistically significant at $p<0.00001$.

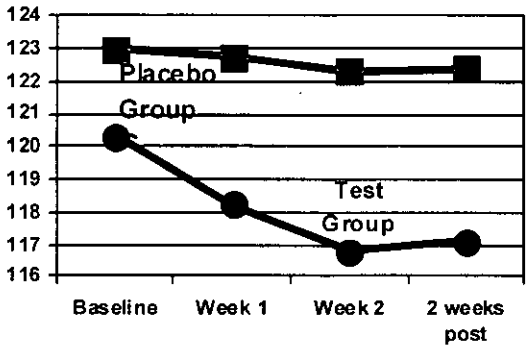
The magnitude of the mean change in total circumference measurement was a decrease of 3.521 inches for subjects who received the study procedures with the actual Erchonia Zerona and a decrease of 0.684 inches for subjects who received the study procedures with a 'fake' (placebo) laser device. A t-test for independent samples found the difference of 2.8378 inches in mean total circumference change between procedure groups to be statistically significant ($t=-7.30$; $df=65$; $p(\text{two-tailed})<0.0001$). In confirmation, a One-Way ANOVA for 2 Independent Samples also found this mean difference between procedure groups in combined inches lost to be statistically significant ($F=53.3623$, $p<0.0001$).

Table 3 and Chart 1 below show the mean change in total circumference measurements across the four study measurement time points.

Table 3: Mean total circumference measurement (ins.) across evaluation points

	Test Group	Placebo Group
Baseline	120.31	122.99
Midpoint (week 1)	118.25	122.73
Endpoint (week 2)	116.79	122.31
Follow-up (week 4)	117.09	122.37

Chart 1: Mean total circumference measurement (ins.) across evaluation points



For test group subjects, total circumference measurements decreased progressively from baseline across the procedure administration phase, indicating a progressive and cumulative treatment effect of the laser.

Total circumference measurements stabilized across the subsequent 2-week follow-up assessment period during which time no laser procedures were administered, indicating duration of the treatment effect up to at least 2 weeks following the end of laser procedure administration. For placebo group subjects, there were no notable changes in total circumference measurements across or between any of the assessment points.

(ii) Individual Area Circumference Measurements: Table 4 below shows the mean circumference measurements for individual body areas.

Table 4: Mean individual body area circumference measurements.

	Test Group n=35				Placebo Group			
inches	Waist	Hips	Right thigh	Left thigh	Waist	Hips	Right thigh	Left thigh
Baseline	33.94	38.99	23.80	23.59	34.85	39.88	24.12	24.14
Week 1	33.38	38.26	23.31	23.30	34.85	39.80	24.10	23.98
Week 2	32.96	37.94	22.95	22.94	34.60	39.67	24.07	23.97
2 weeks post	32.86	38.29	23.02	22.92	34.53	39.66	24.16	24.02

As with total circumference measurements, individual area circumference measurements decreased progressively from baseline across the procedure administration phase for test group subjects, indicating a progressive and cumulative treatment effect of the laser. Individual body area circumference measurements then stabilized across the subsequent 2-week follow-up assessment period during which time no laser procedures were administered, indicating duration of the treatment effect up to at least 2 weeks. For placebo group subjects, there were no notable changes in individual body area circumference measurements across or between any of the measurement points.

(iii) Change in weight in pounds and change in body mass index (BMI): Neither weight measurements nor body mass index (BMI) changed notably across or between any of the four study measurement points for either test or placebo subject groups.

However, individual body area and combined total circumference measurements did change notably across and between measurement points for test group subjects but not for placebo group subjects. This combined finding further supports the effectiveness of the Erchonia Zerona as it demonstrates that the change in body shape (statistically significant reduction in combined inches at the waist, hip and thighs) attained for test group subjects resulted from the Erchonia Zerona application and not from incidental weight loss or change in body mass index as a result of incidental weight loss.

(iv) Study outcome satisfaction ratings: At completion of the study procedure administration phase, the subject was asked to rate how satisfied he or she was with any overall change in body shape attained using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied.

70% of test group subjects reported being 'Satisfied' (Very or Somewhat Satisfied) with the outcome of the study procedures compared with 26% of placebo subjects. Conversely, 36% of placebo group subjects reported being 'Dissatisfied' (Not very satisfied or Not at all satisfied) compared with 3% of test group subjects.

(v) Adverse events: There was no adverse event for any subject throughout the duration of the clinical study. There was no change in skin markers in the treated body areas, and no notable deviation from baseline diet, exercise or concomitant medication use for any study subject.

CONCLUSION: The Erchonia Zerona is an effective tool for body contouring, significantly reducing circumference measurements when applied to the hips, stomach and bilateral thighs over a 2-week period.

Warnings / Cautions / Maintenance

Warnings

1. The long term effects of prolonged use of non-thermal laser exposure are unknown.
2. Laser treatment should not be applied over, or in proximity to, cancerous lesions as conclusive tests have not been conducted.
3. To eliminate any possible danger to the eyes safety glasses must be worn by the patient during treatment.

Cautions

1. Safety of non-thermal lasers for use during pregnancy has not been established.
2. Caution should be used over areas of skin that lack normal sensation.
3. Use only with accessories recommended by manufacturer.
4. Avoid the ingress of any liquid.

Maintenance and Cleaning

The Erchonia Zerona, if used according to the instructions contained within this manual will operate efficiently for years. To ensure proper care, it is advisable for the end-user to perform:

1. Regular visual inspection to make sure there is no external damage other than normal wear and tear. If during these inspections you identify an area of concern, please contact the manufacturer.
2. If you notice a change in the performance of the device while in the ON position, please contact the manufacturer.
3. The internal components should not require any maintenance, however if an issue arises, which will show itself in the form of altered performance, the device must be sent to the manufacturer.
4. Since the device contains a touchscreen interface, periodic cleaning of the touchscreen will be necessary. To clean the touchscreen, use warm soapy water only, applied with a clean cloth that has been wrung out to ensure there is NOT an excess of fluid.
5. The touchscreen back up battery must be replaced every five years. This must be done by manufacturer.
6. The unit must be stored, shipped and used at temperatures not to exceed 41C/105.8ºF.

Disposal

The Erchonia Zerona is a self-contained unit that emits light energy and as such creates no by-product that requires disposal; however, the unit itself, when spent and beyond repair or functional use, should be sent back to the manufacturer for disposal. This process ensures the proper separation and handling of all the internal parts and reduces any risk to the patient and/or environment.

Warranty Information

Limited Warranty
The Erchonia Zerona is warranted to be free from defect in material and workmanship for a period of TWO YEARS from the date of purchase. For warranty to be valid, it is critical that the end-user complete and return the enclosed warranty card. Failure to return warranty card may adversely impact warranty processing and/or void warranty.

Terms and Conditions
• This product contains a 30 day money back guarantee, which covers purchase price only. If for any reason, the end-user is unsatisfied with the product and/or its performance, it can be returned for full refund of purchase price.

• Shipping required facilitating warranty repair and or maintenance issues within the first 90 days will be paid by the manufacturer.

• Shipping required facilitating warranty repair and or maintenance issues after 90 days is the financial responsibility of the end-user.

• Warranty DOES NOT cover instances involving or damages resulting from:
- Accident, misuse or abuse
- Lack of responsible care
- Alteration or disassembly
- Loss of parts
- Exposure to the elements
- Ingress of liquid

• Warranty is NON-TRANSFERABLE. If device is sold to another party, by any one other than an approved Erchonia distributor, the warranty is VOID.

Point of Contact

If for any reason you are dissatisfied with this product, have warranty concerns or questions regarding proper operation of the device; please call 214.544.2227 for immediate assistance.

Warranty Card

Please remove warranty card from packaging, complete and mail within 90 days of purchase. Failure to do so may adversely impact manufacturer's ability to successfully administer warranty.

ERCHONIA

World Leader in Low Level Laser Technology™

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