



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Erchonia Corporation
% Regulatory Insight, Incorporated
Mr. Kevin Walls
Principal Consultant
33 Golden Eagle Lane
Littleton, Colorado 80127

January 25, 2013

Re: K123237

Trade/Device Name: Erchonia® Zerona™ 2.0 Laser
Regulation Number: 21 CFR 878.5400
Regulation Name: Low level laser system for aesthetic use
Regulatory Class: Class II
Product Code: OLI
Dated: December 20, 2012
Received: December 21, 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

Page 2 – Mr. Kevin Walls

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,

Peter D. Rumm -S

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

Enclosure

510(k) Number (if known): K123237

Device Name: Erchonia® Zerona™ 2.0 Laser

Indications for Use: The Erchonia® Zerona™ 2.0 Laser 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)

Neil R Ogden
2013.01.24 13:17:37 -05'00'

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K123237



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

December 11, 2012

ERCHONIA CORPORATION
C/O REGULATORY INSIGHT, INC.
33 GOLDEN EAGLE LANE
LITTLETON, COLORADO 80127
ATTN: KEVIN WALLS

510k Number: K123237
Product: ZERONA 2.0 LASER
On Hold As of 12/10/2012

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/MedicalDeviceProvisionsofFDAModer nizationAct/ucm136685.htm>.

In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, submitters should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in the AI request within 180 calendar days of the date that FDA issued that AI request. In this instance, 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.

Records processed under FOIA Request # 2013-8421. Released by GDRH on 10-29-2015.
For further information regarding 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 Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals". You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>.

Please remember that the Safe Medical Devices Act of 1990 states 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
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Mawii, Lal Pek *

From: Microsoft Outlook
To: KEVIN@REGINSIGHT.COM
Sent: Tuesday, December 11, 2012 4:26 PM
Subject: Relayed: K123237 - hold letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

KEVIN@REGINSIGHT.COM (KEVIN@REGINSIGHT.COM)

Subject: K123237 - hold letter



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

October 17, 2012

ERCHONIA CORPORATION
C/O REGULATORY INSIGHT, INC.
33 GOLDEN EAGLE LANE
LITTLETON, COLORADO 80127
ATTN: KEVIN WALLS

510k Number: K123237

Received: 10/16/2012

Product: ZERONA 2.0 LASER

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

K-8
K12 3237

Regulatory Insight, Inc.



Worldwide Medical
Device Submissions
and Quality Systems

October 15, 2012

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

FDA CDRH DMC

OCT 16 2012

Received

RE: 510(k) Notification for the Erchonia® Zerona™ 2.0 Laser

Dear Sir or Madam:

Please find enclosed a 510(k) premarket notification for the Erchonia® Zerona™ 2.0 Laser manufactured by Erchonia Medical Inc. The Erchonia® Zerona™ 2.0 Laser 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.

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.

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

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b) (4) XXXXXXXXXX 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) REGULATORY INSIGHT INC 33 Golden Eagle Lane Littleton CO 80127 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2. CONTACT NAME Kevin Walls 2.1 E-MAIL ADDRESS kevin@reginsight.com 2.2 TELEPHONE NUMBER (include Area code) 720-9625412 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>

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

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

<input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA	<input checked="" type="checkbox"/> 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?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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.

- | | |
|---|---|
| <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates | <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population |
| <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only | <input type="checkbox"/> 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 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) 

13-Oct-2012

Regulatory Insight, Inc.



Worldwide Medical
Device Submissions
and Quality Systems

October 15, 2012

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

RE: 510(k) Notification for the Erchonia® Zerona™ 2.0 Laser

Dear Sir or Madam:

Please find enclosed a 510(k) premarket notification for the Erchonia® Zerona™ 2.0 Laser manufactured by Erchonia Medical Inc. The Erchonia® Zerona™ 2.0 Laser 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.

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.

Erchonia® Zerona™ 2.0 Laser 510(k) Table of Contents

Name and Address of Sponsor	1
Name and Address of Manufacturer.....	1
Establishment Registration Number	1
Name and Address of Official Correspondent	1
CDRH Premarket Review Submission Cover Sheet.....	1
Truthful and Accuracy Statement	1
510(k) Statement	1
Device Name	1
Classification, Panel and Product Code	2
Previous Submission.....	2
Indications for Use	2
Device Description	2
Labeling	4
Performance Standards	4
Clinical Study Results	4
Software.....	4
Risk Assessment	4
Biocompatibility	4
Compliance with Voluntary Standards.....	5
Substantial Equivalence.....	5

Name and Address of Sponsor

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

Name and Address of Manufacturer

Erchonia Medical, Inc.
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.
33 Golden Eagle Lane
Littleton, Colorado 80127
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™ 2.0 Laser
Common Name: 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 device was not submitted to the FDA in a previous submission.

Indications for Use

The Erchonia® Zerona™ 2.0 Laser 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.

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

Device Description

The Erchonia® Zerona™ 2.0 Laser has the following specifications:

- Configuration: 6 Class 2 Line Generated Laser Diode Modules
- Wavelength: 532nm
- Power Output (Mean): 17mw
- Modulation: Constant Wave (CW)
- Display: Full Color TFT Touch Screen Control Center
- Adjustments:
 - 44" Vertical Arm Height Adjustment.
 - Four Independent Adjustable Arms for Desired Laser Concentration
- Power Source: 100-240VAC 50-60Hz
- Chassis:
 - Metal Frame Powder Coated for Ease of Cleaning
 - 4 Anti-Static Casters (4 Locking)
- Housing: Black Carbon Fiber Finish Thermoformed from Non-Allergen Material/Plastic
- Weight: 70lbs.

The Erchonia® Zerona™ 2.0 Laser is made up of six independent variable frequency, 532 nanometer (green diodes). The variable frequency feature of the Erchonia® Zerona™ 2.0 Laser is a pulsed wave, defined as containing a selected series of breaks, variances that are preprogrammed.

The Erchonia® Zerona™ 2.0 Laser utilizes internal mechanics that collects the light emitted from the each of the laser diodes and processes each through a proprietary patented lens which redirects the beam with a line refractor. The refracted light is then bent into a spiraling circle pattern that is totally random and independent of the other diodes. These patterns overlap each other to guarantee total coverage within the target area. The target area is approximately 8" x 10" inches or 80 square inches, or approximately 516 square centimeters.

The Erchonia® Zerona™ 2.0 Laser contains 6 independent diodes, 4 of which are mounted in scanner devices, positioned 120 degrees apart from the next with each tilted at a 30 degree angle. The fifth and sixth diodes are 4" from center, each tilted at a 15 degree angle. Each scanner emits 17mW, 532nm of green laser light.

The Erchonia® Zerona™ 2.0 Laser is shown in Figures 1, 2 and 3 below.

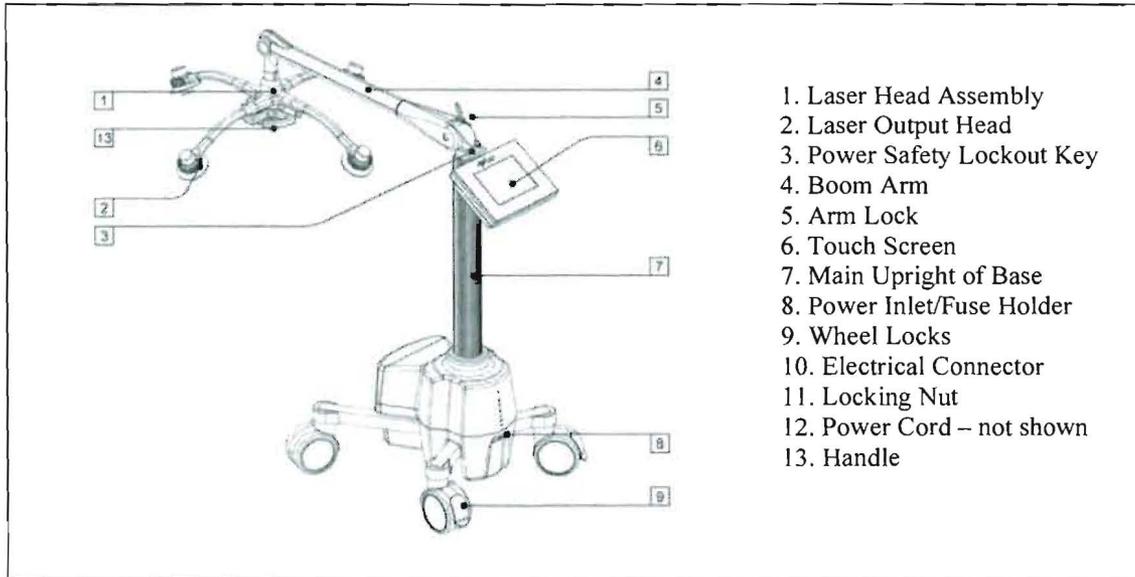


Figure 1.

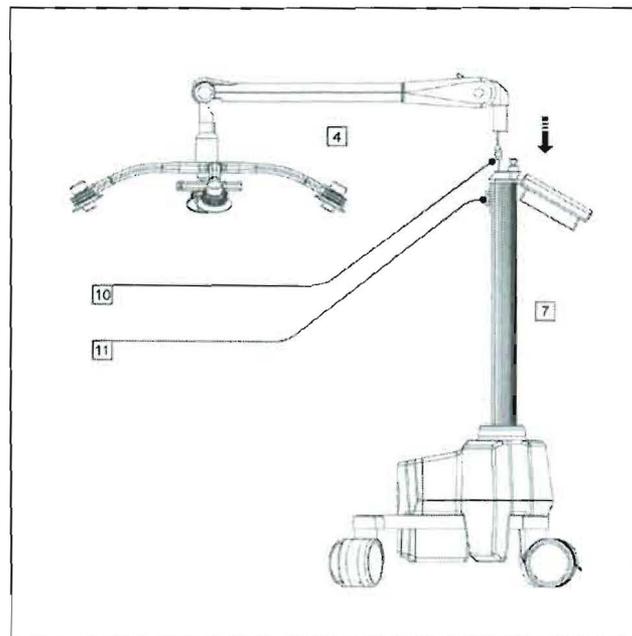


Figure 2.



Figure 3.

Labeling

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

Performance Standards

The Erchonia® Zerona™ 2.0 Laser complies with FDA's performance standards for light-emitting products (21 CFR Part 1040).

Clinical Study Results

Please refer to **Appendix F** for the Clinical Study Protocol and Report, as well as Form FDA 3674

Software

Please refer to **Appendix G** for the software documentation.

Risk Assessment

Please refer to **Appendix H** for the risk assessment

Biocompatibility

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

Compliance with Voluntary Standards

The Erchonia® MLS, Zerona-AD™ 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

Please refer to **Appendix I** for the test reports and the applicable Forms FDA 3654.

Substantial Equivalence

The Erchonia® Zerona™ 2.0 Laser is substantially equivalent to the Erchonia Zerona, which was last cleared under 510(k) #K121695. The difference between the two devices is that the Erchonia® Zerona™ 2.0 Laser employs six 532 nm green diodes in lieu of five 635 nm red diodes in the Erchonia Zerona and the procedure administration time is reduced from 40 minutes with the Erchonia Zerona to 30 minutes with the Erchonia® Zerona™ 2.0 Laser.

Comparison of the New and Predicate Device

Device	Erchonia® Zerona™ 2.0 Laser	Erchonia Zerona
510(k)	N/A	K121695
Indications for Use	The Erchonia® Zerona™ 2.0 Laser 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.	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	1 mw	1 mw
Wavelength	Green 532 nm	Red 635 nm (near infrared)
Waveform	Pulsed	Pulsed
Energy Source	Six 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	30 minutes	40 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 FOOD AND DRUG ADMINISTRATION

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

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 10/15/2012	User Fee Payment ID Number (b) (4)	FDA Submission Document Number (if known)
----------------------------------	---------------------------------------	---

SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

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 Erchonia Corporation		Establishment Registration Number (if known) 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 Texas	ZIP/Postal Code 75069	Country USA
Contact Name Steve Shanks			
Contact Title President		Contact E-mail Address 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 33 Golden Eagle Lane		FAX Number (including area code) 720-962-5413	
City Littleton	State / Province Colorado	ZIP Code 80127	Country USA
Contact Name Kevin Walls			
Contact Title Principal Consultant		Contact E-mail Address kevin@reginsight.com	

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

<input type="checkbox"/> New Device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Response to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	OLI	2		3	
5		6		7	
				<input type="checkbox"/> 510 (k) summary attached <input checked="" type="checkbox"/> 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	K121695	1 ERCHONIA ZERONA	1 ERCHONIA CORPORATION
2		2	2
3		3	3
4		4	4
5		5	5
6		6	6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
 Fat Reducing Low Level Laser

	Trade or Proprietary or Model Name for This Device	Model Number
1	Zerona™ 2.0 Laser	1
2		2
3		3
4		4
5		5

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

1	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 OLI	C.F.R. Section (if applicable) 878.5400	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General & Plastic Surgery		

Indications (from labeling)
 The Erchonia® Zerona™ 2.0 Laser 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.

<p>Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.</p>		<p>FDA Document Number (if known)</p>	
<p>SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION</p>			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	
<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> 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 Texas	ZIP Code 75069
		Country USA	
Contact Name Steve Shanks		Contact Title President	
		Contact E-mail Address SShanks@erchonia.com	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	
<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> 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	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	
<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> 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	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.	Edition 3:2007-03	06/10/2010
3	60825-1	IEC	Safety of laser products - Part 1: Equipment classification, and requirements.	Ed. 2.0 (2007)	09/09/2008
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

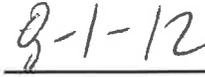
An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Truthful and Accuracy Statement

I believe to the best of my knowledge, in my capacity as President of Erchonia Medical, Inc., 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 Medical, Inc.



Date

510(k) Statement

I certify that, in my capacity as President of Erchonia Medical, Inc., 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.



Steven Shanks
President
Erchonia Medical, Inc.

8-1-12

Date

Indications for Use

510(k) Number (if known): _____

Device Name: Erchonia® Zerona™ 2.0 Laser

Indications for Use: The Erchonia® Zerona™ 2.0 Laser 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 AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)



Zerona™ 2.0

Operation & Maintenance Manual



Proven • Non-invasive • Drug-Free • Healthcare Solutions

O&M-GLS Rev. A

The issue date for the ZERONA™ 2.0 Operator's Guide (**REF O&M-GLS Rev. A**) is **August, 2012**.

If more than 3 years have elapsed since the issue date, contact Erchonia Corporation to determine if additional product information updates are available.

Copyright © 2012 Erchonia Corporation. All rights reserved.



Erchonia Corporation
2021 Commerce Dr.
McKinney, TX USA
75069-8262



QNET LLC
Hommerterweg 286
6436 AM Amstenrade
The Netherlands



0459

FDA Good Manufacturing Practices
ISO 9001-Quality
ISO 13485-Medical
ISO 60825-1-Laser Safety
FDA/IEC Laser Class 2
FDA/IEC Device Class II
MDD 93/42/EEC

Trade Name: Zerona 2.0
EN/IEC 60601-1-2 EMC
EN/IEC EN60601-1-1 Safety
CE Mark
CB Certified Pending
Model Number: GLS
Software Version A

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	CR No.	Rev. Level	Rev. Date
O&M-GLS	08/06/12	Research	A	08/06/12
O&M-GLS	08/06/12	510(k)	B	10/11/12
O&M-GLS	08/06/12	510(k)	C	10/15/12

ATTENTION: By purchase of the Erchonia device, you; the health care professional, acknowledges and bares full responsibly of the knowledge that laser, and the indications for use associated with the laser, are within your disciplines allowed scope of practice, as regulated by the state medical and professional boards.

Table of Contents

SECTION 1 General Information		SECTION 4 Operation	
Product Description	1	Starting, Stopping, & Interrupting the Procedure	14
How to Use this Manual	1	Front of Body	14
Operator's Guide Updates	1	Back of Body	14
Unpacking	1	Mode Screen	15
Symbols Used on Equipment	1	Special Applications	15
Conventions	2	Manufacture's Contact Screen	15
CAUTION	3	Labels	16
WARNING	3		
Contraindications	4		
Notification of Adverse Events	4		
ZERONA™ 2.0 Laser Indications for Use	4		
ZERONA™ 2.0 Laser Specifications	5		
Technical Information	5		
Service and Repair	5		
Returning Device for Service	5		
SECTION 2 Product Overview		SECTION 5 Professional Use Instructions	
Nomenclature	7	Application/Administration	17
Laser Head Assembly	7	Clinical Trial Summary	17
Laser Output Head	7		
Power Safety Lockout Key	8		
Boom Arm	8		
Arm Lock	8		
Touch Screen	8		
Main Upright of Base	8		
Power Inlet/Fuse Holder	8		
Wheel Locks	9		
Electrical Connector	9		
Locking Nut	9		
Power Cord	10		
Handle	10		
Protective Eyewear	10		
SECTION 3 Setup		SECTION 6 Maintenance & Warranty Information	
Assembly Instructions	11	Maintenance and Cleaning	21
Additional Information	13	Maintenance	21
		Cleaning Instructions	21
		Optics Cleaning	22
		Warranty	22
		Limited Warranty	22
		Terms and Conditions	22
		Point of Contact	22
		Troubleshooting	23

Section 1

General Information

Product Description

The ERCHONIA® Zerona™ 2.0 Laser is specially designed for 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 body contouring utilizing 532nm laser diodes. The Zerona™ 2.0 Laser is applied externally and has proven through double-blind clinical trials to emulsify adipose tissue. Zerona™ 2.0 Laser is a new body-sculpting procedure designed to remove fat and contour the body without invasive surgery. ZERONA™ 2.0 Laser unlike other procedures, allows the patient to continue their daily activities without interruptions from surgery, pain, wounds or garments. Zerona™ 2.0 Laser works by emulsifying adipose tissue which then releases into the interstitial space. The excess fat is passed through the body during its normal course of detoxification. The procedure was proven through a double-blind, randomized, multi-site, and placebo controlled study in which patients averaged a loss of 3.895 inches (9.893 cm) compared to the placebo group that lost only 1.135 inches (2.882 cm).

How to Use This Manual

The Zerona™ 2.0 Laser Operator's Guide provides information operators need for the safe and effective use and care of the device. It is important that all persons using this device read and understand all the information contained within.

Please thoroughly read the Caution and Warnings sections.

Procedures for daily checkout and device care are located in "Maintenance and Cleaning".

Operator's Guide Updates

An issue or revision date for this manual is shown on the front cover. If more than three years have elapsed since this date, contact Erchonia Corporation to determine if additional product information updates are available.

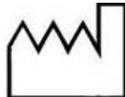
Unpacking

Carefully inspect container for damage. If the shipping container or cushion material is damaged, keep it until the contents have been checked for completeness and the device has been checked for mechanical and electrical integrity. If the contents are incomplete, if there is mechanical damage, contact Erchonia Corporation 1-214-544-2227. If the shipping container is damaged, also notify the carrier.

Symbols Used on the Equipment

Any or all of the following symbols may be used in this manual or on this equipment:

Symbol	Description
	Temperature Limitation
	Type B patient connection - applied parts that are generally not conductive and can be immediately released from the patient.

	Conformité Européenne - Complies with medical device directive 93/42/EEC.
	Power ON/OFF
	Date of Manufacture
	Manufacturer
	Authorized representative in the European Community.
	Consult instructions for use.
	Warning - can result in personal injury or equipment damage.
	Caution - can result in minor to moderate injury or damage to the device
	No pushing

Conventions

This guide uses the following conventions:

Within text, the names and labels for physical buttons appear in boldface type (for example, “Press the **Start** button or press the **Stop** button”).

Warning Warning statements alert you to conditions or actions that can result in personal injury or equipment damage.

Caution Caution statements alert you to conditions or actions that can result in minor to moderate injury or damage to the device.

NOTE: Throughout this Manual “**NOTE**” may be found. These Notes are helpful information to aid in the particular area or function being described.



CAUTION

- Read, understand, and practice the precautionary and operating instructions. Know the limitations and hazards associated with using any laser device. Observe the precautionary and operational decals placed on the device.
- **DO NOT** place/operate this device in close proximity (15 cm) to other devices that emit frequency.
- **DO NOT** use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the touch screen as damage may result.
- Inspect electrical cord and associated connectors before each use.
- This device should be operated in temperatures between 59 to 85°F (15 to 29°C), and transported and stored in temperatures between -22 to 158°F (-30 to 70°C), with relative humidity ranging from 0% - 100%.
- Failure to use and maintain the Erchonia device and its accessories in accordance with the instructions outlined in this manual will void your warranty.
- There are no user-serviceable parts inside the device. If a malfunction occurs, discontinue use immediately and contact Erchonia Corporation for repair service.
- **DO NOT** permit any foreign materials or liquids to enter the device. Take care to prevent any foreign materials including, but not limited to, inflammables, water, and metallic objects from entering the device. These may cause device damage, malfunction, electrical shock, fire, or personal injury.
- To achieve the specified level of protection against spilled or splashed liquids, thoroughly dry all exposed surfaces of this device and allow to dry thoroughly prior to operation
- Avoid contact with flammable anesthetic with air or with oxygen or nitrous oxide.
- Do not position equipment so that in an emergency it is difficult to disconnect power cord from electric supply.
- If you have difficulty operating the device after carefully reviewing this user's manual, contact your Sales Representative for assistance.
- U.S. Federal law restricts the use of this device by order of a physician or licensed practitioner.



WARNING

- Read all instructions for operation before treating a patient.
- **DO NOT** disassemble, modify, or remodel the device or accessories. This may cause device damage, malfunction, electrical shock, fire, or personal injury.
- **DO NOT** drop the device or probes on hard surfaces.
- **DO NOT** submerge the device or probes in water. Damage resulting from these conditions is not covered under the warranty.
- This device should be kept out of the reach of children.
- This device should be used only under the continued supervision of a licensed practitioner.
- Dispose of device in accordance with local and national regulations and codes. When spent and beyond repair or functional use, the device can be sent back to the manufacture for disposal. This ensures the proper separation and handling of all the internal parts and reduces any risk to the end user, patient and the environment.
- Laser treatment should not be applied when in the bath or shower in fear of electrical shock.
- Laser protective eyewear should be worn by the patient to block light energy from the eyes during treatment.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
- To avoid risk of electric shock, this device must only be connected to a supply mains with protective earth. Make certain that the device is electrically grounded by connecting only to a grounded electrical service receptacle conforming to the applicable national and local electrical codes.

Contraindications

- The long-term effects of prolonged use of non-thermal laser exposure are unknown.
- Laser treatment should be applied only to normal, intact, clean skin or treatment will not be effective.
- Laser treatment should not be applied over, or in proximity to, cancerous lesions as conclusive tests have not been conducted.
- Safety of non-thermal lasers for use over a pregnant uterus has not been established.
- Caution should be used over areas of skin that lack normal sensation.
- Avoid direct contact of the laser beam into human and animal eyes.
- Do not use over the chest, neck or face.
- Do not use directly over areas with open wounds.
- Do not use on patients who:
 - Have a personal or family history of cancer
 - Have a history of keloid or hypertrophic scar formation
 - Have a history of herpes simplex
 - Have active infections or a compromised immune system
 - Have had a sunburn on the area being treated
 - Are taking photo-sensitizing drugs, anti-coagulants, or aspirin

Notification of Adverse Events

As a health care provider, you may have responsibilities under the Medical Device Reporting for User Facilities for reporting to Erchonia Corporation, and possibly to the FDA, the occurrence of certain events. These events, described in 21 CFR Part 803, include device-related death and serious injury or illness.

As part of our Quality Assurance Program, Erchonia Corporation requests to be notified of device failures or malfunctions. This information is required to ensure that Erchonia Corporation provides only the highest quality products.

ZERONA™ 2.0 Laser Indications for Use

The Erchonia® Zerona™ 2.0 Laser 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.

Clinical evidence has identified that following exposure to the ZERONA™ 2.0 Laser (Erchonia Corporation) at 532nm 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 ZERONA™ 2.0 Laser 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.

ZERONA™ 2.0 Laser Specifications

- Configuration: 6 Class 2 Line Generated Laser Diode Modules
- Wavelength: 532nm
- Modulation: Constant Wave (CW)
- Display: Full Color TFT Touch Screen Control Center
- Adjustments:
 - 44" Vertical Arm Height Adjustment.
 - Four Independent Adjustable Arms for Desired Laser Concentration
- Power Source: 100-240VAC 50-60Hz
- Chassis:
 - Metal Frame Powder Coated for Ease of Cleaning
 - 4 Anti-Static Casters (4 Locking)
- Housing: Black Carbon Fiber Finish Thermoformed from Non-Allergen Material/Plastic
- Weight: 70lbs.

Technical Information

Technical documentation required by the customer, in case of necessary reparations, will be provided by Erchonia in the US and our EU agent, internationally. These documents will be supplied once the manufacturer makes the determination that the requested documents do not constitute a disclosure of proprietary or patent protected information and are a part of the filed and documented technical file.

Service and Repair

If a device requires service, contact the Erchonia Service and Repair Department at:

Telephone: 1-888-242-0571
1-214-544-2227
Fax: 1-214-544-2228

When requesting service or repair, please provide the following information to the service representative:

- Device serial number (located on the back label)
- Description of the problem
- Name of the person to contact

Returning a Device for Service

- Before sending a device to the Erchonia Service and Repair Department for repair, obtain a service order (SO) number from the service representative.
- Pack the device and charger in the original containers (if available) or equivalent packaging. Be sure the assigned service order number appears on the package.

Return the Device to: For Customers in the U.S.A.

Erchonia Corporation
2021 Commerce Dr.
McKinney, TX 75069
Attention: Service and Repair Department (*SO Number*)

For Customers Outside the U.S.A.

Erchonia Corporation
2021 Commerce Dr.
McKinney, TX 75069
Attention: Service and Repair Department (*SO Number*)

NOTE: For international customers, PRIOR to sending a unit in for repair you must obtain from the Erchonia Service department an annually revised FDA Form 2877. The Radiation Control form (2877) will be sent to you partially complete, containing regulatory information. To complete, fill in the unique information associated with your device and the shipment thereof; such as serial number, port, etc. The completed form 2877 must accompany your shipment affixed to the outside of the package. Failure to include the form in the shipment may result in customs delays and fines. Any resulting fines are the responsibility of the customer.

Section 2

Product Overview

Nomenclature

The Erchonia® ZERONA™ 2.0 Laser emits a 532 nanometer wavelength with a tolerance of ± 5 nanometer, from each of the five specially created and patented electronic diodes.

The Erchonia® ZERONA™ 2.0 Laser is manufactured in accordance to the Good Manufacturing Procedures set forth by the FDA. Per ISO and FDA standards the device and laser are classified as Class II.

Each of these governing agencies requires specific labeling. All required labels are affixed according to the relevant codes. Each label is pictured and described in this manual. Additionally, the placement of each label, on the Erchonia® device, is communicated.

The Erchonia® laser package is comprised of (1) ZERONA™ 2.0 Laser, (1) pair of patient protective eyewear, (1) Power Cord, (2) Keys, and this user guide.

This section is included to familiarize you with the components of the unit ensuring the remainder of this manual is clearly communicated.

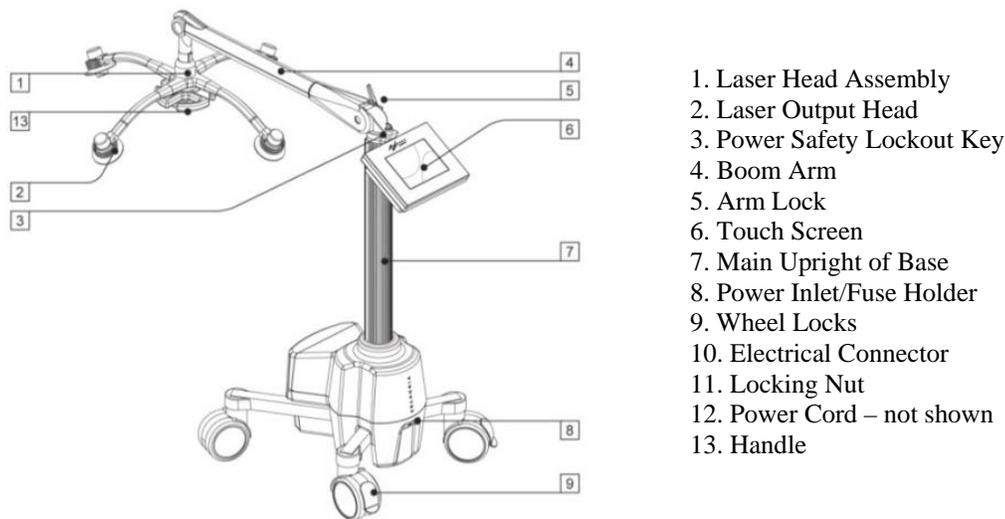


Fig. 1

Laser Head Assembly (1)

This assembly located on the end of the laser arm accommodates the lens, laser diodes and their associated electronics.

Laser Output Head (2)

This aluminum housing located on the end of the flex arms accommodates the lens, laser diodes, motors, and their associated electronics.

Power Safety Lockout Key (3)

The Power Safety Lockout Key is the outwardly visible portion of an internal locking mechanism on top of the touch screen (6) that comes with an external key. Together they allow the end user to turn the device ON or OFF. ("O" = OFF and "I" = ON) In the OFF position the device is locked. From the locked position the external key can be removed. This is a code-regulated feature installed to ensure no unauthorized use of the laser device. The device will not operate if the key is in the OFF position. Turning the key to the OFF position while the device is in operation will immediately shut down the device. The key switch has a failsafe 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.

NOTE: Two keys are included with the Erchonion® ZERONA™ 2.0 Laser. Make sure you have inserted key into the key switch to use.

Boom Arm (4)

The Boom Arm serves to position the Laser Head Assembly (1) vertically only. It is designed to adjust by intentional force from the end user by use of handle (13). This allows the end user to lower and raise the Laser Output Heads for proper positioning to patient for accurate treatment distance.



CAUTION

CAUTION - When moving the head assembly (1) into the desired position, make sure to use the center of the boom arm (4) to avoid the possibility of pinching.

Arm Lock (5)

The Arm Lock is the black handle attached to the side of the Spring Arm. This is a secondary locking mechanism for the boom arm. The arm tension can be adjusted or locked into position with lever. Pull handle out to place in a desired position then ensure to lock back in place before turning.

Touch Screen (6)

The touch screen functions as a display screen and an input panel, providing information to the user and a means to operate the device by touching the appropriate icon.



CAUTION

CAUTION - DO NOT use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the touch screen as damage may result. Avoid using abrasives (including paper towels) on the touch screen display window.

Main Upright of Base (7)

The main upright of base supports the boom arm and contains the electrical connector (See Setup) and the Locking Nut (11).

Power Inlet/Fuse Holder (8)

The device contains an appliance coupler and a flexible detachable power cord (12). This is the location on the device where it is connected. **NOTE:** Make sure the power cord is plugged into device at this location prior to

plugging into a wall socket. The power inlet module also contains a fuse holder. Replacing the fuses is the only service that can be conducted by the end-user. To replace the fuses, unplug the AC power cord and open the fuse carrier door located in the power input module. Fuses to be rated at T2AL 250V with an input to cover 100 – 240V~ 1.5-.5A, 50-60 Hz.



WARNING

WARNING-SHOCK HAZZARD

To avoid risk of electric shock, this device must only be connected to a supply mains with protective earth. Make certain that the device is grounded by connecting only to a grounded electrical socket (3 prong) conforming to the applicable national and local electrical codes.

Use T2AL 250V Fuses only.

The device includes a transformer which converts AC power to match the power output (i.e. 110V or 240V). Only a 3 plug prong adaptor is required (Hospital Grade Only). Once the adaptor is affixed to the plug end, put into wall socket. Input: 100-240V~0.5-1.5A, 50-60 Hz

Wheel Locks (9)

The device includes four antistatic wheels that enable ease for maneuverability. Once the device is transported to the desired location the wheel locks can be engage to eliminate excessive movement of the device.



WARNING

WARNING-TIPPING HAZZARD

When transporting the device (example: from one room to another) ensure that the boom arm (4) is positioned all the way down, securing with the arm lock (5) and take caution to ensure the device does not tip.

Electrical Connector (10)

The device is a two piece assembly. The electrical connector connects the laser head assembly to the main upright of base in order to transfer data and power.



WARNING

WARNING-SHOCK HAZZARD

To avoid risk of electric shock, ensure power cord is disconnect from electric supply when connecting electrical connector.

Locking Nut (11)

The locking nut is utilized to secure the two piece assembly keeping the boom arm assembly from unwanted rotation during use.

Power Cord (12) Not Shown

The device contains a flexible detachable power cord. **NOTE:** Make sure the power cord is plugged into device at prior to plugging into a wall socket. The power cord does not contain any operator-serviceable components. If the power cord needs replacement, contact an Erchonia Corporation representative.

Handle (13)

The device has a handle that surrounds the center hub, in order to adjust the height on the head as needed.



CAUTION

CAUTION - DO NOT connect to an electrical outlet controlled by a wall switch or dimmer. For continued safety and performance, use only the power cord supplied by Erchonia. Do not position equipment so that in an emergency it is difficult to disconnect power cord from electric supply.

Protective Eyewear

The Erchonia® ZERONA™ 2.0 Laser is classified by the FDA/IEC as a Class 2 laser device. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 laser is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging. 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. These safety glasses, manufactured by Laser Safety Industries, sufficiently and effectively block the laser light spectrum at OD6+ @ 190-532nm.

Section 3 Setup

Assembly Instructions

This pictorial shows the simple 2 piece assembly of the scanner. This assembly is best done with 2 people.

The 2 major components are the arm [4] and base [7].

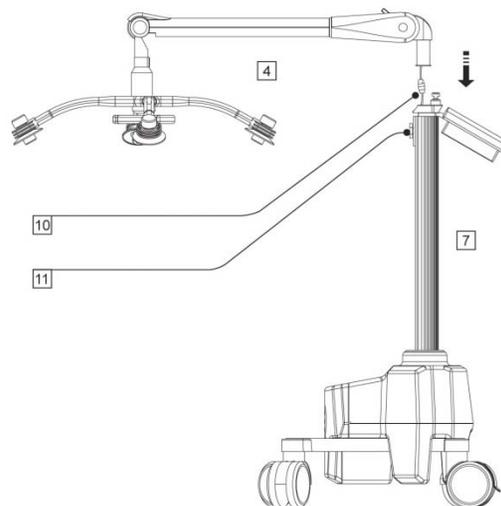


Fig. 2

Step 1:

The electrical connection [10] from the base to the arm must be connected as shown in fig 3.

Simply insert the 2 halves of the electrical connection [10] (fig 3) together slightly pushing the outlet into the inlet. Twist until secure. (The connector can only be connected one way)

After insertion, hold the female connector secure while gently twisting the locking collar until it locks **and can no longer be twisted.**

NOTE: This is important so the two halves do not separate over time.

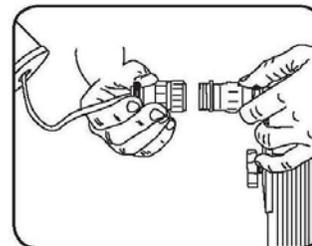


Fig. 3



WARNING

WARNING-SHOCK HAZZARD

To avoid risk of electric shock, ensure power cord is disconnect from electric supply when connecting electrical connector.

Step 2:

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

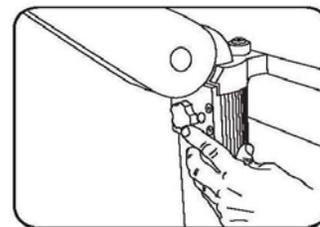


Fig. 4

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

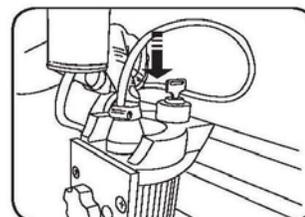


Fig. 5

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.

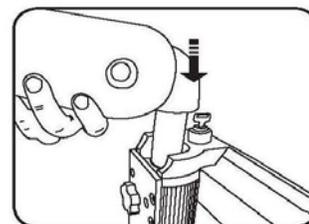


Fig. 6

Step 5:

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 threaded opening in the arm tube and tighten. This will keep the main head assembly from unwanted rotation during use. Your scanner is now ready for use.

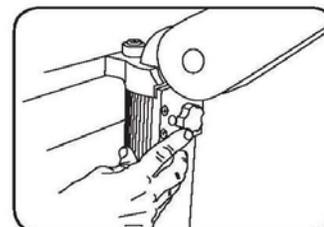


Fig. 7

Additional Information

The arm tension can be adjusted or locked into position with lever [5] as shown in figure 8. Pull handle out to place in a desired position then ensure to lock back in place before turning.

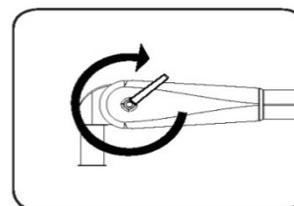


Fig. 8

To activate your scanner 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 scanner has 2 computers when you first turn it on it will take a few moments to boot up before use.

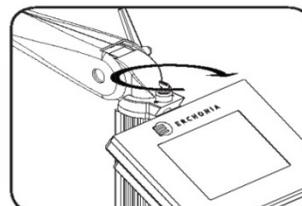


Fig. 9

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.

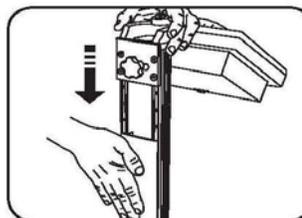


Fig. 10

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 and 11.

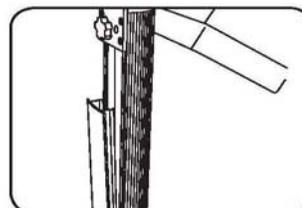


Fig. 11



CAUTION

CAUTION - When moving the head assembly into the desired position, make sure to use the center of the boom arm (4) to avoid the possibility of pinching.

To ensure proper use and mitigate the possibility of interference, avoid placing in close proximity to other electromagnetic devices.

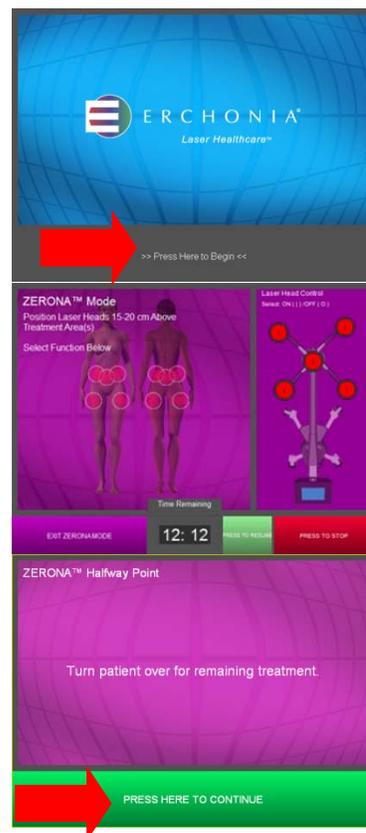
Section 4 Operation

STARTING, STOPPING, AND INTERRUPTING THE ZERONA™ 2.0 LASER PROCEDURE

To turn the unit ON, place the key in the key lock and turn to the ON “I” 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 introductory splash screen. The splash screen shows the manufacture’s logo. Press “>>Press Here to Begin<<” button, this will take you to the Mode screen.

Press “**PRESS TO START**” button to begin the non-invasive body contouring protocol. If for any reason you need to pause, press the “**PRESS TO PAUSE**” button. To restart, press the “**PRESS TO RESUME**” button. The “**Time Remaining**” display shows the elapsed time. When done return the key to the OFF position.

The device is preprogrammed to treat for a total of thirty minutes, pausing at fifteen minutes displaying the Halfway Point screen. Therefore in fifteen minutes you will need to instruct the patient to turn over, manipulate the laser heads, and then press “**PRESS HERE TO CONTINUE**” button to continue with the remainder of the application.



Front of the Body

1. The patient lies comfortably flat on their 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 two center diode of the Erchonia® ZERONA™ 2.0 Laser is positioned above the patient, centered along the body’s midline (the “line” that vertically “dissects” the body into two equal halves).
3. The Erchonia® ZERONA™ 2.0 Laser is activated for 15 minutes. Each laser diode emits to the patient a laser beam of approximately 17mW with a wavelength of 532nm, 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.

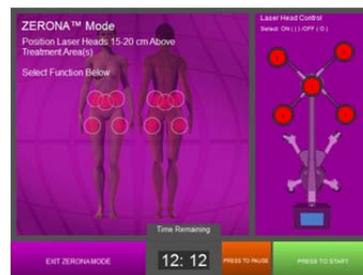
Back of the Body

1. The patient turns over to lie flat on their 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™ 2.0 laser is positioned above the patient, centered along the body’s midline (the “line” that vertically “dissects” the body into two equal halves).
3. The Erchonia® ZERONA™ 2.0 Laser is activated for 15 minutes. Each scanner emits to the patient a laser beam of approximately 17mW with a wavelength of 532nm, 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.

Mode Screen

Located on the bottom are the active command buttons. Starting from left to right the buttons are:

- “**EXIT MODE**” button will return you to the start screen.
- Located to the right of the “**EXIT MODE**” button in the center of the lower window is the “**Time Remaining**” button that displays the time left on current treatment. The countdown display activates only when the treatment is running.
- Next to the “**Time Remaining**” button is the “**PRESS TO PAUSE**” button. This button will change colors and flash “**PRESS TO RESUME**” to continue with treatment allowing the patient to take a break without resetting the time remaining.
- The bottom right corner is the cycle treatment button labeled “**PRESS TO START**”. This will start and stop this treatment



Special Applications

Located to the right in the touch screen is an image of the device, the bottom of the image represents the touch screen and the top represents the 6 laser heads. These heads can be turned off by pressing the “**ON**” buttons located on each head of the image. This may be necessary for custom applications when fewer than 6 lasers are needed as shown in image below. Pressing the “**OFF**” button will turn the lasers back on. (Make sure to reactivate before starting the next application) **NOTE:** The center head controls both center diodes on this device.



| = ON
O = OFF

Manufacturer’s Contact Screen

By touching the Erchonia (E) logo on the introductory splash screen the screen displays the manufacturer’s contact information (Address and Phone Number), and general information for your device, including software revision and serial number.

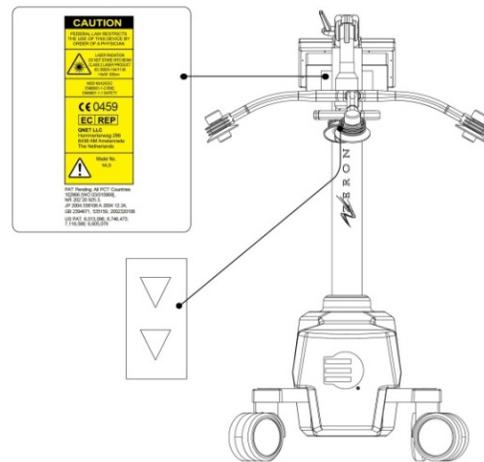


- Top center is the software package information on your device.
- On the bottom right is the device computer date.
- On the bottom center is the “Total Treatments” display. (The numeric value will increase increments of one each time an application is started)
- The device “Serial Number” is located in the gray display.
- On the bottom left is the “Return to START SCREEN” icon. Touching this icon will return you to the introductory splash screen.
- On the upper right is a Green circle with the word OK. This is the device RE-SET button and is only to be used at the instruction of an Erchonia representative.

Labels

The device 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 device, is communicated.

This diagram 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.



Section 5

Professional Use Instructions

Application/Administration

This section defines instructions for the application of the laser energy and established protocols.

The Erchonia® Zerona™ 2.0 Laser 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. The treatment protocol that is hard coded into the device has been developed in conjunction with Medical Doctors, Erchonia Corporation Researchers and IRB advisors (see clinical trial summary). Medical and Healthcare professionals in receipt of this device are to use the preset as their medical training, and experience dictate, in accordance with the laws of the state they practice in allow.

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Clinical Trial Summary

AN EVALUATION OF THE EFFECTIVENESS OF THE ERCHONIA® SCANNER DEVICE (GLS) AS A NON-INVASIVE DERMATOLOGICAL AESTHETIC TREATMENT FOR THE REDUCTION OF CIRCUMFERENCE OF THE WAIST, HIPS AND THIGHS

Erchonia Corporation

BACKGROUND: The purpose of this clinical study was to determine the effectiveness of the Erchonia® Scanner device (GLS) for non-invasive body contouring of the waist, hips and bilateral thighs by applying green diode (532 nm) energy around the waist, hips and thighs for 30 minutes, six times across two weeks.

STUDY DESIGN: The study was a placebo-controlled, randomized, double-blind parallel group design conducted across two 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 males and females aged 18 to 65 years with a Body Mass Index (BMI) of less than 30 kg/m² and who were deemed suitable for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that do not 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 (AACSS)*)

Study subject age ranged from 20 to 63 years and averaged 38 years (n=49). The majority of study subjects were Caucasian females, as illustrated in Table 1 below.

Table 1: Table of Subject Demographics

Gender	Female		Male	
	number	%	number	%
n=55	46	84%	9	16%
Ethnicity	Caucasian		Middle Eastern	
	number	%	number	%
n=61				

	56	92%	3	5%
	African American			
	<i>number</i>	<i>%</i>		
	2	3%		

STUDY MEASURES: Circumference measurements (inches) of the waist, hips, right thigh and left thigh 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 (average) baseline individual body area and combined body circumference measurements (inches/cm) for test and placebo group study subjects.

Table 2: Mean (Average) Baseline Measurements

<i>Circumference Measurements (inches)</i>	Test Group (n=35)	Placebo Group (n=32)
Waist	33.45	32.58
Hips	39.76	39.27
Right Thigh	23.41	22.69
Left Thigh	23.35	22.50
Total Body Circumference	119.97	117.04

<i>Circumference Measurements (cm)</i>	Test Group (n=35)	Placebo Group (n=32)
Waist	84.96	82.75
Hips	100.99	99.74
Right Thigh	59.46	57.63
Left Thigh	59.30	57.15
Total Body Circumference	304.72	297.28

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

STUDY PROCEDURE: Subjects received six procedure administrations with the Erchonia® Scanner device (GLS) (active or sham) across a consecutive two-week period: three procedures per week, each procedure two to three days apart. For each procedure administration, exposure time to the Erchonia® GLS was 15 minutes across the frontal region and 15 minutes across the lateral region.

STUDY RESULTS

(i) Total Circumference Measurements: The study primary outcome measure was defined as the change in total combined inches in circumference measurements (waist, hips and bilateral thighs) from baseline (pre-procedure) to following completion of the two-week procedure administration phase (study endpoint: end of week 2). It was pre-determined that a subject would be considered a study success if he or she attained a 3.0 inch (7.619 cm) or greater reduction in total combined inches in circumference measurements across this primary evaluation period. It was also pre-determined that the study would be considered an overall success if the proportion of individual subject successes in the test (active procedure) group was at least 35% greater than the proportion of individual subject successes in the placebo (sham procedure) group.

68.57% of subjects who received the study procedures with the actual (active) Erchonia® GLS attained a decrease in combined circumference measurements of 3.0 inches or greater compared with 18.75% 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 49.82% between subject procedure groups to be statistically significant at $p < 0.0001$.

The mean change in combined circumference measurement for subjects who received the study procedures with the actual (active) Erchonia® GLS was a decrease of 3.895 inches (9.893 cm), while the mean change in combined circumference measurements for subjects who received the study procedures with the ‘fake’ (placebo) laser device was a decrease of 1.135 inches (2.882 cm). A t-test for two independent samples found the mean change in combined circumference measurements from baseline to study endpoint for test (active procedure) group subjects to be significantly greater than that for placebo (sham procedure) group subjects, at $p < 0.0001$.

Table 3 and Chart 1 below show the mean change in combined circumference measurements (waist, hips, and right and left thigh circumference measurements combined) across the four study measurement time points for the intent-to-treat (ITT) study subject population. ITT analysis was conducted for all randomized subjects who had a measurement recorded at baseline. All 67 randomized subjects had circumference measurements recorded at baseline, at week 1 and at week 2 measurement points. Thirteen (13) of the 67 subjects did not have circumference measurements recorded at the 2 weeks post-procedure measurement point: 8 subjects who had been randomized to the test group and 5 subjects who had been randomized to the placebo group. For these 13 subjects, the last observation carried forward (LOCF) procedure was employed, such that the subject’s week 2 circumference measurement was carried forward as the week 2 post-procedure measurement.

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

	Test Group	Placebo Group
Baseline	119.97	117.04
Midpoint (week 1)	117.03	116.41
Endpoint (week 2)	116.08	115.91
Follow-up (week 4)	115.86	115.72

Chart 1: Mean change in total circumference measurements (ins.) at each study evaluation point relative to baseline

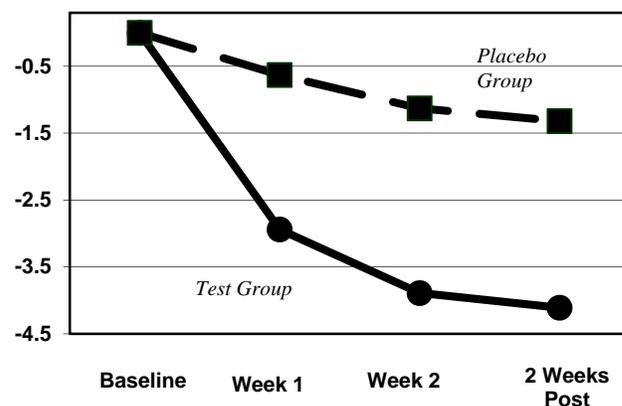
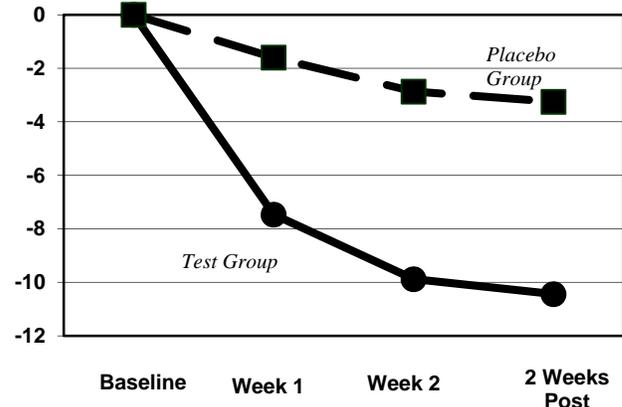


Table 3: Mean total circumference measurements (cm.) across evaluation points

	Test Group	Placebo Group
Baseline	304.72	297.28
Midpoint (week 1)	297.25	295.68
Endpoint (week 2)	294.84	294.41
Follow-up (week 4)	294.28	293.92

Chart 1: Mean change in total circumference measurements (cm.) at each study evaluation point relative to baseline



For test group subjects, combined circumference measurements decreased progressively and significantly from baseline through post-procedure evaluation, indicating a progressive and cumulative treatment effect of the laser that prevailed for at least 2 weeks following the end of the laser procedure administration period. Total circumference measurements for placebo group subjects did not change significantly across the same evaluation period.

(ii) **Individual Body Area Circumference Measurements:** Table 4 below shows the mean circumference measurements for each individual body area of the waist, hips and right and left thighs, by study procedure group, at each of the four evaluation points, for the ITT population.

Table 4: Individual body area circumference measurements across study duration by procedure group for the ITT population

Inches

<i>Waist</i>	Test (n=35)	Placebo (n=32)	<i>Right thigh</i>	Test (n=35)	Placebo (n=32)
Baseline	33.45	32.58	Baseline	23.41	22.69
Week 1 (Mid)	32.77	32.48	Week 1 (Mid)	22.70	22.60
Week 2 (End)	32.48	32.61	Week 2 (End)	22.58	22.32
2 weeks post	32.41	32.45	2 weeks post	22.56	22.35
<i>Hip</i>	Test (n=35)	Placebo (n=32)	<i>Left thigh</i>	Test (n=35)	Placebo (n=32)
Baseline	39.76	39.27	Baseline	23.35	22.50
Week 1 (Mid)	38.90	38.98	Week 1 (Mid)	22.66	22.35
Week 2 (End)	38.64	38.77	Week 2 (End)	22.39	22.20
2 weeks post	38.60	38.68	2 weeks post	22.29	22.24

Centimeters

<i>Waist</i>	Test (n=35)	Placebo (n=32)	<i>Right thigh</i>	Test (n=35)	Placebo (n=32)
Baseline	84.96	82.75	Baseline	59.46	57.63
Week 1 (Mid)	83.23	82.49	Week 1 (Mid)	57.65	57.40
Week 2 (End)	82.49	82.82	Week 2 (End)	57.35	56.69
2 weeks post	82.32	82.42	2 weeks post	57.30	56.76
<i>Hip</i>	Test (n=35)	Placebo (n=32)	<i>Left thigh</i>	Test (n=35)	Placebo (n=32)
Baseline	100.99	99.74	Baseline	59.30	57.15
Week 1 (Mid)	98.80	99.00	Week 1 (Mid)	57.55	56.76
Week 2 (End)	98.14	98.47	Week 2 (End)	56.87	56.38
2 weeks post	98.04	98.24	2 weeks post	56.61	56.48

As with the combined circumference measurements, individual body area circumference measurements decreased progressively and significantly from baseline through post-procedure evaluation for test group subjects, indicating a progressive and cumulative treatment effect of the Erchonia® GLS that prevailed for at least 2 weeks following the end of the laser procedure administration period. Individual body area circumference measurements for placebo group subjects did not change significantly across the same evaluation period.

(iii) **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 the appearance of the waist-hips-bilateral thighs area attained using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied. Sixty-five percent (65%) of test group subjects reported being 'Satisfied' ('Very Satisfied' or 'Somewhat Satisfied') with the outcome of the study procedures compared with 19% of placebo subjects.

(v) **Adverse events:** No adverse event occurred 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® Scanner device (GLS) is an effective tool for body contouring, significantly reducing circumference measurements when applied to the waist, hips and bilateral thighs over a 2-week period.

Section 6

Maintenance & Warranty Information

Maintenance and Cleaning

Maintenance

The Erchonia® ZERONA™ 2.0 Laser, 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 inspections to ensure there is no external damage other than normal wear and tear. Inspect all cords for signs of excessive wear (cuts in insulation or fraying). If during these inspections, you identify an area of concern, please contact the manufacturer to determine if action is required.
2. If you notice a change in the performance of the device, while in the ON position, please contact the manufacturer to determine if action is required.
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 a nearly dry cloth containing one of the mild cleaning agents listed below. 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. In the event that the fuses require replacement, unplug the power cord from plug source, locate power inlet / fuse holder (figure 1 item 8), pull fuse holder out of enclosure, replace the two fuses (**T2AL 250V Fuses only**) and reinsert.

Cleaning Instructions

To clean the ZERONA™ 2.0 Laser device, use a nearly dry cloth containing one of the mild cleaning agents listed below. **DO NOT** allow cleaning agent or water to run into the crevices, connector openings or optics at any time. Thoroughly wipe off any excess cleaning solution from the device with a dry cloth. Always check for unusual wear, damage or dampness while cleaning.

Use only these recommended cleaning agents:

- Warm water
- Diluted Liquid soap
- Windex®
- 409®
- 4 to 1 water to isopropyl alcohol

Never use these cleaning agents:

- Butyl alcohol
- Denatured ethanol
- Freon
- Mild chlorine bleach solution
- Trichloroethane, trichloroethylene
- Acetone
- Vesphene II
- Enviroquat
- Staphene
- Misty

- Glutaraldehyde

If during treatment, any part of the device comes in contact with a patient, perform the cleaning process.

Optics Cleaning

If there is foreign material on the laser optics use lens paper or lens cloth **ONLY**. Abrasive material could cause laser light beam fragmentation, which may reduce the effectiveness of the treatment.

Warranty

Limited Warranty

The Erchonia® laser device is warranted to be free from defect in material and workmanship for a period of TWO YEARS from the date of purchase.

For your device to be processed through the Service and Repair Department efficiently, contact the department prior to submitting your product. Repairs and Warranty work NOT coordinated through the Service and Repair Department prior to receipt can be delayed.

Items being sent in from overseas require special paperwork, available through the warranty department, if this paperwork is not obtained prior to shipping; your package will be delayed by customs.

Terms and Conditions

- Shipping required facilitating warranty repair and or maintenance issues within the first 90-days, will be paid by manufacturer.
- Shipping required to facilitate warranty repair and or maintenance issues after 90-days, is the financial responsibility of the customer.
- Warranties of Erchonia Corporation products are not transferable unless sold by a company-approved distributor, reseller and/or leasing company.
- The 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
 - Exposure to excessive electromagnetic frequency

Point of Contact

If for any reason you are dissatisfied with this product, warranty concerns or questions regarding proper operation, please contact your distributor for immediate assistance.

Troubleshooting

Listed are corrective actions intended as an aid for non-technical personnel. If trouble persists after consulting this guide, contact Erchonia's Service and Repair Department 1-214-544-2227

Observation	Possible Cause	Corrective Action
POWER Device does not power on	AC power cord not plugged into device or line power.	Connect power cord.
	Blown fuse.	Replace using the correct fuses.
	Lockout key not positioned correctly.	("O" = OFF and "I" = ON)
	Blown fuse or tripped circuit breaker in building.	Contact a qualified service technician.
Diode(s) does not power on	Diode turned off.	Turn on laser head from Zerona™ Mode Screen (See Special Applications section)
	Electrical connector came apart.	Remove head assembly from base assembly and reconnect connector. (See Setup Step 1)
Motors does not power on	Electrical connector came apart.	Remove head assembly from base assembly and reconnect connector. (See Setup Step 1)



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

Property of Erchonia® Corporation cannot be duplicated without authorization.



Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER Erchonia Corporation	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES Oct 11, 2012
3. ADDRESS (Number, Street, State, and ZIP Code) 2021 Commerce Drive McKinney, TX 75069	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 214-544-2227 (Fax) 214-544-2228

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Zerona™ 2.0 Laser

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

IND NDA ANDA BLA PMA HDE 510(k) PDP Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s): NCT01292538

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Kevin Walls (Title) Principal Consultant	
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 33 Golden Eagle Lane Littleton, CO 80127	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 720-962-5412 (Fax) 720-962-5413	15. DATE OF CERTIFICATION Oct 10, 2012

Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
 (To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

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

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #5-4

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED * †

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED * †

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED * †

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

† Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

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.

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60601-1-2 Edition 3:2007-03, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential perf

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? FDA Recognition number ³ #5-53Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement Public reporting burden for this collection of information is estimated to average 1 hour 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: <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850 </div> <div style="width: 45%; text-align: right;"> <i>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.</i> </div> </div>		

Department of Health and Human Services
 Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
 (To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

IEC 60825-1 Ed. 2.0 (2007), Safety of laser products - Part 1: Equipment classification, and requirements.

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #12-168

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
 If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
 If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
 If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
 If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
 If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
 If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
 If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>
³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>
⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>
⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ♦		
DESCRIPTION		
JUSTIFICATION		
<p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p>		
Paperwork Reduction Act Statement		
<p>Public reporting burden for this collection of information is estimated to average 1 hour 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:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850</p> </div> <div style="width: 45%; text-align: right;"> <p><i>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.</i></p> </div> </div>		

Kosoglu, Mehmet

From: Kosoglu, Mehmet
Sent: Monday, December 10, 2012 6:21 PM
To: 'Regulatory Insight, Inc.'; 'kevin@reginsight.com'
Cc: Ogden, Neil
Subject: About Erchonia Zerona 2.0 Laser K123237
Attachments: K123237-AllLetter.pdf

Mr. Walls,

I have finished reviewing your 510(K) submission K123237, and I have a number of questions that need to be addressed. I have attached this list to this message. Please also see the information at the end of the document about responding to this additional information request.

Sincerely,

Mehmet A. Kosoglu, Ph.D.
Regulatory Review Scientist
U.S. Food and Drug Administration
General Surgery Devices Branch
Division of Surgery
White Oak (WO) Building 66, Room 1525
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 301-7966930
E-mail: mehmet.kosoglu@fda.hhs.gov



COVER SHEET MEMORANDUM

From: Reviewer Name Mehmet A. Kosogly, Ph.D.
 Subject: 510(k) Number K123237
 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).
- 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 _____, 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)			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?		X	
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	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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
21 CFR 878.5400	II <small>(*If unclassified, see 510(k) Staff)</small>	OLI

Additional Product Codes: _____

Review: *[Signature]* (Branch Chief) GDCB (Branch Code) 12/10/12 (Date)

Final Review: *[Signature]* (Division Director) _____ (Date)

CPT+

[Signature]
12/11/12



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

K123237

Date: 12/10/12

To: The Record

From: Mehmet A. Kosoglu, PhD

Office: ODE

Division: DSD

510(k) Holder: Erchonia Medical, Inc.

Device Name: Erchonia® Zerona™ 2.0 Laser

Contact: Kevin Walls

Phone: 702-9625412

Fax: 720-962-5412

Email: Kevin@reginsight.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce Erchonia® Zerona™ 2.0 Laser into interstate commerce. The earliest predicate for this device is K082609 which was cleared through the DeNovo process. The predicate K121695 is the same device as K082609 but has a different trade name. The proposed device is very similar to the predicates K121695 and K082609 in terms of technology and has identical indications for use.

The sponsor provided two studies one with using the device and one with using the device in conjunction with a Niacin therapy regimen. However, we indicated to the sponsor that we will base our decision on the clinical data provided with the device alone. Niacin produces a compounding effect in the clinical data for the success of the device and the use of niacin would classify the proposed device as a combination product. The sponsor will be requested to remove all references to Niacin in their labeling including the marketing materials.

I recommend that this submission be placed on hold pending receipt of the response to the questions listed in the deficiencies section.

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)?	X		
Are "cleaning" instructions included for the end user?	X		

The Erchonia® Zerona™ 2.0 Laser has the following specifications:

Configuration: 6 Class 2 Line Generated Laser Diode Modules

Wavelength: 532nm

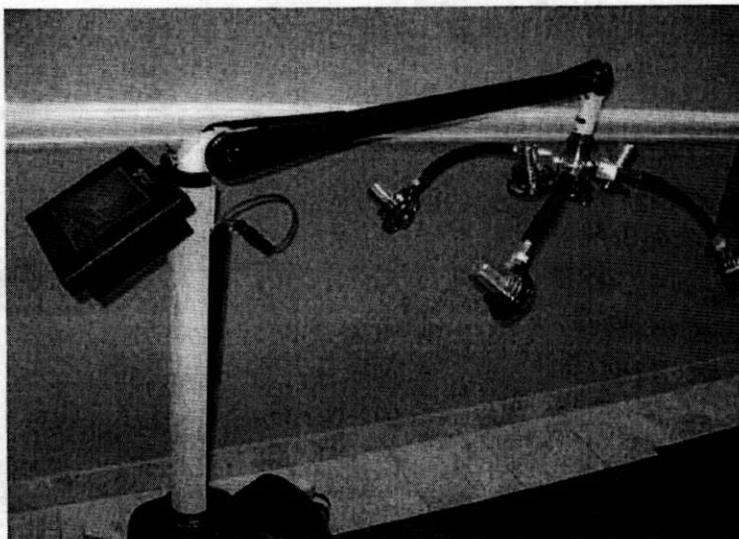
Power Output (Mean): 17mw

Modulation: Constant Wave (CW)

The Erchonia® Zerona™ 2.0 Laser is made up of six independent variable frequency, 532 nanometer (green diodes). The variable frequency feature of the Erchonia® Zerona™ 2.0 Laser is a pulsed wave, defined as containing a selected series of breaks, variances that are preprogrammed.

The Erchonia® Zerona™ 2.0 Laser utilizes internal mechanics that collects the light emitted from the each of the laser diodes and processes each through a proprietary patented lens which redirects the beam with a line refractor. The refracted light is then bent into a spiraling circle pattern that is totally random and independent of the other diodes. These patterns overlap each other to guarantee total coverage within the target area. The target area is approximately 8" x 10" inches or 80 square inches, or approximately 516 square centimeters.

The Erchonia® Zerona™ 2.0 Laser contains 6 independent diodes, 4 of which are mounted in scanner devices, positioned 120 degrees apart from the next with each tilted at a 30 degree angle. The fifth and sixth diodes are 4" from center, each tilted at a 15 degree angle. Each scanner emits 17mW, 532nm of green laser light.



Reviewer's Comment: The proposed device is a low level laser for reduction of fat. This device is unlikely to increase the temperature of the patient's skin due the very low irradiance it delivers (Irradiance = $17 \text{ mW} \times 6 / 80 \text{ square inch} = 1.275 \text{ mW} / \text{square inch} = 0.197 \text{ mW/cm}^2$)

The proposed device is the same as the predicate in design with the exception of the following differences:

- The proposed device delivers 532 nm light while the predicate, K12195 uses 635 nm: Due to the change in wavelength clinical data is required to show that the device can still reduce fat. The sponsor provided clinical data.
- The proposed device uses 6 instead of 5. The 20 percent increase in power does not raise any safety issues as the irradiance delivered by this device is extremely low.
- The treatment time was decreased from 40 minutes to 30 minutes, and thus total dosage (energy) for the treatment was decreased from 204 J to 183.6 Joules.
- Note: $0.017 \text{ W} \times 5 \times 2400 \text{ seconds} = 204 \text{ J}$ and $0.017 \text{ W} \times 6 \times 1800 \text{ seconds} = 183.6 \text{ J}$

IV. Indications for Use

Proposed Device, Zerona 2.0: The Erchonia® Zerona™ 2.0 Laser 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.

Predicate Device, K121695: 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.

Reviewer's Comment: The indications for use for the proposed device is identical to the predicate. However, on pages 1, 4, 17 of the manual, the sponsor referred to body contouring or sculpting, and fat removal and fat or adipose emulsifying. None of these indications were cleared for this device.

Also, throughout the study protocol, the device is stated to be indicated for "body contouring", "body sculpting", "removal of local deposits of fat or adipose", "removing fat or fatty material by emulsifying". The sponsor will be reminded that we did not clear these indications, and the sponsor will be asked to remove them from the labeling and the 510(k) summary.

The sponsor mentioned these different indications on pages 26, 39, 52, 55, 56, 84, 90, 115 of the pdf.

Reviewer's Comment: The sponsor included a 510(K) statement instead of a 510(K) summary.

Reviewer's Comment: The classification name for the predicate K082609 was "Fat Reducing Low Level Laser". No issues will be raised for using this statement as a common name for this device.

V. Predicate Device Comparison

Device	Erchonia® Zerona™ 2.0 Laser	Erchonia Zerona
510(K)	N/A	K121695
Indications for Use	The Erchonia® Zerona™ 2.0 Laser is indicated for use as a non-invasive	The Erchonia Zerona is indicated for use as a non-invasive dermatological

	dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.	aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.
Power	1 mw	1 mw
Wavelength	Green 532 nm	Red 635 nm (near infrared)
Waveform	Pulsed	Pulsed
Energy Source	Six 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	30 minutes	40 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.

Reviewer's Comment: The wavelength of the light used in this device and the treatment time are different than the predicate. However, the sponsor provided clinical data to support substantial equivalence. I have consulted Mr. Richard Felten about whether blood chemistry measurements necessary to evaluate the effects of this device. Mr. Felten indicated that as the predicate K082609 provided this information, it is not necessary.

VI. Labeling

The sponsor included the following statements in their labeling without supporting data.

- The Zerona™ 2.0 Laser is applied externally and has proven through double-blind clinical trials to emulsify adipose tissue.
- Zerona™ 2.0 Laser is a new body sculpting procedure designed to remove fat and contour the body without invasive surgery.
- Zerona™ 2.0 Laser works by emulsifying adipose tissue which then releases into the interstitial space. The excess fat is passed through the body during its normal course of detoxification.

Reviewer's Comment: The sponsor will be requested to remove these statements or provide supporting data.

The procedure was proven through a double-blind, randomized, multi-site, and placebo controlled study in which patients averaged a loss of 3.895 inches (9.893 cm) compared to the placebo group that lost only 1.135 inches (2.882 cm).

Reviewer's Comment: These numbers are taken from the clinical data.

Several contraindications were listed on page 26 of the pdf file

- The long-term effects of prolonged use of non-thermal laser exposure are unknown.
- Laser treatment should be applied only to normal, intact, clean skin or treatment will not be effective.

- Laser treatment should not be applied over, or in proximity to, cancerous lesions as conclusive tests have not been conducted.
- Safety of non-thermal lasers for use over a pregnant uterus has not been established.
- Caution should be used over areas of skin that lack normal sensation.
- Avoid direct contact of the laser beam into human and animal eyes.
- Do not use over the chest, neck or face.
- Do not use directly over areas with open wounds.
- Do not use on patients who:
 - o Have a personal or family history of cancer
 - o Have a history of keloid or hypertrophic scar formation
 - o Have a history of herpes simplex
 - o Have active infections or a compromised immune system
 - o Have had a sunburn on the area being treated
 - o Are taking photo-sensitizing drugs, anti-coagulants, or aspirin

Reviewer's Comment: *Only the open wound contra indication was included in the manual. All other contraindications should be listed as cautionary statements.*

Reviewer's Comment: *The sponsor included the following paragraph in the labeling. Same paragraph was included in the predicate labeling. However, the predicate submission included a journal publication in support of these statements.*

Clinical evidence has identified that following exposure to the ZERONA™ 2.0 Laser (Erchonia Corporation) at 532nm 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 ZERONA™ 2.0 Laser 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.

Reviewer's Comment: *These claims were taken from the reference: Niera, R., Arroyave, Ramirez, H., et al. Fat liquefaction: Effect of low-level laser energy on adipose tissue. *Plast. Reconstr. Surg.* (2002): 110; 912-22. However, this reference used 635 nm wavelength light. The sponsor should not make these claims without supporting data. The sponsor will be asked to either provide supporting article or to remove this section from the labeling.*

These safety glasses, manufactured by Laser Safety Industries, sufficiently and effectively block the laser light spectrum at OD6+ @ 190-532nm.

Reviewer's Comment: *The peak wavelength of the laser was found to be 530 nm in testing accordance IEC to 60825 (page 11 of the IEC60285 test report). Thus the wavelength for the laser is blocked by the safety goggles. However, we will still suggest that the sponsor provides safety goggles that has blocking band that extend beyond 532 nm wavelength as manufacturing variability may change the peak wavelength.*

VII. Sterilization/Shelf Life/Reuse

The device does not contact patient's skin. Cleaning instructions for the device was provided in the labeling.

VIII. Biocompatibility

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

Reviewer's Comment: *I agree with the sponsor's assessment. No biocompatibility information is necessary.*

IX. Software

Reviewer's Comment: *The proposed device has very low power it is not likely to cause any minor injury if eye safety goggles are worn as directed by the labeling. I agree with the sponsor's assessment of minor level of concern for the software for this device. The software for this device has two major functions to control the lenses to generate the treatment protocol (rotating slits of light on the body). If the software is dysfunctional, the device will be defective and has to be returned. The patients are not likely to be harmed by the device. The software does not raise any safety issues.*

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

Reviewer's Comment: *The architectural design chart was not legible. However, this section is not required for minor level of concern software according to the guidance document. The sponsor provided a successful V&V testing. There were no revisions to the software after passing the V&V testing, a revision level history is not necessary for this device. The sponsor provided the necessary documentation according to "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". No further software issues will be raised.*

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The Erchonia® MLS, Ierona-ADTM complies with the following standards:

- The Erchonia® Zerona™ 2.0 Laser complies with FDA's performance standards for light-emitting

products (21 CFR Part 1040).

- 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 sponsor provided electrical safety testing according to IEC 60601-1, and EMC testing according to EN 60601-1-2, and laser safety testing according to IEC 60825-1.

Reviewer's Comment: The sponsor provided electrical, EMC, and laser safety testing. The increase in power from the predicate devices does not raise a thermal safety issue as the total laser power is very low (102 mW).

XI. Performance Testing – Bench

The sponsor provided electrical safety testing according to IEC 60601-1, and EMC testing according to EN 60601-1-2, and laser safety testing according to IEC 60825-1.

XII. Performance Testing – Animal

Not applicable.

XIII. Performance Testing – Clinical

The study was a placebo-controlled, randomized, double-blind parallel group design conducted across two independent test sites. 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 males and females aged 18 to 65 years with a Body Mass Index (BMI) of less than 30 kg/m² and who were deemed suitable for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that do not respond to diet and exercise; specifically for the indication of body contouring in the areas of the waist, hips and bilateral thighs. The purpose of this clinical study was to determine the effectiveness of the Erchonia® Scanner device (GLS) for non-invasive body contouring of the waist, hips and bilateral thighs by applying green diode (532 nm) energy around the waist, hips and thighs for 30 minutes, six times across two weeks. The center diode of the Erchonia® GLS is positioned at a distance of 4.00 inches above the subject's abdomen (stomach), centered along the body's midline (the "line" that vertically "dissects" the body into two equal halves) and focused on the navel.

The proposed device had identical clinical study protocol to the predicate K082609 except these differences:

- The predicate had 3 test sites, the proposed device had 2.
- The predicate has 72 subjects (36 test group, 36 control group) the proposed device has 68 (34 test group, 34 control group).
- The study for the proposed device did not include the photographing of the patient pre-procedure for comparison. Also, the patients did not fill a body shape questionnaire to evaluate their self perception of their bodies.
- For the predicate, the device was placed 6 inches above the patient; for the proposed device, this

distance is 4 inches.

- The study for the predicate device had several additional safety monitoring procedures which were not mentioned for the proposed device study.
- Perceived group allocation (to test the success of blinding) and photographs were not recorded for the proposed device.
- The sponsor stated total energy per area was 6.60 joules per square centimeter, but this is unlikely because:

Predicate: $0.017 W \times 5 \times 1200 \text{ seconds} = 102 J$

Proposed device: $0.017 W \times 6 \times 15 \times 60 = 91.8 J$

Fluence: $91.8 J / 516 \text{ cm}^2 = 0.177 J / \text{cm}^2$ this is much less than what was provided in the submission. The sponsor will be asked their calculation for the 6.60 joules per square centimeter calculation.

Reviewer's Comment: *However, except the omission of the perceived group allocation (evaluating the success of blinding), none of these differences are critical in determining substantial equivalence because of following reasons:*

- *Both the predicate and the proposed device study achieved the minimum sample size of 64 for the assessment of the primary endpoint regardless of the number of test sites.*
- *The distance from the patient is not critical because the light irradiated on the patient seems to be collimated.*
- *The safety of the procedure was established with the predicate.*
- *Photographs or body shape questionnaire were not a part of the primary endpoints of the study.*
- *The total energy delivered per area does not need to be identical to the predicate as long as the clinical results are similar.*

The proposed device and the predicate have the exact blinding methodology. Only the sponsor knows which device is sham, and which device is real. The administration investigator knows which patient is in the A group which patient is in the B group, but he or she doesn't know, if A is the test or the placebo group. The assessment investigator, who records the results, does not know which patient is a part of which group.

Compared to the predicate device, the proposed device had a higher percentage of the test group meeting the goal than the predicate. However the difference between the test group and the placebo group was less for the proposed device compared to the predicate. Still, the proposed device achieved both primary endpoints with 68.57% success rate with the test group (goal was 50%) and 49.82% difference between the test group and the placebo (goal was 35%).

Both the predicate and the proposed device recorded the distance of the measurement location from the hip joint. Both studies used this distance to keep the measurements consistent.

The expected sample size was 32 each for the placebo and test groups. Both the predicate, and the proposed device achieved this sample size for the primary endpoint. However, only 59 subject completed the entire study for the predicate device. Only 54 subjects completed the study for the proposed device.

The predicate device offered the option to the patients in the sham group to receive the treatment.

However, this procedure was not a part of the study.

The figures below show the difference in reduction of circumference between the test group and the placebo group also the final patient satisfaction after two weeks (at end of the treatment procedure).

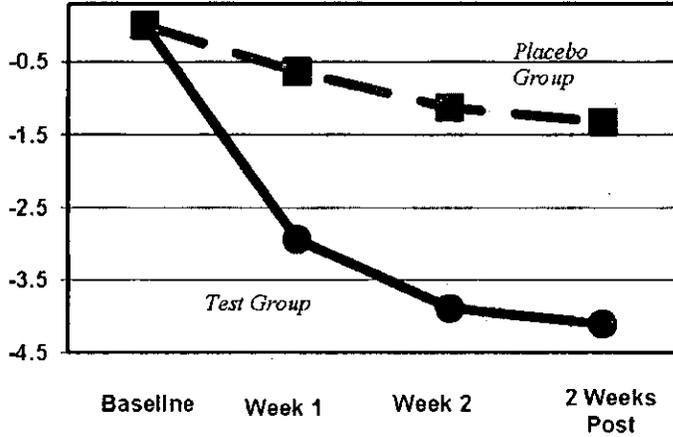


Figure 1: Mean change in total circumference measurements (inches) at each study evaluation point relative to baseline.

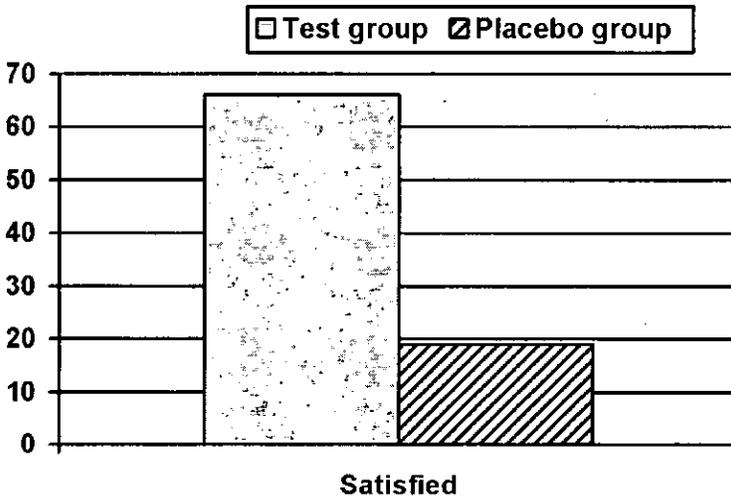


Figure 2: Percentage of test and placebo group subjects who were "satisfied" ("very satisfied" + "somewhat satisfied").

Dr. Janette Alexander, M.D., provided a review of the clinical data provided by the sponsor (please see the attached review) and reached the following conclusions:

- 1) The sponsor met the primary endpoint of reduction in waist, hip and thigh circumference at the completion of two weeks of treatment.
- 2) Almost 20% of the study patients did not have measurements at the 2 week post treatment measurement. It is unclear whether effects documented at the end of 6 treatments persist, and if so, for

how long. Patient satisfaction was not assessed at the 2 week post-procedure visit. I would recommend that the indication for use reflect a temporary reduction in circumference.

3) The indication for use states that the device is indicated in patients intending to undergo liposuction. The protocol inclusion criteria include patients who would be candidates for liposuction, but not with intention to have liposuction. It is unclear how a subsequent liposuction procedure is related, or why the device is to be indicated only for patients intending to undergo liposuction. I would recommend that the indication for use exclude the intention of patients to undergo liposuction.

4) A weakness of the study design is in the measurement methodology. The only criteria discussed for consistency are a single individual doing the measurements, and a measurement from perceived waist to hips and to thighs. Other means to decrease variability such as spring loaded tape measure and measurements from the floor or permanent marks are either not mentioned or not included. The double blind design helps to mitigate bias but not variability.

Lead Reviewer's Comment: I have discussed this issue with Dr. Alexander on 12/05/12. She agreed that as the predicate was cleared for the same indication by providing the same clinical study. A regulatory precedent was set, and asking to limit the indications or changing the measurement method would not be appropriate.

Dr. Harry Bushar, PhD, provided a statistical review of the clinical studies and provided the following deficiencies to be provided to the sponsor.

1. You refer to your body contouring clinical study as a three-center design, but later on correctly refer to this study as a dual-site evaluation. Please explain what happened to your third center.

Lead Reviewer's Comment: That was a prior study with a different device.

2. Although you did attempt to statistically justify your sample sizes of 35 test and 32 placebo subjects, we used PASS 2008 Two Independent Proportions (Null Case) Power Analysis to find that group sample sizes = 37, not 35 and 32, would achieve 80% power to detect a difference between the group proportions = 35%, where the proportion in the placebo group = 15%, using the 2-sided Fisher's Exact test with significance level = 2.5%. Please provide more detail to justify your sample size.

Lead Reviewer's Comment: As mentioned earlier, the regulatory precedent is set when the predicate device was cleared with the same sample size. Also, the difference between the test and the placebo groups exceeded the study goal of 35% by 14% percent.

3. You report that the mean change in circumference measurements from pre-procedure to study end point = -3.521 inches for the test subjects versus -0.684 inches for the placebo subjects, but, later on, modify these results to a mean change in circumference measurements from pre-procedure to study end point = -3.895 inches for the test subjects versus -1.136 inches for the placebo subjects. Please explain which of these two different results is correct.

Lead Reviewer's Comment: Again, that was a prior study with a different device.

4. You report that 62.86% (22/35) of test subjects and 6.25% (2/32) of placebo subjects met the study individual success criteria and that this difference = 56.61 percentage points exceeds the pre-established target of a 35% difference between treatment groups, but, later on, modify these results, which we also verified to be correct, that 68.57% (24/35) of test subjects and 18.75% (6/32) of placebo subjects met the study individual success criteria and that this difference = 49.82 percentage points still exceeds the pre-established target of a 35% difference between treatment groups. Please delete your first report.

Lead Reviewer's Comment: Again, that was a prior study with a different device. The sponsor made the submission really confusing by reporting prior studies and the recent clinical study in the same format and with poor organization.

5. Our analysis of your individual study data uncovered the following anomalies:
- a. The placebo group A had 53% (17/32) anomalies among which
 - i. 28% (9/32) indicated identical summations, measured to within 0.01 of an inch, over waist, hips, and bilateral thighs circumferences for baseline and weeks 1 and 2,
 - ii. 19% (6/32) indicated identical summations, measured to within 0.01 of an inch, over waist, hips, and bilateral thighs circumferences for both baseline and week 2, and
 - iii. 6% (2/32) indicated identical summations, measured to within 0.01 of an inch, over waist, hips, and bilateral thighs circumferences for both weeks 1 and 2.
 - iv. The above anomalies accounted for 62% (16/26) of the placebo subjects who failed to meet the study individual success criteria.
 - b. On the other hand, the test Group B had only 11% (4/35) anomalies each of which indicated identical summations, measured to within 0.01 of an inch, over waist, hips, and bilateral thighs circumferences for both weeks 1 and 2.
 - i. The above anomalies accounted for 13% (3/24) of the test subjects who met the study individual success criteria.

It appears that the blinding of your study may have been compromised and that, for 31% (21/67) of the subjects, later measurements may have been simply copied from earlier measurements to achieve your reported strong effect of test over placebo.

- ii. Your misuse of the biased Last Observation Carried Forward (LOCF) method for handling of missing data may be responsible for 71% (15/21) of the above anomalies, but not for identical summations over both baseline and week 2, which accounts for 19% (6/32) of the placebo group A anomalies.

Please fully explain each of these anomalies.

6. Your pilot study does not address your current submission, which is indicated for 30, not 40, minutes and does not require a Niacin therapy regimen. Also, without any control, your relatively large decrease = 5.85 inches in combined waist-hips-thighs circumference may be inflated over what could be obtained from a study with a control group. Please fully explain your inclusion of your pilot study.

Lead Reviewer's Comment: The sponsor will be informed that we do not accept the niacin combination therapy to be included in the labeling. The device itself was successful in achieving the study goals.

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:

Note: See

http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

(b) (4)



(b) (4)



Clinical Study:

9. Our analysis of your individual study data uncovered the following anomalies:
- a. The placebo group A had 53% (17/32) anomalies among which
 - i. 28% (9/32) indicated identical summations, measured to within 0.01 of an inch, over waist, hips, and bilateral thighs circumferences for baseline and weeks 1 and 2,
 - ii. 19% (6/32) indicated identical summations, measured to within 0.01 of an inch, over waist, hips, and bilateral thighs circumferences for both baseline and week 2, and
 - iii. 6% (2/32) indicated identical summations, measured to within 0.01 of an inch, over waist, hips, and bilateral thighs circumferences for both weeks 1 and 2.
 - iv. The above anomalies accounted for 62% (16/26) of the placebo subjects who failed to meet the study individual success criteria.
 - b. On the other hand, the test Group B had only 11% (4/35) anomalies each of which indicated identical summations, measured to within 0.01 of an inch, over waist, hips, and bilateral thighs circumferences for both weeks 1 and 2.
 - i. The above anomalies accounted for 13% (3/24) of the test subjects who met the study individual success criteria.

It appears that the blinding of your study may have been compromised and that, for 31% (21/67) of the subjects, later measurements may have been simply copied from earlier measurements to achieve your reported strong effect of test over placebo.

- ii. Your misuse of the biased Last Observation Carried Forward (LOCF) method for handling of missing data may be responsible for 71% (15/21) of the above anomalies, but not for identical summations over both baseline and week 2, which accounts for 19% (6/32) of the placebo group A anomalies.

Please fully explain each of these anomalies.

Also, unlike the predicate device, K082609, you did not mention evaluating the success of the blinding via a perceived group allocation study. Please justify this omission from your clinical study.

XVI. Contact History

The sponsor was sent the RTAX letter to the sponsor on 10/31/2012. The sponsor responded to our RTAX request on 11/1/2012.

On 12/03/12, the sponsor was asked via e-mail to state which parts of the submission were related to a pilot study (Niacin study) that was submitted in addition to their clinical study. The sponsor responded the next day.

XVII. Recommendation

Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System for Aesthetic Use
Regulatory Class: Class II
Product Code: OLI

I recommend that this submission be placed on hold pending receipt of the response to the questions listed above.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Mehmet A. Kosoglu 2012.12.10 11:30:42 -05'00'
Branch Chief Sign-Off	Neil R Ogden 2012.12.10 14:30:53 -05'00'
Division Sign-Off	

Records processed under FOIA Request # 2013-8421; Released by CDRH on 10-29-2015

Records processed under FOIA Request # 2013-8421; Released by CDRH on 10-29-2015

Kosoglu, Mehmet

From: Regulatory Insight, Inc. [info@reginsight.com]
Sent: Monday, December 03, 2012 2:50 PM
To: Kosoglu, Mehmet
Cc: Ogden, Neil; 'Elvira Walls'; Steve Shanks
Subject: RE: About Erchonia Zerona 2.0 Laser K123237

Dear Dr. Kosoglu,

(b)(4) Test Data



We hope these responses answer your questions. Please let me know whether you have any additional questions or concerns.

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: Kosoglu, Mehmet [mailto:Mehmet.Kosoglu@fda.hhs.gov]
Sent: Monday, December 03, 2012 9:48 AM
To: Regulatory Insight, Inc.; kevin@reginsight.com
Cc: Ogden, Neil
Subject: RE: About Erchonia Zerona 2.0 Laser K123237

Mr. Walls,

In your submission, you included a section explaining the study titled:

"ERCHONIA® Scanner device (GLS) A double-blind, placebo-controlled, randomized evaluation of the effect of the Erchonia® Scanner device (GLS) Green Diode on body contouring of the waist, hips and thighs"

Please indicate if this section will be a part of the labeling. Also, on the pages 15 thru 18 of this section, you provided the results for a study that was conducted with this device in conjunction with a Niacin therapy regimen. In the following pages, you described the study protocol. It's not clear if this study protocol is related to the Niacin study or to the study with only the device? Please state what parts of the submission (and results) are related to the Niacin study.

Sincerely,

Mehmet A. Kosoglu, Ph.D.

Regulatory Review Scientist

U.S. Food and Drug Administration

General Surgery Devices Branch

Division of Surgical, Orthopedic and Restorative Devices

White Oak (WO) Building 66, Room 1525

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Phone: 301-7966930

E-mail: mehmet.kosoglu@fda.hhs.gov

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0396
Expiration Date: August 31, 2012

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

- (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators	(b) (6)
------------------------	---------

- (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).
- (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME Steve Shanks	TITLE President
FIRM/ORGANIZATION Erchonia Medical Inc.	
SIGNATURE 	DATE (mm/dd/yyyy) 11/01/2012

Paperwork Reduction Act Statement

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. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

Kosoglu, Mehmet

From: Regulatory Insight, Inc. [info@reginsight.com]
Sent: Thursday, November 01, 2012 11:23 AM
To: Kosoglu, Mehmet
Cc: Ogden, Neil
Subject: RE: About Erchonia Zerona 2.0 Laser K123237
Attachments: Signed Form FDA 3454.pdf

Dear Dr. Kosoglu,

Here is the signed Form FDA 3454. Please let me know if there is anything else you need.

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: Kosoglu, Mehmet [mailto:Mehmet.Kosoglu@fda.hhs.gov]
Sent: Wednesday, October 31, 2012 3:16 PM
To: info@reginsight.com
Cc: Ogden, Neil
Subject: About Erchonia Zerona 2.0 Laser K123237

Mr. Walls,

I have conducted a Refuse-to-Accept review of your submission. Please provide us with signed Financial Disclosure 3454 Forms for each of your investigators as soon as possible. Please see the attached RTA checklist.

Sincerely,

Mehmet A. Kosoglu, Ph.D.
Regulatory Review Scientist
U.S. Food and Drug Administration
General Surgery Devices Branch
Division of Surgical, Orthopedic and Restorative Devices
White Oak (WO) Building 66, Room 1525
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 301-7966930
E-mail: mehmet.kosoglu@fda.hhs.gov

*Contains Nonbinding Recommendations
Draft - Not for Implementation*

**Acceptance Checklist
for Traditional 510(k)s**

(should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.

510(k) Number: K123237

Date Received: 10/16/2012

Lead Reviewer Name: Mehmet A. Kosoglu, Ph.D. Branch: GSDB Division: DSORD Office: ODE

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	Yes	No
<p>1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?</p> <p>If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If the product does not appear to be a device or such a combination product, mark "No."</p>	X	
<p>Comments: This is a low level laser, generally reviewed by GSDB.</p>		
<p>2. Is the application with the appropriate Center?</p> <p>If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If application should not be reviewed by your Center mark "No."</p>	X	
<p>Comments:</p>		
<p>3. Is a 510(k) the appropriate regulatory submission?</p> <p>If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."</p>	X	

Contains Nonbinding Recommendations
Draft - Not for Implementation

Comments:		
<p>4. Is there a pending PMA for the same device with the same indications for use?</p> <p>If there is a pending PMA for the same device, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.</p>		X
Comments:		
<p>5. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?</p> <p>If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm.</p>		X

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter. If the answer to 3 is no, the lead reviewer should consult division management and other Center resources to determine the appropriate action.

If the answer to 4 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

If the answer to 5 is "Yes," then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements		
<i>Failure to include these items alone generally should not result in an RTA designation</i>		
	Yes	No
a. Submission contains Table of Contents	X	
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
c. All pages of the submission are numbered <i>All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).</i>	X	
d. Type of 510(k) is identified– traditional, abbreviated, or special <i>If type of 510(k) is not designated, review as a traditional</i>	X	
Comments:		

*Contains Nonbinding Recommendations
Draft - Not for Implementation*

<u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u>				
Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	<ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 	Yes	N/A	No
A.	Administrative			
	1. All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X		<input type="checkbox"/>
	Comments:			
	2. 510(k) cover letter that identifies:	X		<input type="checkbox"/>
	a. Device trade name or proprietary name	X		<input type="checkbox"/>
	b. Device common name	X		<input type="checkbox"/>
	c. Device class and panel	X		<input type="checkbox"/>
	Comments:			
	3. Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 801.109) <i>Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.</i>	X		<input type="checkbox"/>
	Comments:			
	4. Submission contains 510(k) Summary or 510(k) Statement <i>Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) as Comments.</i>	X		<input type="checkbox"/>
	a. Summary contains all elements per 21 CFR 807.92 <i>See also <u>510(k) Summary Checklist</u></i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b. Statement contains all elements per 21 CFR 807.93	X	<input type="checkbox"/>	<input type="checkbox"/>
	Comments:			

Contains Nonbinding Recommendations
Draft - Not for Implementation

<u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u>					
Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	<ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 	Yes	N/A	No	
5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) <i>See recommended <u>format</u></i>	X		<input type="checkbox"/>	
	Comments:				
6.	Submission contains Class III Summary and Certification <i>See recommended <u>content</u></i> <i>Form should be signed by a responsible person of the firm, not a consultant. CDRH is not currently able to accept a digital signature. "N/A" only if submission is not a Class III 510(k).</i>	<input type="checkbox"/>	X	<input type="checkbox"/>	
	Comments:				
7.	If submission relies upon a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (<u>FDA Form 3654</u>) or includes detailed information about how and the extent to which the standard has been followed <i>There should be a completed form for each referenced national or international standard.</i> <i>"N/A" only if submission does not reference any standards.</i>	X	<input type="checkbox"/>	<input type="checkbox"/>	
	Comments:				
8.	Does submission contain clinical data? <i>Select "N/A" for this item and 8.a. and 8.b. if the submission does not contain clinical data. If submission does contain clinical data, parts a. and b. must be answered "yes" for the 510(k) to be complete.</i>	X	<input type="checkbox"/>		
	a.	Submission includes Financial Certification/Disclosure Statement	<input type="checkbox"/>	<input type="checkbox"/>	X

*Contains Nonbinding Recommendations
Draft - Not for Implementation*

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)						
Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
<ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 				Yes	N/A	No
	b.	Submission includes Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (<u>FDA Form 3674</u>) (42 U.S.C. 282(j)(5)(B))		X	<input type="checkbox"/>	<input type="checkbox"/>
Comments:						
9.	If this is a bundled submission, the submission has been appropriately bundled [i.e., the correct user fee(s) have been paid for the devices/indications (section 738 of the FD&C Act)] <u>See Guidance for Industry and FDA Staff: Bundling Multiple Devices or Multiple Indications in a Single Submission.</u> <i>"N/A" if not a bundled submission</i>			<input type="checkbox"/>	X	<input type="checkbox"/>
Comments:						
10.	The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions.			X		<input type="checkbox"/>
	a.	If there were prior submissions: within current submission, the sponsor has identified where in the current submission any issues related to substantial equivalence outlined in prior communications are addressed.		<input type="checkbox"/>	X	<input type="checkbox"/>
Comments:						
B.	Device Description					
11.	If there is a device-specific guidance document or special controls applicable to this submission, documentation has been provided to establish that the submitter has followed the recommendations in the applicable device-specific guidance document or special controls			<input type="checkbox"/>	X	<input type="checkbox"/>

Contains Nonbinding Recommendations
Draft - Not for Implementation

<u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u>					
Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
			Yes	N/A	No
	<ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 				
	regarding the device description or otherwise met the applicable statutory or regulatory criteria through an alternative approach. <i>Select "No" if the submission does not include a rationale for any omitted information or any alternative approaches.</i> <i>Select "N/A" if there is no device-specific guidance document</i>				
	Comments:				
	12.	All descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:			
	a.	A description of the principle of operation and mechanism of action for achieving the intended therapeutic/diagnostic effect.	X		<input type="checkbox"/>
	b.	A description of all conditions of use such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X		<input type="checkbox"/>
	c.	A list and description of each model for which clearance is requested. <i>Select "N/A" if there is only one model.</i>	X	<input type="checkbox"/>	<input type="checkbox"/>
	Comments: Model name: GLS				
	13.	Where applicable, submission contains engineering drawing(s), schematics, illustrations and/or figures of the device that are clear and legible, and include dimensions	X	<input type="checkbox"/>	<input type="checkbox"/>
	a.	If engineering drawings, schematics, illustrations and/or figures are provided, one is provided for each model to be marketed	X	<input type="checkbox"/>	<input type="checkbox"/>
	Comments:				

Contains Nonbinding Recommendations
Draft - Not for Implementation

<u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u>					
Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
			Yes	N/A	No
	<ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 				
	14.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, <i>Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.</i>		X	
	a.	A description (as detailed in item 12.a. and b. and 13 above) is provided for each component or accessory.	X		<input type="checkbox"/>
	b.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. <i>Select "N/A" if the submission states that the component(s)/ accessory(ies) do not have a prior 510(k) clearance.</i>	<input type="checkbox"/>	X	<input type="checkbox"/>
	Comments:				
C.	Substantial Equivalence Discussion				
	15.	Submitter has identified a predicate(s) device	X		<input type="checkbox"/>
	a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided	X		<input type="checkbox"/>
	b.	The identified predicate(s) is consistent throughout the submission (i.e., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing	X		<input type="checkbox"/>
	Comments:				
	16.	Submission includes a comparison of the following for the predicate(s) and subject device			
	a.	Indications for use	X		<input type="checkbox"/>
	b.	Technology, including features, materials, and principles of operation	X		<input type="checkbox"/>

Contains Nonbinding Recommendations
Draft - Not for Implementation

<u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u>				
Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	<ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 	Yes	N/A	No
	Comments:			
17.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., do not constitute a new intended use, affect safety or effectiveness, or raise different questions of safety and effectiveness) (see section 513(i)(1)(A) of the FD&C Act) <i>If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that due to potential differences in manufacturing that may not be known to the submitter, no identified differences does not necessarily mean that no performance testing is needed.</i>	X	<input type="checkbox"/>	<input type="checkbox"/>
	Comments:			
D.	Proposed Labeling (see also 21 CFR part 801)			
18.	Submission includes proposed labels, labeling (e.g., instructions for use, package insert, operator's manual), and advertisements that describe the device, its intended use, and the directions for use			
	a. Indications for use stated in labeling (21 CFR 801.61) and identical to IFU form and 510(k) Summary (if applicable)	X		<input type="checkbox"/>
	b. Directions for use included (including relevant hazards, warnings, precautions, contraindications), including directions for layperson (see 21 CFR 801.5) unless submission states that device qualifies for exemption per 21 CFR 801 Subpart D.	X		<input type="checkbox"/>
	Comments:			

Contains Nonbinding Recommendations
Draft - Not for Implementation

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)					
Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
			Yes	N/A	No
	<ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 				
19.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements] <i>Select "N/A" if not indicated for prescription use.</i>		X	<input type="checkbox"/>	<input type="checkbox"/>
	Comments:				
20.	General labeling provisions				
a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)		X		<input type="checkbox"/>
b.	Labeling includes device common or usual name (21 CFR 801.61)		X		<input type="checkbox"/>
	Comments:				
21.	If there is a device-specific guidance, special controls, or regulation, the provided labeling establishes that the submitter has followed the recommendations in the applicable guidance document, special controls, or regulation, or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. <i>Select "N/A" if there is no device-specific guidance or regulation.</i>		<input type="checkbox"/>	X	<input type="checkbox"/>
	Comments:				
22.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. <i>Select "N/A" if not an in vitro diagnostic device.</i>		<input type="checkbox"/>	X	<input type="checkbox"/>
E.	Performance Data – General				
	Submission: <i>(one of the below must be checked)</i> X does <input type="checkbox"/> does not contain performance data. <i>If "does not" is selected, the performance data-related criteria below are omitted from the checklist.</i>				

*Contains Nonbinding Recommendations
Draft - Not for Implementation*

<u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u>				
Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
		Yes	N/A	No
<ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 				
Comments:				
23.	Full test report is provided for each completed test to explain how the data generated from the test supports a finding of substantial equivalence. (A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, and conclusions.)	X		<input type="checkbox"/>
Comments:				
24.	Submission includes document to establish that the submitter has followed the recommendations for performance data outlined in the applicable device-specific guidance document or special controls, or otherwise met the applicable statutory or regulatory criteria through an alternative approach. <i>Select "N/A" if there is no device-specific guidance document.</i>	<input type="checkbox"/>	X	<input type="checkbox"/>
Comments:				
25.	If literature was used as performance data, submission includes reprints or a summary of each article, and a discussion as to how each article is applicable to support the substantial equivalence of the subject device to the predicate.	<input type="checkbox"/>	X	<input type="checkbox"/>
Comments:				
26.	If an animal study was conducted, <i>Select "N/A" if no animal study was conducted.</i>		X	
a.	Submission includes a study protocol and final study report to explain how the data generated from the study supports a finding of substantial equivalence. (A final study report includes a contributing scientist report for each preclinical endpoint of evaluation within the protocol, such as performance/handling, in life, imaging, pathology, etc.)	<input type="checkbox"/>		<input type="checkbox"/>

Contains Nonbinding Recommendations
Draft - Not for Implementation

<u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u>							
Submission should be designated RTA if not addressed							
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
<ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 					Yes	N/A	No
		b.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	<input type="checkbox"/>		<input type="checkbox"/>	
		Comments:					
F.	Sterilization						
	Submission states that the device and/or accessories are: <i>(one of the below must be checked)</i> <input type="checkbox"/> sterile <input type="checkbox"/> non-sterile but sterilized by the end user <input checked="" type="checkbox"/> non-sterile when used This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "non-sterile when used" is selected, the sterility-related criteria below are omitted from the checklist.</i> <i>If information regarding the sterility status of the device is not provided, select "No."</i>					<input type="checkbox"/>	
	Comments:						
	27.	Assessment of the need for sterilization information					
		a.	Identification of device, and/or accessories, and/or components that are provided sterile.	<input type="checkbox"/>	X	<input type="checkbox"/>	
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized	<input type="checkbox"/>	X	<input type="checkbox"/>	

*Contains Nonbinding Recommendations
Draft - Not for Implementation*

<u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u>						
Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
<ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 				Yes	N/A	No
	c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	X	<input type="checkbox"/>	<input type="checkbox"/>	
	Comments:					
	28.	If the device, and/or accessory, and/or a component is provided sterile: <i>Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.</i>		X		
	a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	<input type="checkbox"/>		<input type="checkbox"/>	
	b.	A description of method to validate the sterilization cycle (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided	<input type="checkbox"/>		<input type="checkbox"/>	
	c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. <i>Select "N/A" if not sterilized using chemical sterilants.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package)	<input type="checkbox"/>		<input type="checkbox"/>	
	e.	Sterility Assurance Level (SAL) stated	<input type="checkbox"/>		<input type="checkbox"/>	
	f.	If device is blood-contacting, a permanent implant, or contacts cerebrospinal fluid, or device is labeled "non-pyrogenic," submission contains a description of the endotoxin method used to make a determination (e.g., LAL), endotoxin release specification (e.g., 20 EU/device), and a rationale for the specification.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

*Contains Nonbinding Recommendations
Draft - Not for Implementation*

<u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u>								
Submission should be designated RTA if not addressed								
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.								
<ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 					Yes	N/A	No	
			<i>Select "N/A" if device is not blood-contacting, not a permanent implant, does not contact cerebrospinal fluid, and is not labeled "non-pyrogenic." Select "N/A" if a rationale for omission is provided.</i>					
			Comments:					
	29.	All sterility information provided as recommended in the following guidance documents or special controls, or information provided indicating the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach: <i>Either "a" or "b" must be answered "Yes" to be considered complete.</i>						
	a.	Device-specific guidance document or special controls <i>Select "N/A" if no device-specific guidance document.</i>				<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	b.	Cross-cutting guidance document (for more information see "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile") <i>Select "N/A" if device-specific guidance followed instead.</i>				<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			Comments:					
G.	Shelf Life							
	30.	If the device is provided sterile or the device is provided non-sterile and storage conditions (i.e., aging) could impact device safety or effectiveness, address the following: <i>Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.</i>					<input checked="" type="checkbox"/>	
	a.	Proposed shelf life/expiry date stated				<input type="checkbox"/>		<input type="checkbox"/>

*Contains Nonbinding Recommendations
Draft - Not for Implementation*

<u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u>				
Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
		Yes	N/A	No
	<ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
	b. Submission includes description of shelf life validation method(s) used to ensure device performance and sterility, as applicable, remain substantially equivalent to that of the predicate device throughout the stated shelf life.	<input type="checkbox"/>		<input type="checkbox"/>
	Comments: The proposed device is a low level laser with an extended shelf life if properly maintained.			
H.	Biocompatibility			
	Submission states that there: <i>(one of the below must be checked)</i> <input type="checkbox"/> are <input checked="" type="checkbox"/> are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."</i>			<input type="checkbox"/>
	Comments:			
	31. Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present	<input type="checkbox"/>		<input type="checkbox"/>
	Comments:			
	32. Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)	<input type="checkbox"/>		<input type="checkbox"/>
	Comments:			

*Contains Nonbinding Recommendations
Draft - Not for Implementation*

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)				
Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
		Yes	N/A	No
	<ul style="list-style-type: none"> • Any "No" answer will result in a "Refuse to Accept" decision. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
33.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	<input type="checkbox"/>		<input type="checkbox"/>
I.	Software			
	Submission states that the device: <i>(one of the below must be checked)</i> X does <input type="checkbox"/> does not contain software. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."</i>			<input type="checkbox"/>
	Comments:			
34.	All appropriate categories of software verification and validation documentation provided based on stated level of concern, as described in <u>Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices</u> , or the submitter has provided documentation that it has otherwise met the applicable statutory or regulatory criteria through an alternative approach.	X		<input type="checkbox"/>
	Comments:			

*Contains Nonbinding Recommendations
Draft - Not for Implementation*

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)				
Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
	<ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 	Yes	N/A	No
J.	EMC and Electrical Safety			
	Submission states that the device: <i>(one of the below must be checked)</i> X does <input type="checkbox"/> does not require EMC and Electrical Safety evaluation. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. <i>If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."</i>			<input type="checkbox"/>
	Comments:			
	35. Submission includes evaluation of electrical safety per IEC 60601-1 or equivalent FDA-recognized standard and if applicable, the device-specific standard OR submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and information indicating that these methods/standards otherwise meet applicable statutory and regulatory requirements.	X		<input type="checkbox"/>
	Comments:			
	36. Submission includes evaluation of electromagnetic compatibility per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard OR submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and information indicating that these methods/standards otherwise meet applicable	X		<input type="checkbox"/>

*Contains Nonbinding Recommendations
Draft - Not for Implementation*

<u>Elements of a Complete Submission (RTA Items)</u> <u>(21 CFR 807.87 unless otherwise indicated)</u>				
Submission should be designated RTA if not addressed				
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.				
		Yes	N/A	No
	<ul style="list-style-type: none"> Any "No" answer will result in a "Refuse to Accept" decision. Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission. 			
	statutory and regulatory requirements.			
	Comments:			
K.	Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))			
	Submission indicates that device: <i>(one of the below must be checked)</i> <input type="checkbox"/> is <input type="checkbox"/> is not an in vitro diagnostic device (IVD). <i>If "is not" is selected, the performance data-related criteria below are omitted from the checklist.</i>			
	Comments:			
	37.	Submission includes the following analytical studies, including associated protocols and line data:		
	a.	Precision/reproducibility (at least 3 sites generally necessary)	<input type="checkbox"/>	<input type="checkbox"/>
	b.	Accuracy (includes linearity, assay cut-off, method comparison or comparison to clinical outcome, matrix comparison, reference range, and stability protocol and acceptance criteria)	<input type="checkbox"/>	<input type="checkbox"/>
	c.	Sensitivity (detection limits (LoB, LoD, and LoQ))	<input type="checkbox"/>	<input type="checkbox"/>
	d.	Analytical specificity	<input type="checkbox"/>	<input type="checkbox"/>
	Comments:			

Contains Nonbinding Recommendations
Draft - Not for Implementation

Decision: Accept ___ Refuse to Accept X

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Mehmet A. Kosoglu 2012.10.29 18:35:40 -04'00'
Branch Chief Sign-Off	Neil R Ogden 2012.11.01 15:05:47 -04'00'
Division Sign-Off	

K123237/ SI



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

V.1

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

Erchonia Corporation
% Regulatory Insight, Incorporated
Mr. Kevin Walls
Principal Consultant
33 Golden Eagle Lane
Littleton, Colorado 80127

January 25, 2013

Re: K123237

Trade/Device Name: Erchonia® Zerona™ 2.0 Laser
Regulation Number: 21 CFR 878.5400
Regulation Name: Low level laser system for aesthetic use
Regulatory Class: Class II
Product Code: OLI
Dated: December 20, 2012
Received: December 21, 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

Page 2 – Mr. Kevin Walls

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/CDRHOices/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,

Peter D. Rumm -S

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

Enclosure

Page 3 – Mr. Kevin Walls

Concurrence & Template History Page
 [THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number:

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off	
Division Sign-Off	Peter D. Rumm -S 2013.01.29 10:32:35 -05'00'

f/t:MAK:kdm:1/29/13

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1 st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and

		the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".
--	--	--

510(k) Number (if known): K123237

Device Name: Erchonia® Zerona™ 2.0 Laser

Indications for Use: The Erchonia® Zerona™ 2.0 Laser 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)

Neil R Ogden
2013.01.24 13:17:37 -05'00'

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K123237

Page 1 of 1

* * * COMMUNICATION RESULT REPORT (JAN. 30. 2013 12:53PM) * * *

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : JAN. 30. 2013 12:50PM
FILE MODE OPTION

ADDRESS

RESULT

PAGE

2821 MEMORY TX

917209625413

OK

3/3

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-3) NO ANSWER

E-2) BUSY
E-4) NO FACSIMILE CONNECTION



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Erchonia Corporation
% Regulatory Insight, Incorporated
Mr. Kevin Walls
Principal Consultant
33 Golden Eagle Lane
Littleton, Colorado 80127

January 25, 2013

Re: K123237

Trade/Device Name: Erchonia® Zerona™ 2.0 Laser
Regulation Number: 21 CFR 878.5400
Regulation Name: Low level laser system for aesthetic use
Regulatory Class: Class II
Product Code: OLI
Dated: December 20, 2012
Received: December 21, 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



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

COVER SHEET MEMORANDUM

From: Reviewer Name Mehmet A. Kosoglu, Ph.D.
Subject: 510(k) Number K123237
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/eRoomReq/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	<i>Attach IFU</i>	X	
510(k) Summary /510(k) Statement	<i>Attach Summary</i>	X	
Truthful and Accurate Statement.	<i>Must be present for a Final Decision</i>	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	<i>Must be present for a Final Decision</i>		
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 _____, 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)			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?		X	
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			

Rev. 9/20/12 – added digital concurrence table

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank?</i> (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?		X
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		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	X

Regulation Number	Class*	Product Code
21 CFR 878.5400	II	OLI

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

Additional Product Codes: _____

Digital Signature Concurrence Table	
Reviewer Sign-Off	Mehmet A. Kosoglu 2013.01.24 13:28:15 -05'00'
Branch Chief Sign-Off	Neil R Ogden 2013.01.24 13:06:17 -05'00'
Division Sign-Off	

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

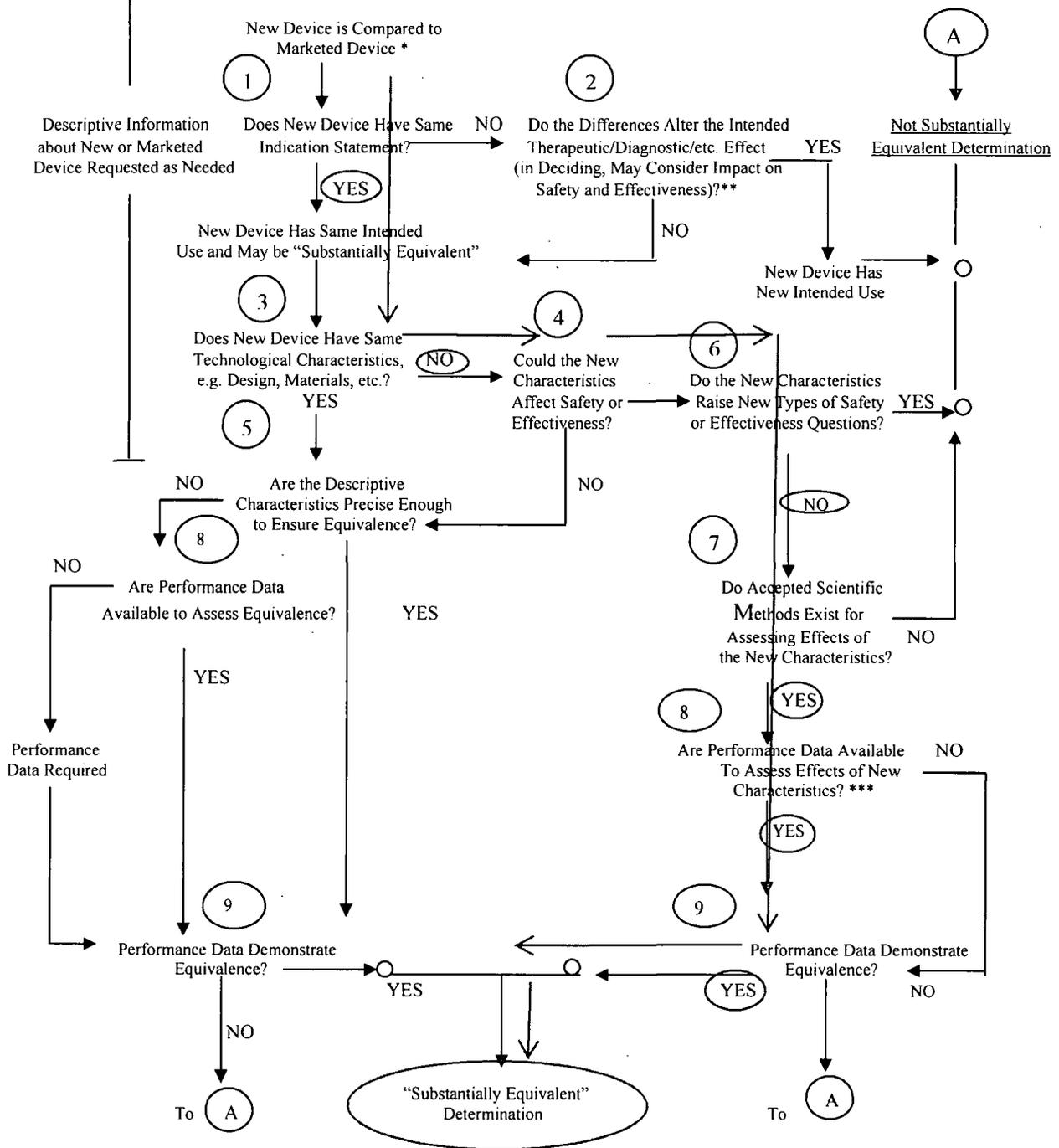
Regulation Number	Class*	Product Code
21 CFR 878.5400	II	OLI

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

Additional Product Codes: _____

Digital Signature Concurrence Table	
Reviewer Sign-Off	Mehmet A. Kosoglu 2013.01.24 13:28:15 -05'00'
Branch Chief Sign-Off	Neil R Ogden 2013.01.24 13:06:17 -05'00'
Division Sign-Off	Peter D. Rumm -S 2013.01.24 17:15:15 -05'00'

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



Neil R Ogden
2013.01.24 10:58:20 -05'00'

* 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
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

K123237 – S1

Date: 01/22/13

To: The Record

From: Mehmet A. Kosoglu, PhD

Office: ODE

Division: DSD

510(k) Holder: Erchonia Medical, Inc.

Device Name: Erchonia® Zerona™ 2.0 Laser

Contact: Kevin Walls

Phone: 702-9625412

Fax: 720-962-5412

Email: Kevin@reginsight.com

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce Erchonia® Zerona™ 2.0 Laser into interstate commerce. The earliest predicate for this device is K082609 which was cleared through the DeNovo process. The predicate K121695 is the same device as K082609 but has a different trade name. The proposed device is very similar to the predicates K121695 and K082609 in terms of technology and has identical indications for use.

The sponsor provided two studies one with using the device and one with using the device in conjunction with a Niacin therapy regimen. However, we indicated to the sponsor that we will base our decision on the clinical data provided with the device alone. Niacin produces a compounding effect in the clinical data for the success of the device and the use of niacin would classify the proposed device as a combination product. The sponsor will be requested to remove all references to Niacin in their labeling including the marketing materials. The sponsor agreed to remove all references to Niacin regimen.

I recommend that this submission be placed on hold pending receipt of the response to the questions listed in the deficiencies section.

S1 – The sponsor responded to all our information requests. There was a suspicion that blinding might be compromised in the placebo arm due to high number of same readings. However, the sponsor explained these readings by consistency of the measurement technique and the subject group's diet and exercise regiment. Also the sponsor used the same blinding method that was validated in the predicate device's study. As the device is almost identical to the predicate (except the color of the light it delivered), I and our branch chief, Mr. Neil Ogden, were not able to invoke a hypothesis why would the blinding become compromised. We accepted the sponsor's explanation.

As all of the issues were resolved, I recommend that this submission be found **Substantially Equivalent** to the predicate.

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)?	X		
Are "cleaning" instructions included for the end user?	X		

The Erchonia® Zerona™ 2.0 Laser has the following specifications:

Configuration: 6 Class 2 Line Generated Laser Diode Modules

Wavelength: 532nm

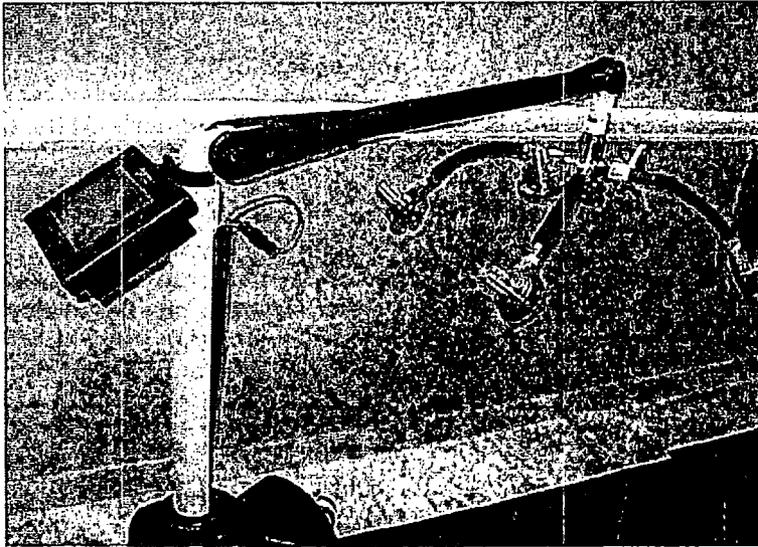
Power Output (Mean): 17mw

Modulation: Constant Wave (CW)

The Erchonia® Zerona™ 2.0 Laser is made up of six independent variable frequency, 532 nanometer (green diodes). The variable frequency feature of the Erchonia® Zerona™ 2.0 Laser is a pulsed wave, defined as containing a selected series of breaks, variances that are preprogrammed.

The Erchonia® Zerona™ 2.0 Laser utilizes internal mechanics that collects the light emitted from the each of the laser diodes and processes each through a proprietary patented lens which redirects the beam with a line refractor. The refracted light is then bent into a spiraling circle pattern that is totally random and independent of the other diodes. These patterns overlap each other to guarantee total coverage within the target area. The target area is approximately 8" x 10" inches or 80 square inches, or approximately 516 square centimeters.

The Erchonia® Zerona™ 2.0 Laser contains 6 independent diodes, 4 of which are mounted in scanner devices, positioned 120 degrees apart from the next with each titled at a 30 degree angle. The fifth and sixth diodes are 4" from center, each tilted at a 15 degree angle. Each scanner emits 17mW, 532nm of green laser light.



Reviewer's Comment: The proposed device is a low level laser for reduction of fat. This device is unlikely to increase the temperature of the patient's skin due the very low irradiance it delivers (Irradiance = $17 \text{ mW} \times 6 / 80 \text{ square inch} = 1.275 \text{ mW} / \text{square inch} = 0.197 \text{ mW/cm}^2$)

The proposed device is the same as the predicate in design with the exception of the following differences:

- The proposed device delivers 532 nm light while the predicate, K12195 uses 635 nm. Due to the change in wavelength clinical data is required to show that the device can still reduce fat. The sponsor provided clinical data.
- The proposed device uses 6 instead of 5. The 20 percent increase in power does not raise any safety issues as the irradiance delivered by this device is extremely low.
- The treatment time was decreased from 40 minutes to 30 minutes, and thus total dosage (energy) for the treatment was decreased from 204 J to 183.6 Joules.
- Note: $0.017 \text{ W} \times 5 \times 2400 \text{ seconds} = 204 \text{ J}$ and $0.017 \text{ W} \times 6 \times 1800 \text{ seconds} = 183.6 \text{ J}$

IV. Indications for Use

Proposed Device, Zerona 2.0: The Erchonia® Zerona™ 2.0 Laser 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.

Predicate Device, K121695: 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.

Reviewer's Comment: The indications for use for the proposed device is identical to the predicate. However, on pages 1,4, 17 of the manual, the sponsor referred to body contouring or sculpting, and fat removal and fat or adipose emulsifying. None of these indications were cleared for this device.

Also, throughout the study protocol, the device is stated to be indicated for "body contouring", "body

sculpting”, “removal of local deposits of fat or adipose”, “removing fat or fatty material by emulsifying”. The sponsor will be reminded that we did not clear these indications, and the sponsor will be asked to remove them from the labeling and the 510(k) summary.

The sponsor mentioned these different indications on pages 26, 39, 52, 55, 56, 84, 90, 115 of the pdf.

Reviewer’s Comment: The sponsor included a 510(K) statement instead of a 510(K) summary.

Reviewer’s Comment: The classification name for the predicate K082609 was “Fat Reducing Low Level Laser”. No issues will be raised for using this statement as a common name for this device.

V. Predicate Device Comparison

Device	Erchonia® Zerona™ 2.0 Laser	Erchonia Zerona
510(K)	N/A	K121695
Indications for Use	The Erchonia® Zerona™ 2.0 Laser 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.	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	1 mw	1 mw
Wavelength	Green 532 nm	Red 635 nm (near infrared)
Waveform	Pulsed	Pulsed
Energy Source	Six 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	30 minutes	40 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.

Reviewer’s Comment: The wavelength of the light used in this device and the treatment time are different than the predicate. However, the sponsor provided clinical data to support substantial equivalence. I have consulted Mr. Richard Felten about whether blood chemistry measurements necessary to evaluate the effects of this device. Mr. Felten indicated that as the predicate K082609 provided this information, it is not necessary.

VI. Labeling

The sponsor included the following statements in their labeling without supporting data.

- The Zerona™ 2.0 Laser is applied externally and has proven through double-blind clinical trials to emulsify adipose tissue.

- Zerona™ 2.0 Laser is a new body sculpting procedure designed to remove fat and contour the body without invasive surgery.
- Zerona™ 2.0 Laser works by emulsifying adipose tissue which then releases into the interstitial space. The excess fat is passed through the body during its normal course of detoxification.

Reviewer's Comment: *The sponsor will be requested to remove these statements or provide supporting data.*

The procedure was proven through a double-blind, randomized, multi-site, and placebo controlled study in which patients averaged a loss of 3.895 inches (9.893 cm) compared to the placebo group that lost only 1.135 inches (2.882 cm).

Reviewer's Comment: *These numbers are taken from the clinical data.*

Several contraindications were listed on page 26 of the pdf file

- The long-term effects of prolonged use of non-thermal laser exposure are unknown.
- Laser treatment should be applied only to normal, intact, clean skin or treatment will not be effective.
- Laser treatment should not be applied over, or in proximity to, cancerous lesions as conclusive tests have not been conducted.
- Safety of non-thermal lasers for use over a pregnant uterus has not been established.
- Caution should be used over areas of skin that lack normal sensation.
- Avoid direct contact of the laser beam into human and animal eyes.
- Do not use over the chest, neck or face.
- Do not use directly over areas with open wounds.
- Do not use on patients who:
 - o Have a personal or family history of cancer
 - o Have a history of keloid or hypertrophic scar formation
 - o Have a history of herpes simplex
 - o Have active infections or a compromised immune system
 - o Have had a sunburn on the area being treated
 - o Are taking photo-sensitizing drugs, anti-coagulants, or aspirin

Reviewer's Comment: *Only the open wound contra indication was included in the manual. All other contraindications should be listed as cautionary statements.*

Reviewer's Comment: *The sponsor included the following paragraph in the labeling. Same paragraph was included in the predicate labeling. However, the predicate submission included a journal publication in support of these statements.*

Clinical evidence has identified that following exposure to the ZERONA™ 2.0 Laser (Erchonia Corporation) at 532nm 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 ZERONA™ 2.0 Laser 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.

Reviewer's Comment: *These claims were taken from the reference: Niera, R., Arroyave, Ramirez, H., et al. Fat liquefaction: Effect of low-level laser energy on adipose tissue. Plast. Reconstr. Surg. (2002): 110; 912-22. However, this reference used 635 nm wavelength light. The sponsor should not make these claims without supporting data. The sponsor will be asked to either provide supporting article or to remove this section from the labeling.*

These safety glasses, manufactured by Laser Safety Industries, sufficiently and effectively block the laser light spectrum at OD6+ @ 190-532nm.

Reviewer's Comment: *The peak wavelength of the laser was found to be 530 nm in testing accordance IEC to 60825 (page 11 of the IEC60285 test report). Thus the wavelength for the laser is blocked by the safety goggles. However, we will still suggest that the sponsor provides safety goggles that has blocking band that extend beyond 532 nm wavelength as manufacturing variability may change the peak wavelength.*

VII. Sterilization/Shelf Life/Reuse

The device does not contact patient's skin. Cleaning instructions for the device was provided in the labeling.

VIII. Biocompatibility

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

Reviewer's Comment: *I agree with the sponsor's assessment. No biocompatibility information is necessary.*

IX. Software

Reviewer's Comment: *The proposed device has very low power it is not likely to cause any minor injury if eye safety goggles are worn as directed by the labeling. I agree with the sponsor's assessment of minor level of concern for the software for this device. The software for this device has two major functions to control the lenses to generate the treatment protocol (rotating slits of light on the body). If the software is dysfunctional, the device will be defective and has to be returned. The patients are not likely to be harmed by the device. The software does not raise any safety issues.*

Version:		
Level of Concern: Minor		
	Yes	No
Software description:	X	
Device Hazard Analysis:	X	
Software Requirements Specifications:	X	
Architecture Design Chart:	X	
Design Specifications:	X	
Traceability Analysis/Matrix:	X	

Development:	X	
Verification & Validation Testing:	X	
Revision level history:		
Unresolved anomalies:		X

Reviewer's Comment: *The architectural design chart was not legible. However, this section is not required for minor level of concern software according to the guidance document. The sponsor provided a successful V&V testing. There were no revisions to the software after passing the V&V testing, a revision level history is not necessary for this device. The sponsor provided the necessary documentation according to "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". No further software issues will be raised.*

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

The Erchonia® MLS, Ierona-ADTM complies with the following standards:

- The Erchonia® Zerona™ 2.0 Laser complies with FDA's performance standards for light-emitting products (21 CFR Part 1040).
- 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 sponsor provided electrical safety testing according to IEC 60601-1, and EMC testing according to EN 60601-1-2, and laser safety testing according to IEC 60825-1.

Reviewer's Comment: *The sponsor provided electrical, EMC, and laser safety testing. The increase in power from the predicate devices does not raise a thermal safety issue as the total laser power is very low (102 mW).*

XI. Performance Testing – Bench

The sponsor provided electrical safety testing according to IEC 60601-1, and EMC testing according to EN 60601-1-2, and laser safety testing according to IEC 60825-1.

XII. Performance Testing – Animal

Not applicable.

XIII. Performance Testing – Clinical

The study was a placebo-controlled, randomized, double-blind parallel group design conducted across two independent test sites. 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 males and females aged 18 to 65 years with a Body Mass Index (BMI) of less than 30 kg/m² and who were deemed suitable for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that do not respond to diet and exercise; specifically for the indication of body contouring in the areas of the waist, hips and bilateral thighs. The purpose of this

clinical study was to determine the effectiveness of the Erchonia® Scanner device (GLS) for non-invasive body contouring of the waist, hips and bilateral thighs by applying green diode (532 nm) energy around the waist, hips and thighs for 30 minutes, six times across two weeks. The center diode of the Erchonia® GLS is positioned at a distance of 4.00 inches above the subject's abdomen (stomach), centered along the body's midline (the "line" that vertically "dissects" the body into two equal halves) and focused on the navel.

The proposed device had identical clinical study protocol to the predicate K082609 except these differences:

- The predicate had 3 test sites, the proposed device had 2.
- The predicate has 72 subjects (36 test group, 36 control group) the proposed device has 68 (34 test group, 34 control group).
- The study for the proposed device did not include the photographing of the patient pre-procedure for comparison. Also, the patients did not fill a body shape questionnaire to evaluate their self perception of their bodies.
- For the predicate, the device was placed 6 inches above the patient; for the proposed device, this distance is 4 inches.
- The study for the predicate device had several additional safety monitoring procedures which were not mentioned for the proposed device study.
- Perceived group allocation (to test the success of blinding) and photographs were not recorded for the proposed device.
- The sponsor stated total energy per area was 6.60 joules per square centimeter, but this is unlikely because:

Predicate: $0.017 W \times 5 \times 1200 \text{ seconds} = 102 J$

Proposed device: $0.017 W \times 6 \times 15 \times 60 = 91.8 J$

Fluence: $91.8 J / 516 \text{ cm}^2 = 0.177 J / \text{cm}^2$ this is much less than what was provided in the submission. The sponsor will be asked their calculation for the 6.60 joules per square centimeter calculation.

Reviewer's Comment: *However, except the omission of the perceived group allocation (evaluating the success of blinding), none of these differences are critical in determining substantial equivalence because of following reasons:*

- *Both the predicate and the proposed device study achieved the minimum sample size of 64 for the assessment of the primary endpoint regardless of the number of test sites.*
- *The distance from the patient is not critical because the light irradiated on the patient seems to be collimated.*
- *The safety of the procedure was established with the predicate.*
- *Photographs or body shape questionnaire were not a part of the primary endpoints of the study.*
- *The total energy delivered per area does not need to be identical to the predicate as long as the clinical results are similar.*

The proposed device and the predicate have the exact blinding methodology. Only the sponsor knows which device is sham, and which device is real. The administration investigator knows which patient is in the A group which patient is in the B group, but he or she doesn't know, if A is the test or the placebo group. The assessment investigator, who records the results, does not know which patient is a part of which group.

Compared to the predicate device, the proposed device had a higher percentage of the test group meeting the goal than the predicate. However the difference between the test group and the placebo group was less for the proposed device compared to the predicate. Still, the proposed device achieved both primary endpoints with 68.57% success rate with the test group (goal was 50%) and 49.82% difference between the test group and the placebo (goal was 35%).

Both the predicate and the proposed device recorded the distance of the measurement location from the hip joint. Both studies used this distance to keep the measurements consistent.

The expected sample size was 32 each for the placebo and test groups. Both the predicate, and the proposed device achieved this sample size for the primary endpoint. However, only 59 subject completed the entire study for the predicate device. Only 54 subjects completed the study for the proposed device.

The predicate device offered the option to the patients in the sham group to receive the treatment. However, this procedure was not a part of the study.

The figures below show the difference in reduction of circumference between the test group and the placebo group also the final patient satisfaction after two weeks (at end of the treatment procedure).

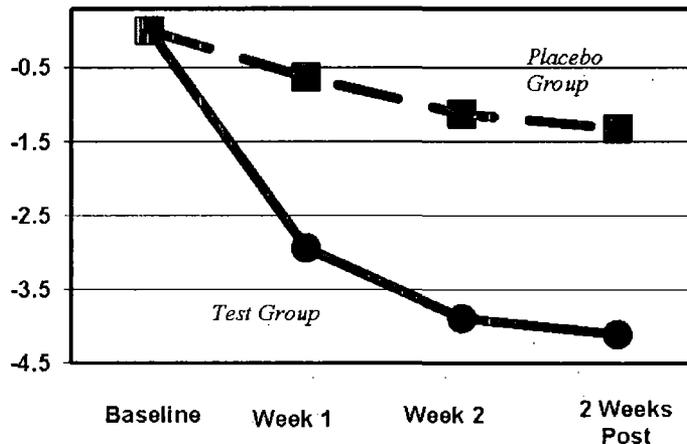


Figure 1: Mean change in total circumference measurements (inches) at each study evaluation point relative to baseline.

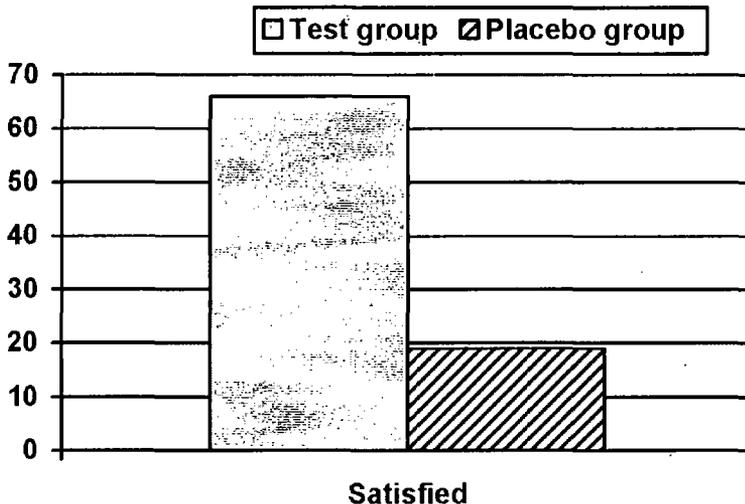


Figure 2: Percentage of test and placebo group subjects who were “satisfied” (“very satisfied” + “somewhat satisfied”).

Dr. Janette Alexander, M.D., provided a review of the clinical data provided by the sponsor (please see the attached review) and reached the following conclusions:

- 1) The sponsor met the primary endpoint of reduction in waist, hip and thigh circumference at the completion of two weeks of treatment.
- 2) Almost 20% of the study patients did not have measurements at the 2 week post treatment measurement. It is unclear whether effects documented at the end of 6 treatments persist, and if so, for how long. Patient satisfaction was not assessed at the 2 week post-procedure visit. I would recommend that the indication for use reflect a temporary reduction in circumference.
- 3) The indication for use states that the device is indicated in patients intending to undergo liposuction. The protocol inclusion criteria include patients who would be candidates for liposuction, but not with intention to have liposuction. It is unclear how a subsequent liposuction procedure is related, or why the device is to be indicated only for patients intending to undergo liposuction. I would recommend that the indication for use exclude the intention of patients to undergo liposuction.
- 4) A weakness of the study design is in the measurement methodology. The only criteria discussed for consistency are a single individual doing the measurements, and a measurement from perceived waist to hips and to thighs. Other means to decrease variability such as spring loaded tape measure and measurements from the floor or permanent marks are either not mentioned or not included. The double blind design helps to mitigate bias but not variability.

Lead Reviewer’s Comment: *I have discussed this issue with Dr. Alexander on 12/05/12. She agreed that as the predicate was cleared for the same indication by providing the same clinical study. A regulatory precedent was set, and asking to limit the indications or changing the measurement method would not be appropriate.*

Dr. Harry Bushar, PhD, provided a statistical review of the clinical studies and provided the following deficiencies to be provided to the sponsor.

1. You refer to your body contouring clinical study as a three-center design, but later on correctly refer to this study as a dual-site evaluation. Please explain what happened to your third center.

Lead Reviewer's Comment: That was a prior study with a different device.

2. Although you did attempt to statistically justify your sample sizes of 35 test and 32 placebo subjects, we used PASS 2008 Two Independent Proportions (Null Case) Power Analysis to find that group sample sizes = 37, not 35 and 32, would achieve 80% power to detect a difference between the group proportions = 35%, where the proportion in the placebo group = 15%, using the 2-sided Fisher's Exact test with significance level = 2.5%. Please provide more detail to justify your sample size.

Lead Reviewer's Comment: As mentioned earlier, the regulatory precedent is set when the predicate device was cleared with the same sample size. Also, the difference between the test and the placebo groups exceeded the study goal of 35% by 14% percent.

3. You report that the mean change in circumference measurements from pre-procedure to study end point = -3.521 inches for the test subjects versus -0.684 inches for the placebo subjects, but, later on, modify these results to a mean change in circumference measurements from pre-procedure to study end point = -3.895 inches for the test subjects versus -1.136 inches for the placebo subjects. Please explain which of these two different results is correct.

Lead Reviewer's Comment: Again, that was a prior study with a different device.

4. You report that 62.86% (22/35) of test subjects and 6.25% (2/32) of placebo subjects met the study individual success criteria and that this difference = 56.61 percentage points exceeds the pre-established target of a 35% difference between treatment groups, but, later on, modify these results, which we also verified to be correct, that 68.57% (24/35) of test subjects and 18.75% (6/32) of placebo subjects met the study individual success criteria and that this difference = 49.82 percentage points still exceeds the pre-established target of a 35% difference between treatment groups. Please delete your first report.

Lead Reviewer's Comment: Again, that was a prior study with a different device. The sponsor made the submission really confusing by reporting prior studies and the recent clinical study in the same format and with poor organization.

5. Our analysis of your individual study data uncovered the following anomalies:
 - a. The placebo group A had 53% (17/32) anomalies among which
 - i. 28% (9/32) indicated identical summations, measured to within 0.01 of an inch, over waist, hips, and bilateral thighs circumferences for baseline and weeks 1 and 2,
 - ii. 19% (6/32) indicated identical summations, measured to within 0.01 of an inch, over waist, hips, and bilateral thighs circumferences for both baseline and week 2, and
 - iii. 6% (2/32) indicated identical summations, measured to within 0.01 of an inch, over waist, hips, and bilateral thighs circumferences for both weeks 1 and 2.
 - iv. The above anomalies accounted for 62% (16/26) of the placebo subjects who failed to meet the study individual success criteria.
 - b. On the other hand, the test Group B had only 11% (4/35) anomalies each of which indicated identical summations, measured to within 0.01 of an inch, over waist, hips, and bilateral thighs circumferences for both weeks 1 and 2.
 - i. The above anomalies accounted for 13% (3/24) of the test subjects who met the study individual success criteria.

It appears that the blinding of your study may have been compromised and that, for 31% (21/67) of the subjects, later measurements may have been simply copied from earlier measurements to achieve your reported strong effect of test over placebo.

- ii. Your misuse of the biased Last Observation Carried Forward (LOCF) method for handling of missing data may be responsible for 71% (15/21) of the above

anomalies, but not for identical summations over both baseline and week 2, which accounts for 19% (6/32) of the placebo group A anomalies.

Please fully explain each of these anomalies.

- Your pilot study does not address your current submission, which is indicated for 30, not 40, minutes and does not require a Niacin therapy regimen. Also, without any control, your relatively large decrease = 5.85 inches in combined waist-hips-thighs circumference may be inflated over what could be obtained from a study with a control group. Please fully explain your inclusion of your pilot study.

Lead Reviewer's Comment: The sponsor will be informed that we do not accept the niacin combination therapy to be included in the labeling. The device itself was successful in achieving the study goals.

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?	X		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?		X	If YES = Stop NSE
7. Accepted Scientific Methods Exist?	X		If NO = Stop NSE
8. Performance Data Available?	X		If NO = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: See

http://erom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

- Explain how the new indication differs from the predicate device's indication:
- Explain why there is or is not a new effect or safety or effectiveness issue:
- Describe the new technological characteristics:

The new device uses a new wavelength of light of 532 nm. The new device also has one more diode.

- Explain how new characteristics could or could not affect safety or effectiveness:

The new characteristics are not likely to affect safety; however the effectiveness in reducing circumference might be different than the predicate.

- Explain how descriptive characteristics are not precise enough:

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

No effectiveness endpoint is the same as the predicate: reduction in total circumference of hip, waist, and thighs.

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

A randomized, double-blinded, placebo-controlled study was necessary.

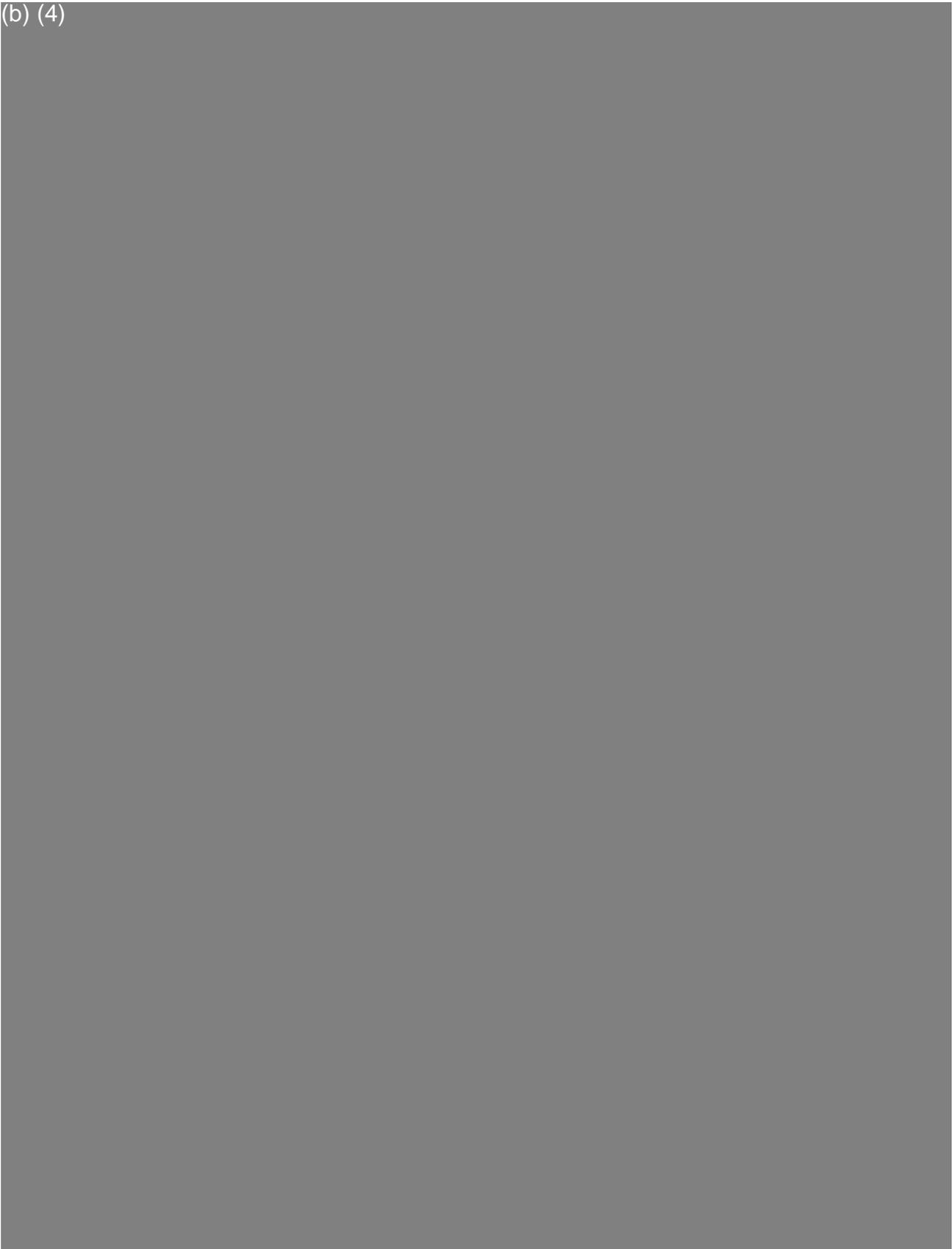
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

The sponsor provided a study using the same protocol as the predicate. The study results met the three inches total reduction primary endpoint which was specified for the predicate.

(b) (4)



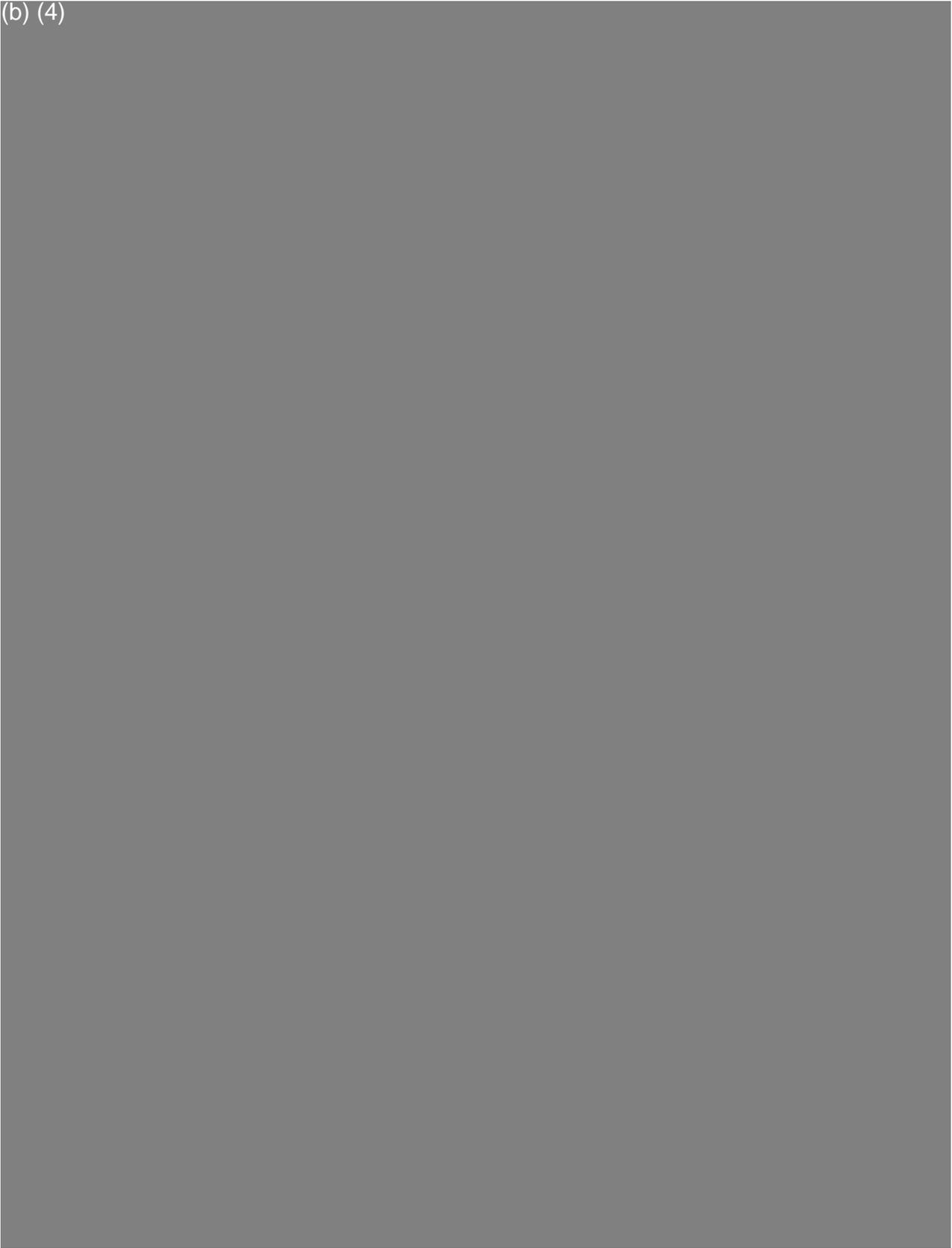
(b) (4)



(b) (4)



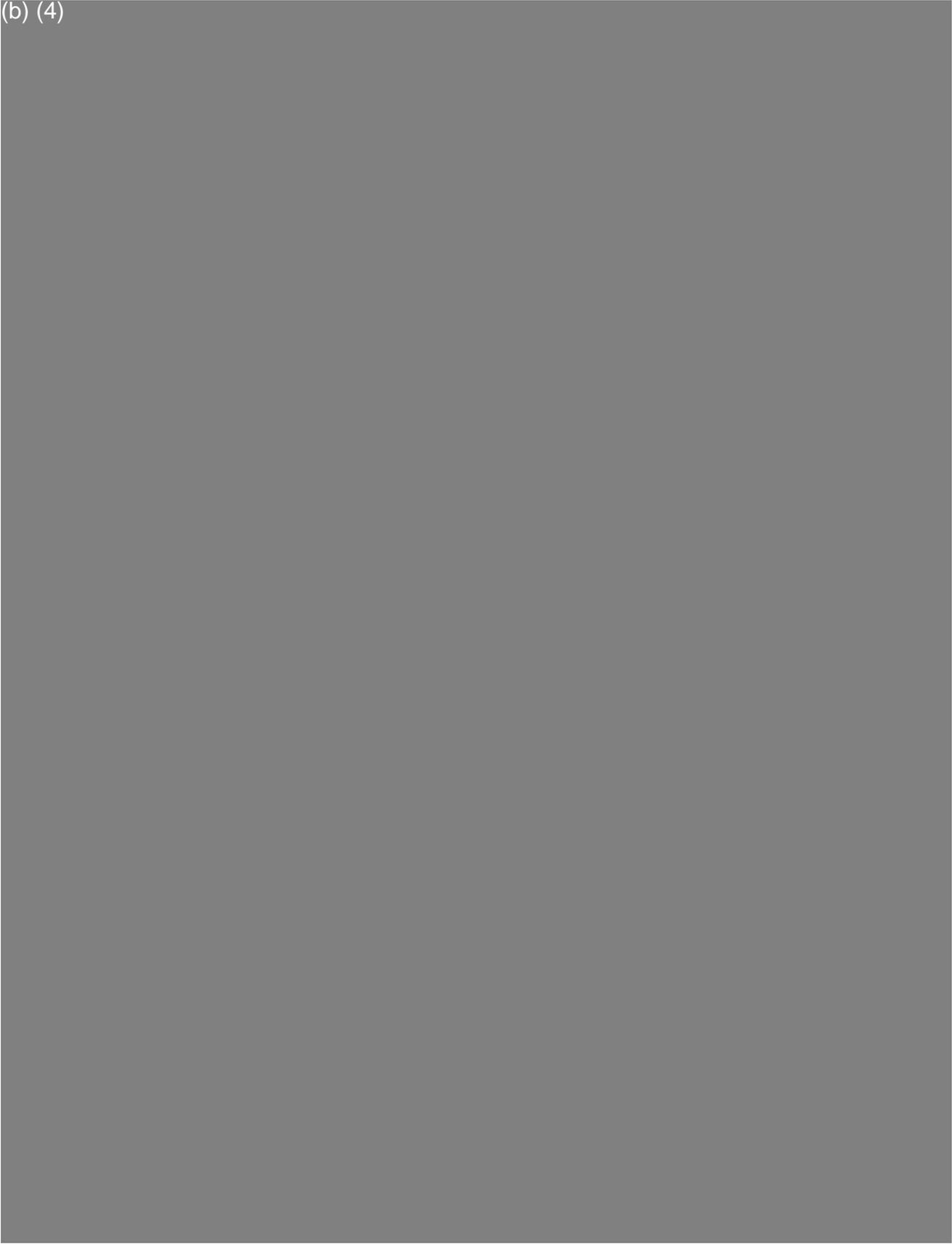
(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



XVI. Contact History

The sponsor was sent the RTAX letter to the sponsor on 10/31/2012. The sponsor responded to our RTAX request on 11/1/2012.

On 12/03/12, the sponsor was asked via e-mail to state which parts of the submission were related to a pilot study (Niacin study) that was submitted in addition to their clinical study. The sponsor responded the next day.

XVII. Recommendation

Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System for Aesthetic Use
Regulatory Class: Class II
Product Code: OLI

I recommend that this submission be placed on hold pending receipt of the response to the questions listed above.

S1 – As all of the issues were resolved, I recommend that this submission be found **Substantially Equivalent** to the predicate.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Mehmet A. Kosoglu 2013.01.22 18:10:51 -05'00'
Branch Chief Sign-Off	Neil R Ogden 2013.01.24 13:24:51 -05'00'
Division Sign-Off	Peter D. Rumm -S 2013.01.24 17:15:56 -05'00'

Digital Signature Concurrence Table	
Reviewer Sign-Off	Mehmet A. Kosoglu 2013.01.22 18:10:51 -05'00'
Branch Chief Sign-Off	Neil R Ogden 2013.01.24 13:24:51 -05'00'
Division Sign-Off	

Kosoglu, Mehmet

From: Bushar, Harry *
Sent: Wednesday, January 09, 2013 10:41 PM
To: Kosoglu, Mehmet
Subject: RE: K123237 - S01

Hi Mehmet,

(b) (4)



Harry F. Bushar
Statistical Contractor, DBS, OSB
(301) 929-1425

From: Kosoglu, Mehmet
Sent: Tuesday, January 08, 2013 5:06 PM
To: Bushar, Harry *
Subject: K123237 - S01

Hi Harry,

They responded to your questions (please see item 9). May I place a consult for you in CTS? The 17th would be great for me. If you are busy, 22nd would work too.

Thanks,
Mehmet

<< File: eCopy Doc.pdf >>

From: Bushar, Harry *
Sent: Monday, November 26, 2012 6:46 PM
To: Kosoglu, Mehmet
Cc: Alexander, Janette; Ogden, Neil; Silverman, Phyllis M.; Irony, Telba Z.; DBS Reviews
Subject: Statistical Review of 510(k) K123237 for Erchonia Zerona 2.0 laser

Hi Mehmet,

I've attached my statistical review of 510(k) K123237 for Erchonia Zerona 2:0 laser.

<< File: K123237.doc >>

Harry F. Bushar
Statistical Contractor, DBS, OSB



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

December 21, 2012

ERCHONIA CORPORATION
C/O REGULATORY INSIGHT, INC.
33 GOLDEN EAGLE LANE
LITTLETON, COLORADO 80127
ATTN: KEVIN WALLS

510k Number: K123237

Product: ZERONA 2.0 LASER

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. Please remember 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

Jones, Ashlee *

From: Microsoft Outlook
o: 'info@reginsight.com'
sent: Friday, December 21, 2012 2:58 PM
Subject: Relayed: K123237 AI Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

'info@reginsight.com' (info@reginsight.com) <mailto:info@reginsight.com>

Subject: K123237 AI Letter

K123237/S001

Regulatory Insight, Inc.



Worldwide Medical
Device Submissions
and Quality Systems

December 20, 2012

Dr. Mehmet A. Kosoglu, Ph.D.
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC

DEC 21 2012

Received

**RE: Response to FDA's Request for Additional Information for K123237 - Erchonia®
Zerona™ 2.0 Laser**

Dear Dr. Kosoglu:

(b) (4)



33 Golden Eagle Lane ♦ Littleton, Colorado 80127 ♦ U.S.A.

Phone: (720) 962-5412 ♦ Fax: (720) 962-5413

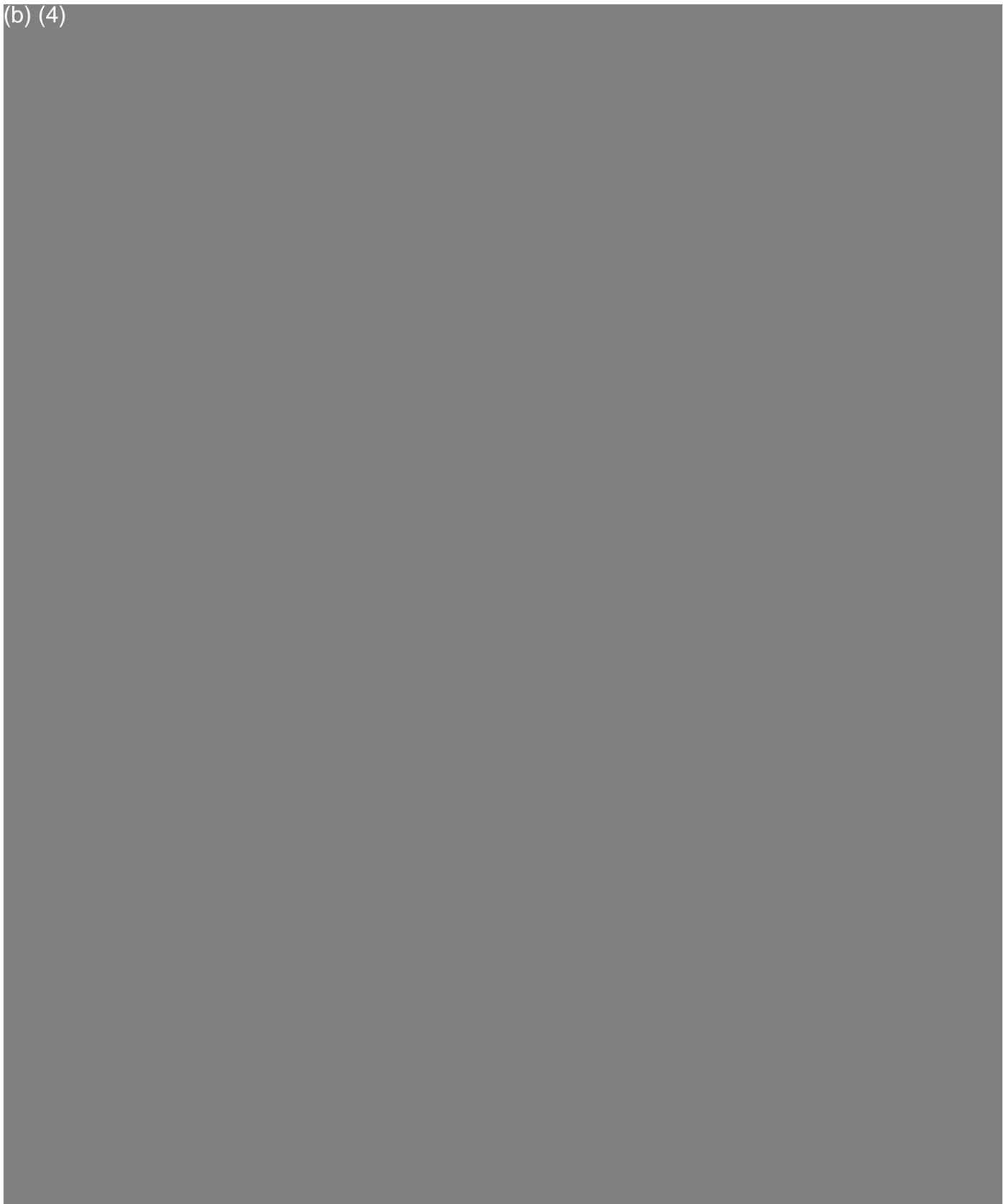
E-mail: info@reginsight.com ♦ Web: www.reginsight.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4)



(b) (4)

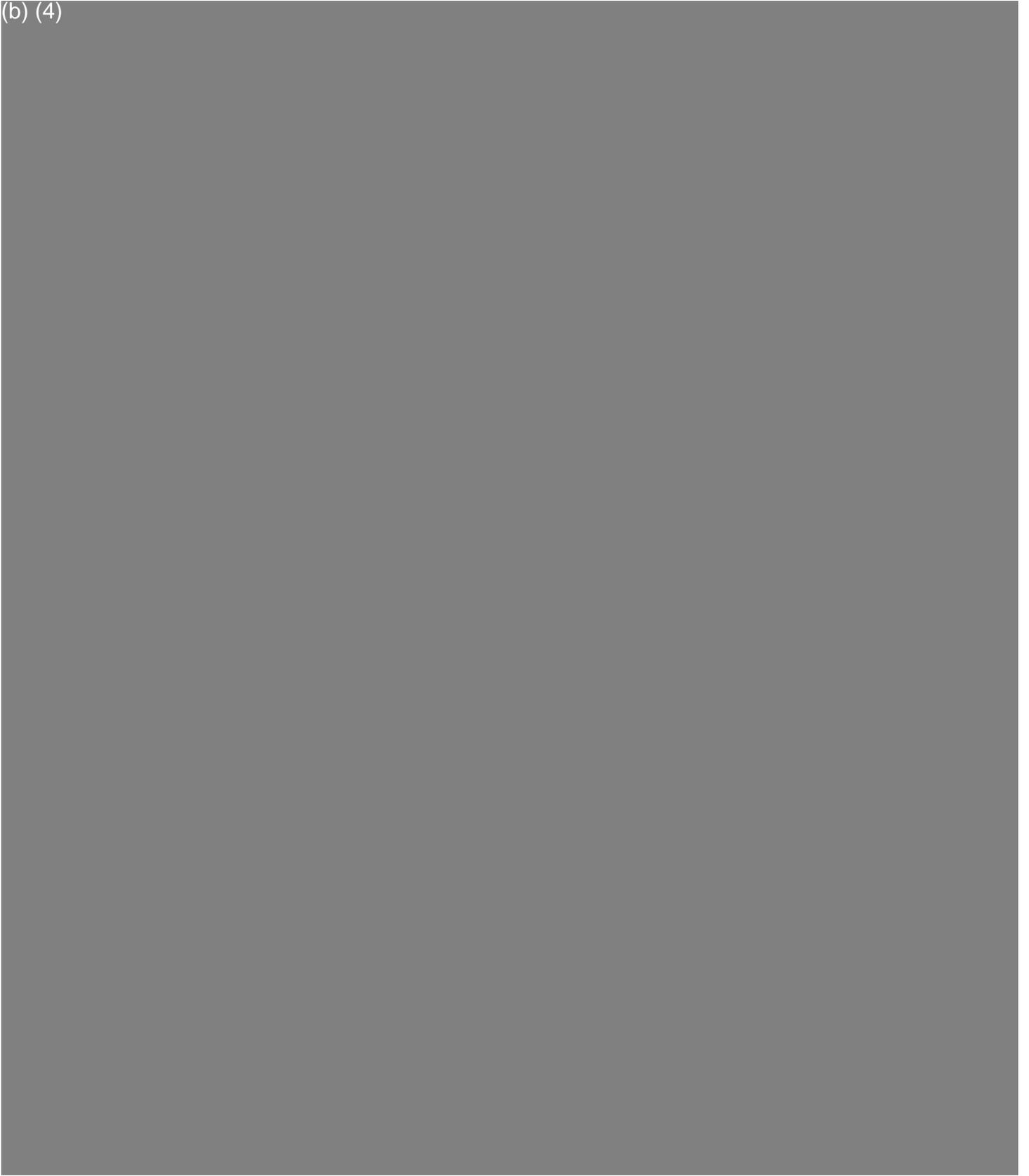


Dr. Mehmet A. Kosoglu, Ph.D., FDA

K123237 RAI Response

December 20, 2012

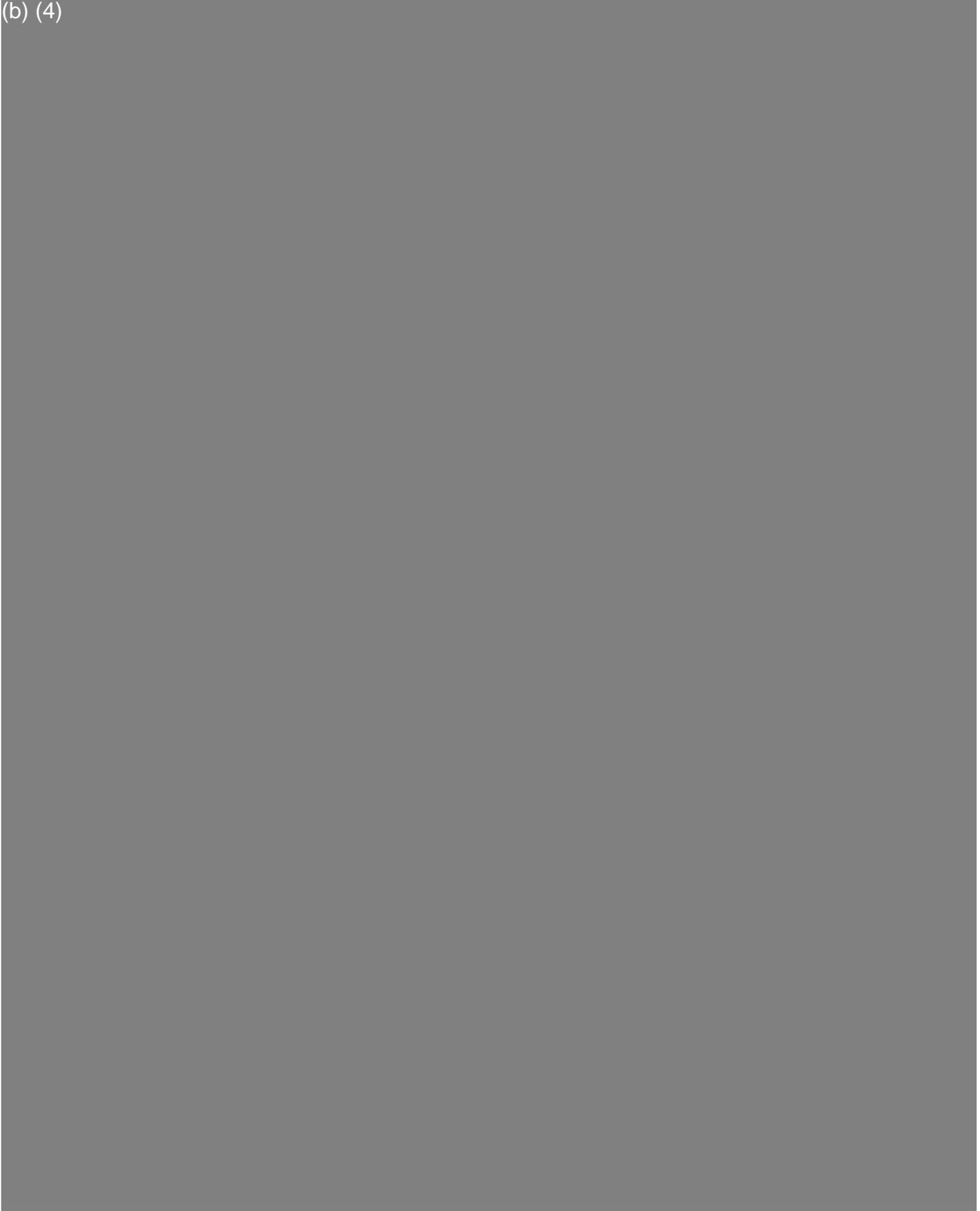
(b) (4)



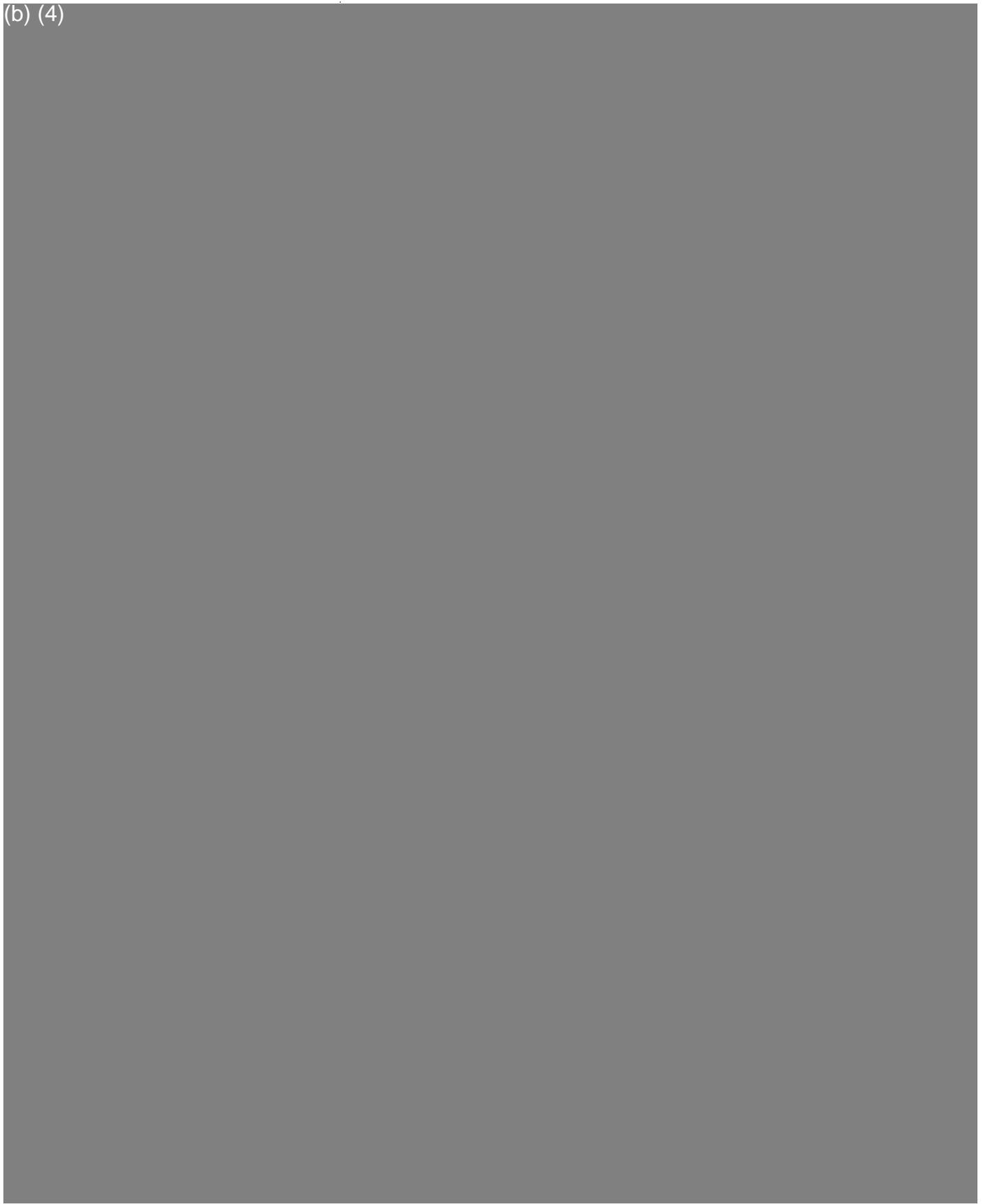
(b) (4)



(b) (4)



(b) (4)

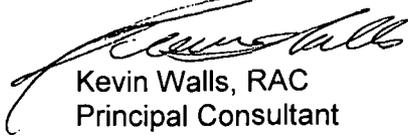


(b) (4)

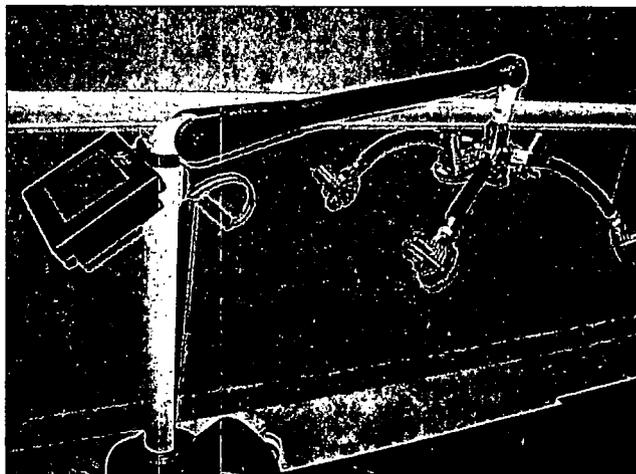


We hope that the information provided in this response is adequate for finding the Erchonia® Zerona™ 2.0 Laser substantially equivalent. Please contact me if you have any additional questions or concerns or require any additional information.

Respectfully yours,



Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.



Zerona™ 2.0

Operation & Maintenance Manual



Proven • Non-invasive • Drug-Free • Healthcare Solutions

O&M-GLS Rev. A

The issue date for the ZERONA™ 2.0 Operator's Guide (**REF O&M-GLS Rev. A**) is **August, 2012**.
 If more than 3 years have elapsed since the issue date, contact Erchonia Corporation to determine if additional product information updates are available.
 Copyright © 2012 Erchonia Corporation. All rights reserved.



Erchonia Corporation
 2021 Commerce Dr.
 McKinney, TX USA
 75069-8262



QNET LLC
 Hommerterweg 286
 6436 AM Amstenrade
 The Netherlands



0459

FDA Good Manufacturing Practices
 ISO 9001-Quality
 ISO 13485-Medical
 ISO 60825-1-Laser Safety
 FDA/IEC Laser Class 2
 FDA/IEC Device Class II
 MDD 93/42/EEC

Trade Name: Zerona 2.0
 EN/IEC 60601-1-2 EMC
 EN/IEC EN60601-1-1 Safety
 CE Mark
 CB Certified Pending
 Model Number: GLS
 Software Version A

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	CR No.	Rev. Level	Rev. Date
O&M-GLS	08/06/12	510(k)	C	10/15/12
O&M-GLS	08/06/12	510(k)	D	12/19/12

ATTENTION: By purchase of the Erchonia device, you; the health care professional, acknowledges and bares full responsibly of the knowledge that laser, and the indications for use associated with the laser, are within your disciplines allowed scope of practice, as regulated by the state medical and professional boards.

Table of Contents

SECTION 1 General Information		SECTION 4 Operation	
Product Description	1	Starting, Stopping, & Interrupting the Procedure	13
How to Use this Manual	1	Front of Body	13
Operator's Guide Updates	1	Back of Body	13
Unpacking	1	Mode Screen	14
Symbols Used on Equipment	1	Manufacture's Contact Screen	14
Conventions	2	Labels	15
CAUTION	3		
WARNING	3		
Notification of Adverse Events	4		
ZERONA™ 2.0 Laser Indications for Use	4		
ZERONA™ 2.0 Laser Specifications	4		
Technical Information	5		
Service and Repair	5		
Returning Device for Service	5		
SECTION 2 Product Overview		SECTION 5 Professional Use Instructions	
Nomenclature	6	Application/Administration	
Laser Head Assembly	6	Clinical Trial Summary	16
Laser Output Head	6		16
Power Safety Lockout Key	7		
Boom Arm	7		
Arm Lock	7		
Touch Screen	7		
Main Upright of Base	7		
Power Inlet/Fuse Holder	8		
Wheel Locks	8		
Electrical Connector	8		
Locking Nut	9		
Power Cord	9		
Handle	9		
Protective Eyewear	9		
SECTION 3 Setup		SECTION 6 Maintenance & Warranty Information	
Assembly Instructions	10	Maintenance and Cleaning	
Additional Information	12	Maintenance	20
		Cleaning Instructions	20
		Optics Cleaning	20
		Warranty	21
		Limited Warranty	21
		Terms and Conditions	21
		Point of Contact	21
		Troubleshooting	21
			22

Section 1

General Information

Product Description

The ERCHONIA® ZERONA™ 2.0 Laser is specially designed for 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 utilizing 532nm laser diodes. The ZERONA™ 2.0 Laser is applied externally and has proven through double-blind clinical trials to reduce the circumference of the hips waste and thighs. ZERONA™ 2.0 Laser is a new procedure designed to reduce the circumference of the hips waste and thighs without invasive surgery. ZERONA™ 2.0 Laser unlike other non-Erchonnia procedures, allows the patient to continue their daily activities without interruptions from surgery, pain, wounds or garments. The procedure was proven through a double-blind, randomized, multi-site, and placebo controlled study in which patients averaged a loss of 3.895 inches (9.893 cm) compared to the placebo group that lost only 1.135 inches (2.882 cm).

How to Use This Manual

The ZERONA™ 2.0 Laser Operator's Guide provides information operators need for the safe and effective use and care of the device. It is important that all persons using this device read and understand all the information contained within.

Please thoroughly read the Caution and Warnings sections.

Procedures for daily checkout and device care are located in "Maintenance and Cleaning".

Operator's Guide Updates

An issue or revision date for this manual is shown on the front cover. If more than three years have elapsed since this date, contact Erchonnia Corporation to determine if additional product information updates are available.

Unpacking

Carefully inspect container for damage. If the shipping container or cushion material is damaged, keep it until the contents have been checked for completeness and the device has been checked for mechanical and electrical integrity. If the contents are incomplete, if there is mechanical damage, contact Erchonnia Corporation 1-214-544-2227. If the shipping container is damaged, also notify the carrier.

Symbols Used on the Equipment

Any or all of the following symbols may be used in this manual or on this equipment:

Symbol	Description
	Temperature Limitation
	Type B patient connection - applied parts that are generally not conductive and can be immediately released from the patient.

	Conformité Européenne - Complies with medical device directive 93/42/EEC.
	Power ON/OFF
	Date of Manufacture
	Manufacturer
	Authorized representative in the European Community.
	Consult instructions for use.
	Warning - can result in personal injury or equipment damage.
	Caution - can result in minor to moderate injury or damage to the device
	No pushing

Conventions

This guide uses the following conventions:

Within text, the names and labels for physical buttons appear in boldface type (for example, “Press the **Start** button or press the **Stop** button”).

Warning Warning statements alert you to conditions or actions that can result in personal injury or equipment damage.

Caution Caution statements alert you to conditions or actions that can result in minor to moderate injury or damage to the device.

NOTE: Throughout this Manual “NOTE” may be found. These Notes are helpful information to aid in the particular area or function being described.



CAUTION

- Read, understand, and practice the precautionary and operating instructions. Know the limitations and hazards associated with using any laser device. Observe the precautionary and operational decals placed on the device.
- **DO NOT** place/operate this device in close proximity (15 cm) to other devices that emit frequency.
- **DO NOT** use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the touch screen as damage may result.
- Inspect electrical cord and associated connectors before each use.
- This device should be operated in temperatures between 59 to 85°F (15 to 29°C), and transported and stored in temperatures between -22 to 158°F (-30 to 70°C), with relative humidity ranging from 0% - 100%.
- Failure to use and maintain the Erchonia device and its accessories in accordance with the instructions outlined in this manual will void your warranty.
- There are no user-serviceable parts inside the device. If a malfunction occurs, discontinue use immediately and contact Erchonia Corporation for repair service.
- **DO NOT** permit any foreign materials or liquids to enter the device. Take care to prevent any foreign materials including, but not limited to, inflammables, water, and metallic objects from entering the device. These may cause device damage, malfunction, electrical shock, fire, or personal injury.
- To achieve the specified level of protection against spilled or splashed liquids, thoroughly dry all exposed surfaces of this device and allow to dry thoroughly prior to operation
- Avoid contact with flammable anesthetic with air or with oxygen or nitrous oxide.
- Do not position equipment so that in an emergency it is difficult to disconnect power cord from electric supply.
- If you have difficulty operating the device after carefully reviewing this user's manual, contact your Sales Representative for assistance.
- U.S. Federal law restricts the use of this device by order of a physician or licensed practitioner.



WARNING

- Read all instructions for operation before treating a patient.
- **DO NOT** disassemble, modify, or remodel the device or accessories. This may cause device damage, malfunction, electrical shock, fire, or personal injury.
- **DO NOT** drop the device or probes on hard surfaces.
- **DO NOT** submerge the device or probes in water. Damage resulting from these conditions is not covered under the warranty.
- This device should be kept out of the reach of children.
- This device should be used only under the continued supervision of a licensed practitioner.
- Dispose of device in accordance with local and national regulations and codes. When spent and beyond repair or functional use, the device can be sent back to the manufacture for disposal. This ensures the proper separation and handling of all the internal parts and reduces any risk to the end user, patient and the environment.
- Laser treatment should not be applied when in the bath or shower in fear of electrical shock.
- Laser protective eyewear should be worn by the patient to block light energy from the eyes during treatment.
- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
- To avoid risk of electric shock, this device must only be connected to a supply mains with protective earth. Make certain that the device is electrically grounded by connecting only to a grounded electrical service receptacle conforming to the applicable national and local electrical codes.
- The long-term effects of prolonged use of non-thermal laser exposure are unknown.
- Laser treatment should be applied only to normal, intact, clean skin or treatment will not be effective.
- Laser treatment should not be applied over, or in proximity to, cancerous lesions as conclusive tests have not been conducted.

- Safety of non-thermal lasers for use over a pregnant uterus has not been established.
- Caution should be used over areas of skin that lack normal sensation.
- Avoid direct contact of the laser beam into human and animal eyes.
- Do not use over the chest, neck or face.
- Do not use directly over areas with open wounds.
- Do not use on patients who:
 - Have a personal or family history of cancer
 - Have a history of keloid or hypertrophic scar formation
 - Have a history of herpes simplex
 - Have active infections or a compromised immune system
 - Have had a sunburn on the area being treated
 - Are taking photo-sensitizing drugs and / or anti-coagulants

Notification of Adverse Events

As a health care provider, you may have responsibilities under the Medical Device Reporting for User Facilities for reporting to Erchonia Corporation, and possibly to the FDA, the occurrence of certain events. These events, described in 21 CFR Part 803, include device-related death and serious injury or illness.

As part of our Quality Assurance Program, Erchonia Corporation requests to be notified of device failures or malfunctions. This information is required to ensure that Erchonia Corporation provides only the highest quality products.

ZERONA™ 2.0 Laser Indications for Use

The Erchonia® Zerona™ 2.0 Laser 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.

ZERONA™ 2.0 Laser Specifications

- Configuration: 6 Class 2 Line Generated Laser Diode Modules
- Wavelength: 532nm
- Modulation: Constant Wave (CW)
- Display: Full Color TFT Touch Screen Control Center
- Adjustments:
 - 44" Vertical Arm Height Adjustment.
 - Four Independent Adjustable Arms for Desired Laser Concentration
- Power Source: 100-240VAC 50-60Hz
- Chassis:
 - Metal Frame Powder Coated for Ease of Cleaning
 - 4 Anti-Static Casters (4 Locking)
- Housing: Black Carbon Fiber Finish Thermoformed from Non-Allergen Material/Plastic
- Weight: 70lbs.

Technical Information

Technical documentation required by the customer, in case of necessary reparations, will be provided by Erchonia in the US and our EU agent, internationally. These documents will be supplied once the manufacturer makes the determination that the requested documents do not constitute a disclosure of proprietary or patent protected information and are a part of the filed and documented technical file.

Service and Repair

If a device requires service, contact the Erchonia Service and Repair Department at:

Telephone: 1-888-242-0571
1-214-544-2227
Fax: 1-214-544-2228

When requesting service or repair, please provide the following information to the service representative:

- Device serial number (located on the back label)
- Description of the problem
- Name of the person to contact

Returning a Device for Service

- Before sending a device to the Erchonia Service and Repair Department for repair, obtain a service order (SO) number from the service representative.
- Pack the device and charger in the original containers (if available) or equivalent packaging. Be sure the assigned service order number appears on the package.

Return the Device to: For Customers in the U.S.A.

Erchonia Corporation
2021 Commerce Dr.
McKinney, TX 75069
Attention: Service and Repair Department (*SO Number*)

For Customers Outside the U.S.A.

Erchonia Corporation
2021 Commerce Dr.
McKinney, TX 75069
Attention: Service and Repair Department (*SO Number*)

NOTE: For international customers, PRIOR to sending a unit in for repair you must obtain from the Erchonia Service department an annually revised FDA Form 2877. The Radiation Control form (2877) will be sent to you partially complete, containing regulatory information. To complete, fill in the unique information associated with your device and the shipment thereof; such as serial number, port, etc. The completed form 2877 must accompany your shipment affixed to the outside of the package. Failure to include the form in the shipment may result in customs delays and fines. Any resulting fines are the responsibility of the customer.

Section 2 Product Overview

Nomenclature

The Erchonia® ZERONA™ 2.0 Laser emits a 532 nanometer wavelength with a tolerance of ± 5 nanometer, from each of the five specially created and patented electronic diodes.

The Erchonia® ZERONA™ 2.0 Laser is manufactured in accordance to the Good Manufacturing Procedures set forth by the FDA. Per ISO and FDA standards the device and laser are classified as Class II.

Each of these governing agencies requires specific labeling. All required labels are affixed according to the relevant codes. Each label is pictured and described in this manual. Additionally, the placement of each label, on the Erchonia® device, is communicated.

The Erchonia® laser package is comprised of (1) ZERONA™ 2.0 Laser, (1) pair of patient protective eyewear, (1) Power Cord, (2) Keys, and this user guide.

This section is included to familiarize you with the components of the unit ensuring the remainder of this manual is clearly communicated.

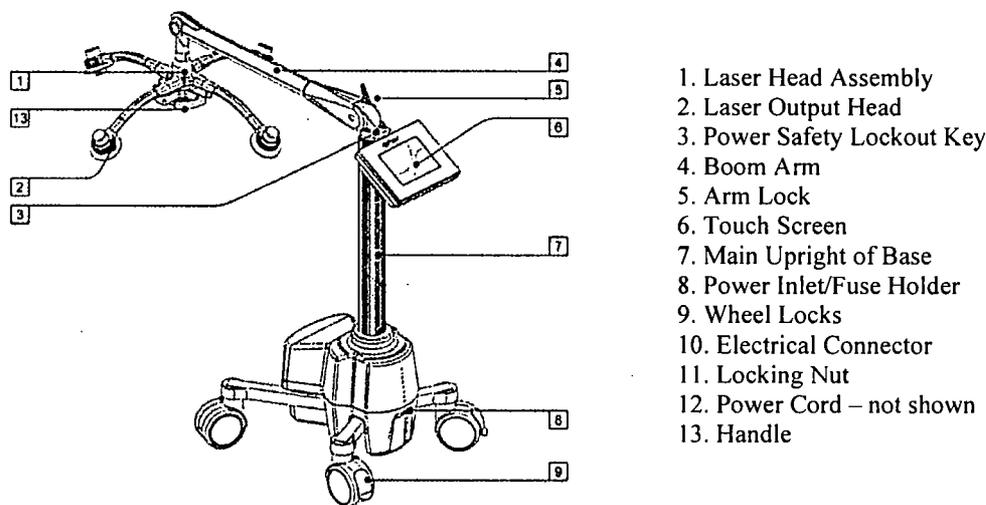


Fig. 1

Laser Head Assembly (1)

This assembly located on the end of the laser arm accommodates the lens, laser diodes and their associated electronics.

Laser Output Head (2)

This aluminum housing located on the end of the flex arms accommodates the lens, laser diodes, motors, and their associated electronics.

Power Safety Lockout Key (3)

The Power Safety Lockout Key is the outwardly visible portion of an internal locking mechanism on top of the touch screen (6) that comes with an external key. Together they allow the end user to turn the device ON or OFF. ("O" = OFF and "I" = ON) In the OFF position the device is locked. From the locked position the external key can be removed. This is a code-regulated feature installed to ensure no unauthorized use of the laser device. The device will not operate if the key is in the OFF position. Turning the key to the OFF position while the device is in operation will immediately shut down the device. The key switch has a failsafe 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.

NOTE: Two keys are included with the Erchonia® ZERONA™ 2.0 Laser. Make sure you have inserted key into the key switch to use.

Boom Arm (4)

The Boom Arm serves to position the Laser Head Assembly (1) vertically only. It is designed to adjust by intentional force from the end user by use of handle (13). This allows the end user to lower and raise the Laser Output Heads for proper positioning to patient for accurate treatment distance.



CAUTION

CAUTION - When moving the head assembly (1) into the desired position, make sure to use the center of the boom arm (4) to avoid the possibility of pinching.

Arm Lock (5)

The Arm Lock is the black handle attached to the side of the Spring Arm. This is a secondary locking mechanism for the boom arm. The arm tension can be adjusted or locked into position with lever. Pull handle out to place in a desired position then ensure to lock back in place before turning.

Touch Screen (6)

The touch screen functions as a display screen and an input panel, providing information to the user and a means to operate the device by touching the appropriate icon.



CAUTION

CAUTION - DO NOT use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the touch screen as damage may result. Avoid using abrasives (including paper towels) on the touch screen display window.

Main Upright of Base (7)

The main upright of base supports the boom arm and contains the electrical connector (See Setup) and the Locking Nut (11).

Power Inlet/Fuse Holder (8)

The device contains an appliance coupler and a flexible detachable power cord (12). This is the location on the device where it is connected. **NOTE:** Make sure the power cord is plugged into device at this location prior to plugging into a wall socket. The power inlet module also contains a fuse holder. Replacing the fuses is the only service that can be conducted by the end-user. To replace the fuses, unplug the AC power cord and open the fuse carrier door located in the power input module. Fuses to be rated at T2AL 250V with an input to cover 100 – 240V~ 1.5-.5A, 50-60 Hz.



WARNING-SHOCK HAZZARD

To avoid risk of electric shock, this device must only be connected to a supply mains with protective earth. Make certain that the device is grounded by connecting only to a grounded electrical socket (3 prong) conforming to the applicable national and local electrical codes.
Use T2AL 250V Fuses only.

The device includes a transformer which converts AC power to match the power output (i.e. 110V or 240V). Only a 3 plug prong adaptor is required (Hospital Grade Only). Once the adaptor is affixed to the plug end, put into wall socket. Input: 100-240V~0.5-1.5A, 50-60 Hz

Wheel Locks (9)

The device includes four antistatic wheels that enable ease for maneuverability. Once the device is transported to the desired location the wheel locks can be engaged to eliminate excessive movement of the device.



WARNING-TIPPING HAZZARD

When transporting the device (example: from one room to another) ensure that the boom arm (4) is positioned all the way down, securing with the arm lock (5) and take caution to ensure the device does not tip.

Electrical Connector (10)

The device is a two piece assembly. The electrical connector connects the laser head assembly to the main upright of base in order to transfer data and power.



WARNING-SHOCK HAZZARD

To avoid risk of electric shock, ensure power cord is disconnect from electric supply when connecting electrical connector.

Locking Nut (11)

The locking nut is utilized to secure the two piece assembly keeping the boom arm assembly from unwanted rotation during use.

Power Cord (12) Not Shown

The device contains a flexible detachable power cord. **NOTE:** Make sure the power cord is plugged into device prior to plugging into a wall socket. The power cord does not contain any operator-serviceable components. If the power cord needs replacement, contact an Erchonia Corporation representative.

Handle (13)

The device has a handle that surrounds the center hub, in order to adjust the height on the head as needed.



CAUTION

CAUTION - DO NOT connect to an electrical outlet controlled by a wall switch or dimmer. For continued safety and performance, use only the power cord supplied by Erchonia. Do not position equipment so that in an emergency it is difficult to disconnect power cord from electric supply.

Protective Eyewear

The Erchonia® ZERONA™ 2.0 Laser is classified by the FDA/IEC as a Class 2 laser device. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 laser is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging. 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. These safety glasses, manufactured by Laser Safety Industries, sufficiently and effectively block the laser light spectrum at OD6+ @ 190-532nm.

Section 3 Setup

Assembly Instructions

This pictorial shows the simple 2 piece assembly of the scanner. This assembly is best done with 2 people.

The 2 major components are the arm [4] and base [7].

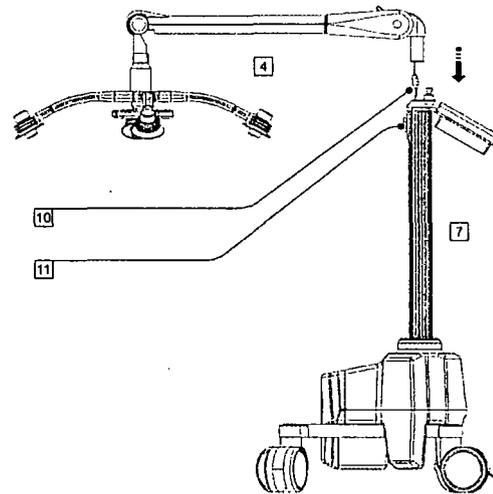


Fig. 2

Step 1:

The electrical connection [10] from the base to the arm must be connected as shown in fig 3.

Simply insert the 2 halves of the electrical connection [10] (fig 3) together slightly pushing the outlet into the inlet. Twist until secure. (The connector can only be connected one way)

After insertion, hold the female connector secure while gently twisting the locking collar until it locks **and can no longer be twisted.**

NOTE: This is important so the two halves do not separate over time.

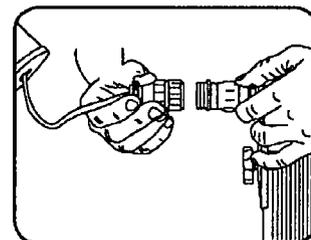


Fig. 3



WARNING-SHOCK HAZZARD

To avoid risk of electric shock, ensure power cord is disconnect from electric supply when connecting electrical connector.

Step 2:

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

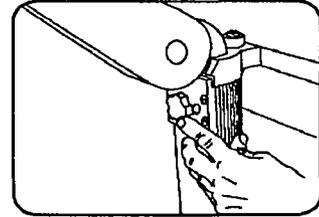


Fig. 4

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

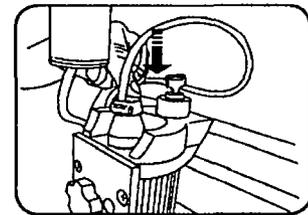


Fig. 5

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.

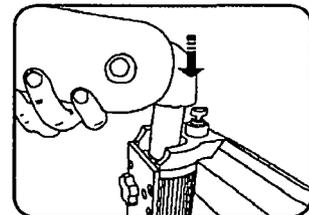


Fig. 6

Step 5:

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 threaded opening in the arm tube and tighten. This will keep the main head assembly from unwanted rotation during use. Your scanner is now ready for use.

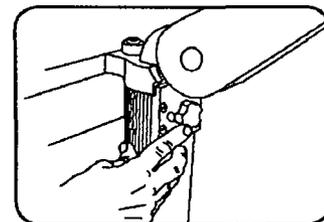


Fig. 7

Additional Information

The arm tension can be adjusted or locked into position with lever [5] as shown in figure 8. Pull handle out to place in a desired position then ensure to lock back in place before turning.

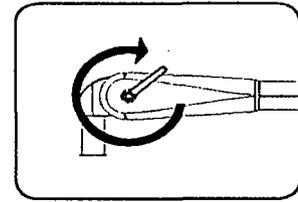


Fig. 8

To activate your scanner 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 scanner has 2 computers when you first turn it on it will take a few moments to boot up before use.

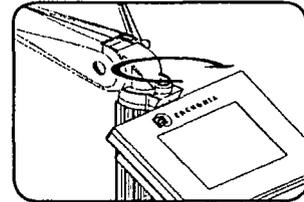


Fig. 9

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.

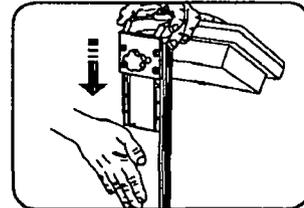


Fig. 10

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 and 11.

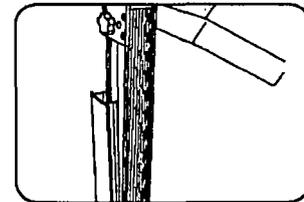


Fig. 11



CAUTION

CAUTION - When moving the head assembly into the desired position, make sure to use the center of the boom arm (4) to avoid the possibility of pinching.
To ensure proper use and mitigate the possibility of interference, avoid placing in close proximity to other electromagnetic devices.

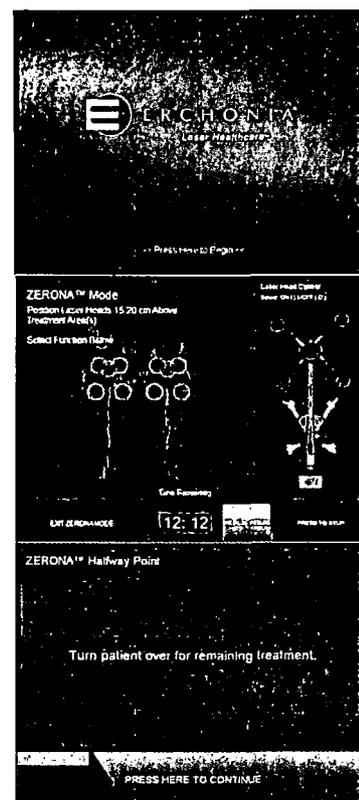
Section 4 Operation

STARTING, STOPPING, AND INTERRUPTING THE ZERONA™ 2.0 LASER PROCEDURE

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 introductory splash screen. The splash screen shows the manufacture’s logo. Press “>>Press Here to Begin<<” button, this will take you to the Mode screen.

Press “**PRESS TO START**” button to begin the protocol. If for any reason you need to pause, press the “**PRESS TO PAUSE**” button. To restart, press the “**PRESS TO RESUME**” button. The “**Time Remaining**” display shows the elapsed time. When done return the key to the OFF position.

The device is preprogrammed to treat for a total of thirty minutes, pausing at fifteen minutes displaying the Halfway Point screen. Therefore in fifteen minutes you will need to instruct the patient to turn over, manipulate the laser heads, and then press “**PRESS HERE TO CONTINUE**” button to continue with the remainder of the application.



Front of the Body

1. The patient lies comfortably flat on their 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™ 2.0 Laser is positioned above the patient, centered along the body’s midline (the “line” that vertically “dissects” the body into two equal halves).
3. The Erchonia® ZERONA™ 2.0 Laser is activated for 15 minutes. Each laser diode emits to the patient a laser beam of approximately 17mW with a wavelength of 532nm, 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

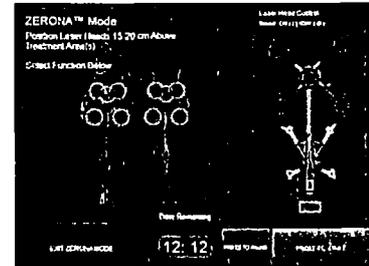
1. The patient turns over to lie flat on their stomach such that the back area of the patient’s body encompassing the region spanning from the patient’s back down through the hips and back aspect of both thighs, is facing upwards.
2. The center diode of the Erchonia® ZERONA™ 2.0 laser is positioned above the patient, centered along the body’s midline (the “line” that vertically “dissects” the body into two equal halves).

3. The Erchonia® ZERONA™ 2.0 Laser is activated for 15 minutes. Each scanner emits to the patient a laser beam of approximately 17mW with a wavelength of 532nm, 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.

Mode Screen

Located on the bottom are the active command buttons. Starting from left to right the buttons are:

- “EXIT MODE” button will return you to the start screen.
- Located to the right of the “EXIT MODE” button in the center of the lower window is the “Time Remaining” button that displays the time left on current treatment. The countdown display activates only when the treatment is running.
- Next to the “Time Remaining” button is the “PRESS TO PAUSE” button. This button will change colors and flash “PRESS TO RESUME” to continue with treatment allowing the patient to take a break without resetting the time remaining.
- The bottom right corner is the cycle treatment button labeled “PRESS TO START”. This will start and stop this treatment



Manufacture's Contact Screen

By touching the Erchonia (E) logo on the introductory splash screen the screen displays the manufacturer's contact information (Address and Phone Number), and general information for your device, including software revision and serial number.

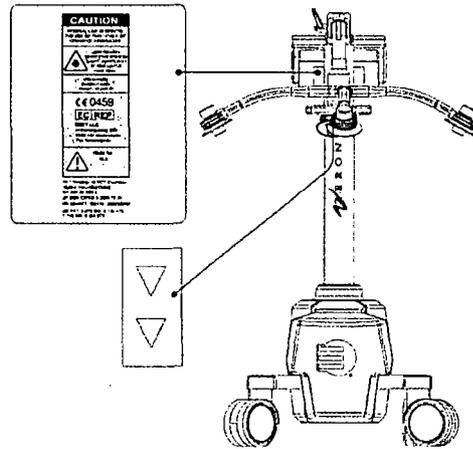


- Top center is the software package information on your device.
- On the bottom right is the device computer date.
- On the bottom center is the “Total Treatments” display. (The numeric value will increase increments of one each time an application is started)
- The device “Serial Number” is located in the gray display.
- On the bottom left is the “Return to START SCREEN” icon. Touching this icon will return you to the introductory splash screen.
- On the upper right is a Green circle with the word OK. This is the device RE-SET button and is only to be used at the instruction of an Erchonia representative.

Labels

The device 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 device, is communicated.

This diagram 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.



Section 5

Professional Use Instructions

Application/Administration

This section defines instructions for the application of the laser energy and established protocols.

The Erchonia® Zerona™ 2.0 Laser 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. The treatment protocol that is hard coded into the device has been developed in conjunction with Medical Doctors, Erchonia Corporation Researchers and IRB advisors (see clinical trial summary). Medical and Healthcare professionals in receipt of this device are to use the preset as their medical training, and experience dictate, in accordance with the allowable limits of the laws of the state in which they practice; including but not limited to medical board, radiation control (if applicable) and the discipline license board.

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Clinical Trial Summary

AN EVALUATION OF THE EFFECTIVENESS OF THE ERCHONIA® SCANNER DEVICE (GLS) AS A NON-INVASIVE DERMATOLOGICAL AESTHETIC TREATMENT FOR THE REDUCTION OF CIRCUMFERENCE OF THE WAIST, HIPS AND THIGHS

Erchonia Corporation

BACKGROUND: The purpose of this clinical study was to determine the effectiveness of the Erchonia® Scanner device (GLS) for reduction in the circumference of the waist, hips and bilateral thighs by applying green diode (532 nm) energy around the waist, hips and thighs for 30 minutes, six times across two weeks.

STUDY DESIGN: The study was a placebo-controlled, randomized, double-blind parallel group design conducted across two 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 males and females aged 18 to 65 years with a Body Mass Index (BMI) of less than 30 kg/m² and who were deemed suitable for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that do not respond to diet and exercise; specifically for the indication of reduction of circumference 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 Lipo-Suction Surgery (ASLSS) and the American Academy of Cosmetic Surgery (AACS))

Study subject age ranged from 20 to 63 years and averaged 38 years (n=49). The majority of study subjects were Caucasian females, as illustrated in Table 1 below.

Table 1: Table of Subject Demographics

Gender	Female		Male	
	<i>number</i>	<i>%</i>	<i>number</i>	<i>%</i>
n=55	46	84%	9	16%
Ethnicity	Caucasian		Middle Eastern	
	<i>number</i>	<i>%</i>	<i>number</i>	<i>%</i>
n=61	56	92%	3	5%
African American				
	<i>number</i>	<i>%</i>		

	2	3%
--	---	----

STUDY MEASURES: Circumference measurements (inches) of the waist, hips, right thigh and left thigh 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 (average) baseline individual body area and combined body circumference measurements (inches/cm) for test and placebo group study subjects.

Table 2: Mean (Average) Baseline Measurements

<i>Circumference Measurements (inches)</i>	Test Group (n=35)	Placebo Group (n=32)
Waist	33.45	32.58
Hips	39.76	39.27
Right Thigh	23.41	22.69
Left Thigh	23.35	22.50
Total Body Circumference	119.97	117.04

<i>Circumference Measurements (cm)</i>	Test Group (n=35)	Placebo Group (n=32)
Waist	84.96	82.75
Hips	100.99	99.74
Right Thigh	59.46	57.63
Left Thigh	59.30	57.15
Total Body Circumference	304.72	297.28

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

STUDY PROCEDURE: Subjects received six procedure administrations with the Erchonia® Scanner device (GLS) (active or sham) across a consecutive two-week period: three procedures per week, each procedure two to three days apart. For each procedure administration, exposure time to the Erchonia® GLS was 15 minutes across the frontal region and 15 minutes across the lateral region.

STUDY RESULTS

(i) **Total Circumference Measurements:** The study primary outcome measure was defined as the change in total combined inches in circumference measurements (waist, hips and bilateral thighs) from baseline (pre-procedure) to following completion of the two-week procedure administration phase (study endpoint: end of week 2). It was pre-determined that a subject would be considered a study success if he or she attained a 3.0 inch (7.619 cm) or greater reduction in total combined inches in circumference measurements across this primary evaluation period. It was also pre-determined that the study would be considered an overall success if the proportion of individual subject successes in the test (active procedure) group was at least 35% greater than the proportion of individual subject successes in the placebo (sham procedure) group.

68.57% of subjects who received the study procedures with the actual (active) Erchonia® GLS attained a decrease in combined circumference measurements of 3.0 inches or greater compared with 18.75% 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 49.82% between subject procedure groups to be statistically significant at $p < 0.0001$.

The mean change in combined circumference measurement for subjects who received the study procedures with the actual (active) Erchonia® GLS was a decrease of 3.895 inches (9.893 cm), while the mean change in combined circumference measurements for subjects who received the study procedures with the 'fake' (placebo) laser device was a decrease of 1.135 inches (2.882 cm). A t-test for two independent samples found the mean change in

combined circumference measurements from baseline to study endpoint for test (active procedure) group subjects to be significantly greater than that for placebo (sham procedure) group subjects, at $p < 0.0001$.

Table 3 and Chart 1 below show the mean change in combined circumference measurements (waist, hips, and right and left thigh circumference measurements combined) across the four study measurement time points for the intent-to-treat (ITT) study subject population. ITT analysis was conducted for all randomized subjects who had a measurement recorded at baseline. All 67 randomized subjects had circumference measurements recorded at baseline, at week 1 and at week 2 measurement points. Thirteen (13) of the 67 subjects did not have circumference measurements recorded at the 2 weeks post-procedure measurement point: 8 subjects who had been randomized to the test group and 5 subjects who had been randomized to the placebo group. For these 13 subjects, the last observation carried forward (LOCF) procedure was employed, such that the subject's week 2 circumference measurement was carried forward as the week 2 post-procedure measurement.

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

	Test Group	Placebo Group
Baseline	119.97	117.04
Midpoint (week 1)	117.03	116.41
Endpoint (week 2)	116.08	115.91
Follow-up (week 4)	115.86	115.72

Chart 1: Mean change in total circumference measurements (ins.) at each study evaluation point relative to baseline

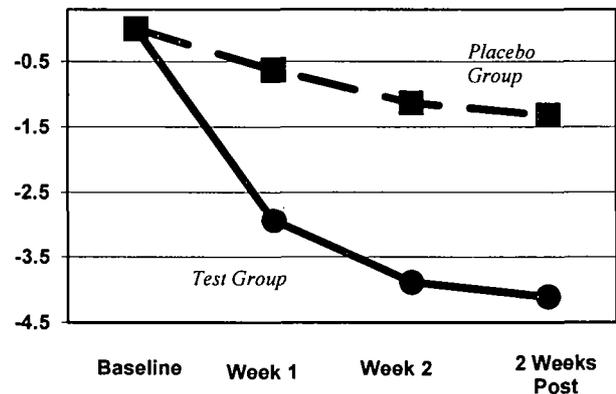
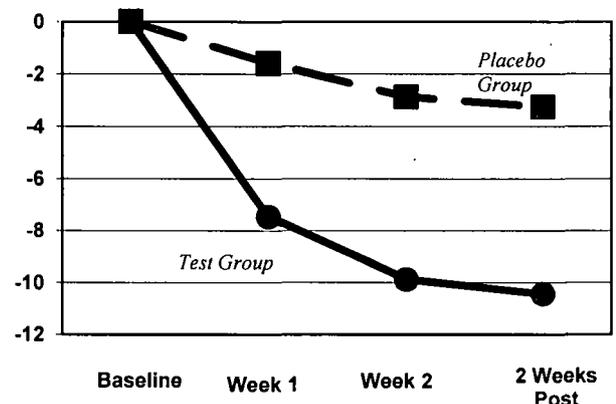


Table 3: Mean total circumference measurements (cm.) across evaluation points

	Test Group	Placebo Group
Baseline	304.72	297.28
Midpoint (week 1)	297.25	295.68
Endpoint (week 2)	294.84	294.41
Follow-up (week 4)	294.28	293.92

Chart 1: Mean change in total circumference measurements (cm.) at each study evaluation point relative to baseline



For test group subjects, combined circumference measurements decreased progressively and significantly from baseline through post-procedure evaluation, indicating a progressive and cumulative treatment effect of the laser that prevailed for at least 2 weeks following the end of the laser procedure administration period. Total circumference measurements for placebo group subjects did not change significantly across the same evaluation period.

(ii) Individual Body Area Circumference Measurements: Table 4 below shows the mean circumference measurements for each individual body area of the waist, hips and right and left thighs, by study procedure group, at each of the four evaluation points, for the ITT population.

Table 4: Individual body area circumference measurements across study duration by procedure group for the ITT population

Inches

<i>Waist</i>	Test (n=35)	Placebo (n=32)	<i>Right thigh</i>	Test (n=35)	Placebo (n=32)
Baseline	33.45	32.58	Baseline	23.41	22.69
Week 1 (Mid)	32.77	32.48	Week 1 (Mid)	22.70	22.60
Week 2 (End)	32.48	32.61	Week 2 (End)	22.58	22.32
2 weeks post	32.41	32.45	2 weeks post	22.56	22.35
<i>Hip</i>	Test (n=35)	Placebo (n=32)	<i>Left thigh</i>	Test (n=35)	Placebo (n=32)
Baseline	39.76	39.27	Baseline	23.35	22.50
Week 1 (Mid)	38.90	38.98	Week 1 (Mid)	22.66	22.35
Week 2 (End)	38.64	38.77	Week 2 (End)	22.39	22.20
2 weeks post	38.60	38.68	2 weeks post	22.29	22.24

Centimeters

<i>Waist</i>	Test (n=35)	Placebo (n=32)	<i>Right thigh</i>	Test (n=35)	Placebo (n=32)
Baseline	84.96	82.75	Baseline	59.46	57.63
Week 1 (Mid)	83.23	82.49	Week 1 (Mid)	57.65	57.40
Week 2 (End)	82.49	82.82	Week 2 (End)	57.35	56.69
2 weeks post	82.32	82.42	2 weeks post	57.30	56.76
<i>Hip</i>	Test (n=35)	Placebo (n=32)	<i>Left thigh</i>	Test (n=35)	Placebo (n=32)
Baseline	100.99	99.74	Baseline	59.30	57.15
Week 1 (Mid)	98.80	99.00	Week 1 (Mid)	57.55	56.76
Week 2 (End)	98.14	98.47	Week 2 (End)	56.87	56.38
2 weeks post	98.04	98.24	2 weeks post	56.61	56.48

As with the combined circumference measurements, individual body area circumference measurements decreased progressively and significantly from baseline through post-procedure evaluation for test group subjects, indicating a progressive and cumulative treatment effect of the Erchonia® GLS that prevailed for at least 2 weeks following the end of the laser procedure administration period. Individual body area circumference measurements for placebo group subjects did not change significantly across the same evaluation period.

(iii) **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 the appearance of the waist-hips-bilateral thighs area attained using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied. Sixty-five percent (65%) of test group subjects reported being ‘Satisfied’ (‘Very Satisfied’ or ‘Somewhat Satisfied’) with the outcome of the study procedures compared with 19% of placebo subjects.

(v) **Adverse events:** No adverse event occurred 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® Scanner device (GLS) is an effective tool for reducing circumference measurements when applied to the waist, hips and bilateral thighs over a 2-week period.

Section 6

Maintenance & Warranty Information

Maintenance and Cleaning

Maintenance

The Erchonia® ZERONA™ 2.0 Laser, 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 inspections to ensure there is no external damage other than normal wear and tear. Inspect all cords for signs of excessive wear (cuts in insulation or fraying). If during these inspections, you identify an area of concern, please contact the manufacturer to determine if action is required.
2. If you notice a change in the performance of the device, while in the ON position, please contact the manufacturer to determine if action is required.
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 a nearly dry cloth containing one of the mild cleaning agents listed below. 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. In the event that the fuses require replacement, unplug the power cord from plug source, locate power inlet / fuse holder (figure 1 item 8), pull fuse holder out of enclosure, replace the two fuses (**T2AL 250V Fuses only**) and reinsert.

Cleaning Instructions

To clean the ZERONA™ 2.0 Laser device, use a nearly dry cloth containing one of the mild cleaning agents listed below. **DO NOT** allow cleaning agent or water to run into the crevices, connector openings or optics at any time. Thoroughly wipe off any excess cleaning solution from the device with a dry cloth. Always check for unusual wear, damage or dampness while cleaning.

Use only these recommended cleaning agents:

- Warm water
- Diluted Liquid soap
- Windex®
- 409®
- 4 to 1 water to isopropyl alcohol

Never use these cleaning agents:

- Butyl alcohol
- Denatured ethanol
- Freon
- Mild chlorine bleach solution
- Trichloroethane, trichloroethylene
- Acetone
- Vesphene II
- Enviroquat
- Staphene
- Misty
- Glutaraldehyde

If during treatment, any part of the device comes in contact with a patient, perform the cleaning process.

Optics Cleaning

If there is foreign material on the laser optics use lens paper or lens cloth **ONLY**. Abrasive material could cause laser light beam fragmentation, which may reduce the effectiveness of the treatment.

Warranty

Limited Warranty

The Erchonia® laser device is warranted to be free from defect in material and workmanship for a period of TWO YEARS from the date of purchase.

For your device to be processed through the Service and Repair Department efficiently, contact the department prior to submitting you product. Repairs and Warranty work NOT coordinated through the Service and Repair Department prior to receipt can be delayed.

Items being sent in from overseas require special paperwork, available through the warranty department, if this paperwork is not obtained prior to shipping; your package will be delayed by customs.

Terms and Conditions

- Shipping required facilitating warranty repair and or maintenance issues within the first 90-days, will be paid by manufacturer.
- Shipping required to facilitate warranty repair and or maintenance issues after 90-days, is the financial responsibility of the customer.
- Warranties of Erchonia Corporation products are not transferable unless sold by a company-approved distributor, reseller and/or leasing company.
- The 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
 - Exposure to excessive electromagnetic frequency

Point of Contact

If for any reason you are dissatisfied with this product, warranty concerns or questions regarding proper operation, please contact your distributor for immediate assistance.

Troubleshooting

Listed are corrective actions intended as an aid for non-technical personnel. If trouble persists after consulting this guide, contact Erchonia's Service and Repair Department 1-214-544-2227

Observation	Possible Cause	Corrective Action
POWER Device does not power on	AC power cord not plugged into device or line power.	Connect power cord.
	Blown fuse.	Replace using the correct fuses.
	Lockout key not positioned correctly.	("O" = OFF and "I" = ON)
	Blown fuse or tripped circuit breaker in building.	Contact a qualified service technician.
	Electrical connector came apart.	Remove head assembly from base assembly and reconnect connector. (See Setup Step 1)
Motors does not power on	Electrical connector came apart.	Remove head assembly from base assembly and reconnect connector. (See Setup Step 1)



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

Property of Erchonia® Corporation cannot be duplicated without authorization.

Comparison of the New and Predicate Device

Device	Erchonia® Zerona™ 2.0 Laser	Erchonia Zerona
510(k)	N/A	K121695
Indications for Use	The Erchonia® Zerona™ 2.0 Laser 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.	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	Green 532 nm	Red 635 nm (near infrared)
Waveform	Pulsed	Pulsed
Energy Source	Six 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	30 minutes	40 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.