DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

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

MAY 14 2012

Re: K120257
Trade/Device Name: Erchonia MLS, Zerona™
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Lever Laser System for Aesthetic Use
Regulatory Class: II
Product Code: OLI, GEX
Dated: May 8, 2012
Received: May 9, 2012

Dear Mr. Walls:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K120257

Device Name: Erchonia® MLS, Zerona™

Indications for Use: The Erchonia® MLS, Zerona™ is indicated for non-invasive dermatological aesthetic treatment for the reduction of the circumference of the upper arms.

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. P. Ogden for mtm

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

510(k) Number K120257

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

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

May 03, 2012

ERCHONIA MEDICAL, INC.
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT
GREENWOOD VILLAGE, COLORADO 80127
ATTN: KEVIN WALLS

510k Number: K120257

Product: MLS, ZERONA-AD

The additional information you have submitted has been received.

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

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

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

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

Sincerely,

510(k) Staff

DEPARTMENT OF
HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
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10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 07, 2012

ERCHONIA MEDICAL, INC.
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT
GREENWOOD VILLAGE, COLORADO 80127
ATTN: KEVIN WALLS

510k Number: K120257
Product: MLS, ZERONA-AD
On Hold As of 5/4/2012

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

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

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

Please remember that the Safe Medical Devices Act 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
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF
HEALTH & HUMAN SERVICES

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K120257 | A3

Regulatory Insight, Inc.

Worldwide Medical Device Submissions and Quality Systems

May 14, 2012

Mr. Richard Felten
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
MAY 15 2012
Received K7

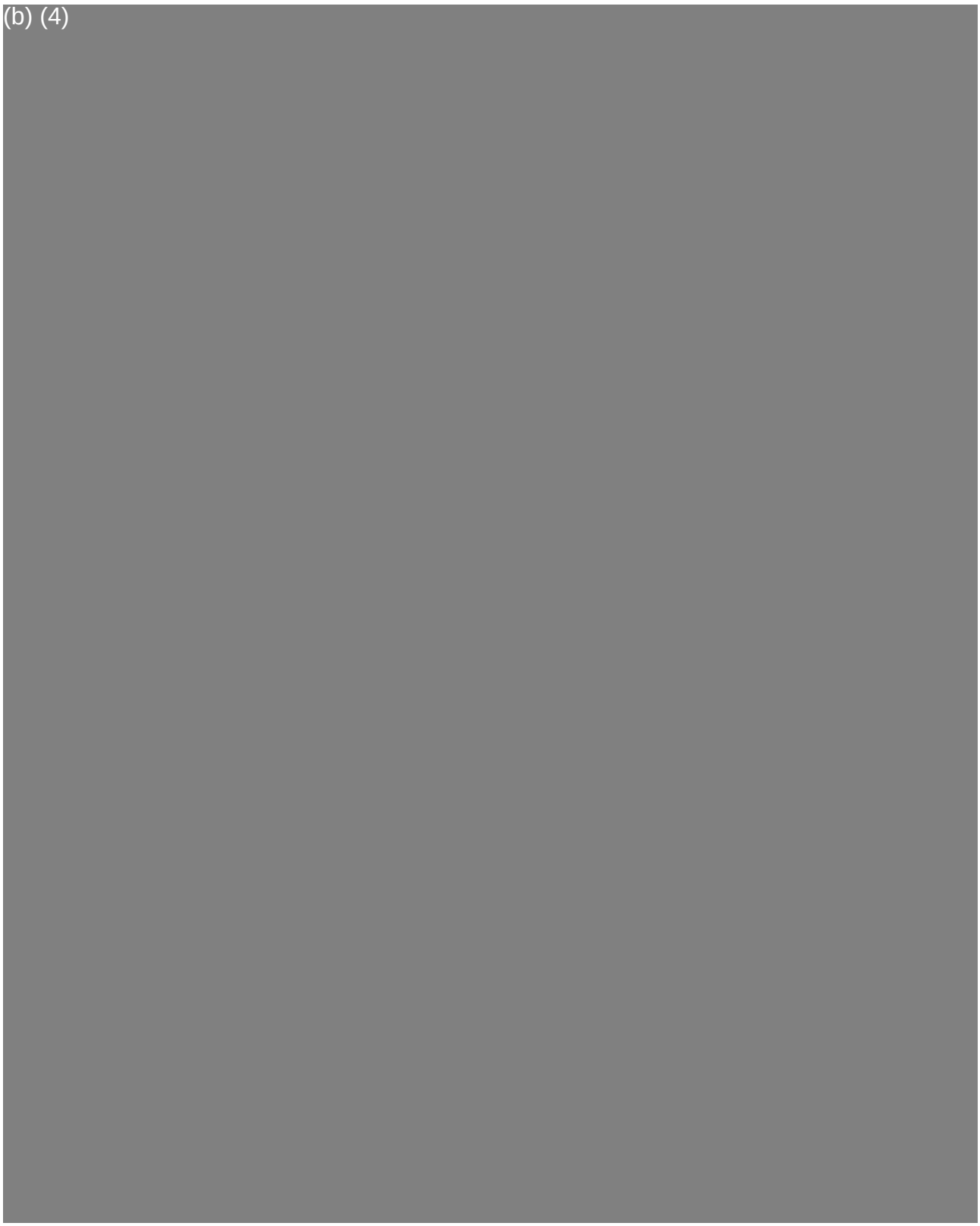
RE: Response to FDA's Request for Additional Information for K120257 - Erchonia® MLS, Zerona

Dear Mr. Felten,

(b) (4)

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

(b) (4)



(b) (4)

(b) (4)

We hope the information provided in this response is sufficient for finding the Erchonia® MLS, Zerona substantially equivalent. Please let me know if you require any additional information or have any other questions or concerns.

Respectfully yours,

Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.

Acknowledgements & Accreditations

We at Erchonia ® Corporation would like to thank you for purchasing the Erchonia® MLS, Zerona™ device.

Erchonia ® Corporation is an ISO certified company and is audited from time to time by outside governing agencies, including the FDA, to be sure to stay in compliance with the highest quality standards. Our company operates according to and our devices are manufactured according with:

- FDA Good Manufacturing Practices
- ISO 9001 :2000 - Quality
- ISO 13485:2003 – Medical
- ISO 60825-1 - Laser Safety
- FDA Laser Class 2
- FDA Device Class II
- IEC Laser Class 2
- IEC Device Class 1
- MDD 93/42/EEC
- EN/IEC 60601-1-2 EMC
- EN/IEC EN60601-1-1 Safety
- Model Number: ARC
- Software Version ARM-E Rev A (1-9-12)
  - **ARM-E-TS Rev A**
  - **ARM-E-PLC Rev A**

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

Doc. No.	Issue Date	CR #	Revision	Rev Date
ARC-O&M	8/29/2011	Initial Release	1	1/11/2012

Legend:
The following symbols are used throughout this manual to show areas of concern. For your safety, and for the care of the device, please read and take note of these warnings and cautions.

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

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

Refers to the part of the medical device which comes into physical contact with the patient in order for the device to carry out its intended function.

US National Consideration:
When using in the US, the equipment is intended to be powered by a 120V source. If powered by a 240V source in the US, then the power source must be a center-tapped, 240V single phase circuit.

Erchonia® Corporation
2021 Commerce Dr. McKinney, TX 75069
Phone +1 888-242-0571 • Fax +1 214.544.2228
www.Erchonia.com
Patent(s): US – 6,013,096, Patent Pending

Table of Contents

Section 1

CAUTION: FEDERAL LAW RESTRICTS THE USE OF THIS DEVICE BY ORDER OF PHYSICIAN

Introduction to Contents

Identifies and describes each item included in the Erchonia ® laser package

The Erchonia ® MLS, ZERONA™ device package is made up of the following items:

- The Erchonia® MLS, ZERONA™ device.
- A power cord
- Operation & Maintenance manual
- Laser Safety Glasses
- 2 keys

In addition to the equipment items, we have included this Operation & Maintenance manual that contains:

- Written instructions for use and care
- Compliance information and label identification

Each Erchonia® device has been through a complete Quality Assurance check to be sure that you, the user, get the best quality product. Through the shipping process, it is possible that some loss or damage will occur. Please take the time to check that you have received each

item, and that each item looks to be in good working order.

The Erchonia® MLS, ZERONA Device

The Erchonia® MLS, ZERONA™ device is a self-contained device created for use of the reduction of circumference of the upper arms. It is easy to use, compact, all in one, mains powered unit.

The Erchonia® MLS, ZERONA™ device has been classified by the FDA as a Class 2 Laser product and a Class 2 in accordance to IEC 60825-1 (EU). These are the current standards for use that ensures the safety of the user.

Technical Information

Technical documentation required by international end-users, in case of necessary reparations, will be provided by our EU agent. These documents will be supplied once the manufacturer, working with the EU agent, makes the determination that the requested documents do not constitute a disclosure of priority or patent protected information and are a part of the filed and documented technical file.

Transportation and Storage

The unit must be stored and/or transported in conditions not to exceed -30 to +70°C (-22 to +158°F) @ 0-100% Relative Humidity Non-Condensing.

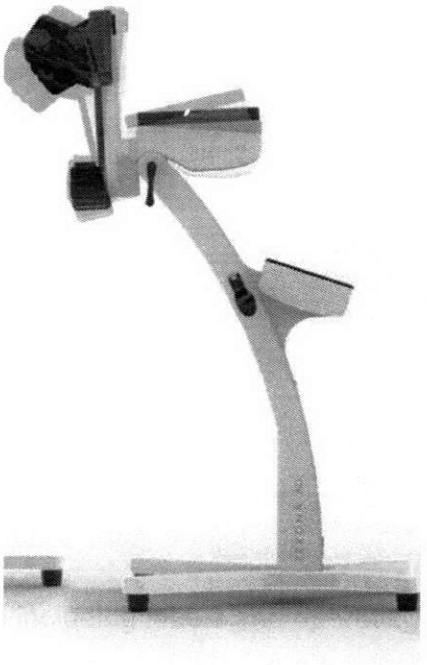
Device Specification

Wavelength	635 nm
Modulation	Constant Wave
Diode Output (each)	17 mW +/1 0.5
Total Energy Output	85 mW
Diode Delivery	Emitted as a line with measured at 1mW on each point of line, then rotated to create a circular pattern
Laser Class	2

Description of the Erchonia® MLS, ZERONA device

Detailed description of the Erchonia® MLS, ZERONA™ device including labels and operating (how to use) instructions.

The Erchonia® MLS, ZERONA™ device contains five diodes, each 635nm with a tolerance of ±5 nanometer. The diode output is 17 mW +/- .5 for each of the didoes with a total of 85 mW. These diodes are specially created and patented electric diodes that do not exceed FDA Laser Class 2.



The Erchonia® MLS, ZERONA™ device is made according to the FDA Good Manufacturing Practices, according to IEC / CE standards and in compliance to ISO standards. The Erchonia® MLS, ZERONA™ device is a Class II Medical device.

Each of these governing agencies asks for certain labeling. All required labels are fixed to the device according to the relevant codes. Each label is shown and described in Figure 2.

Intended Use

The MLS, ZERONA™ is intended for use of the reduction of circumference of the upper arms.

Device Identification

This section shows and describes the different parts of the Erchonia® MLS, ZERONA™ device. These are shown to help get familiar with the device and all of its parts to make sure the device operated properly. Fig 1 Shows the MLS, ZERONA device in three positions.

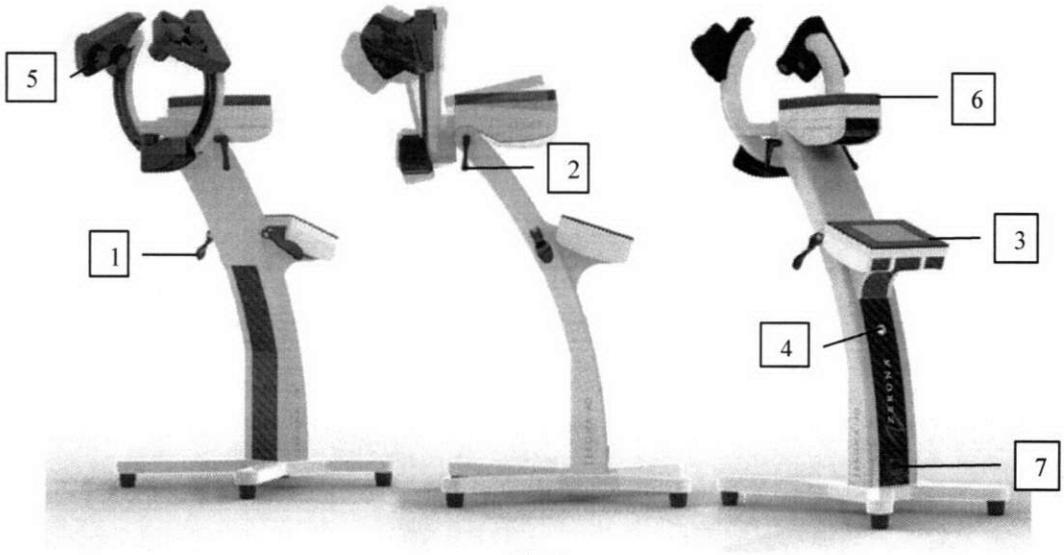


Fig. 1

1. Base Adjustment Lever (2)
2. Angle Adjustment Lever (2)
3. Touch Screen
4. Key Switch
5. Laser Output Head
6. Arm Rest Pad
7. Power Inlet Module/Fuse Holder

1) ***Base Adjustment Lever*** – On both sides of the base, there are two levers that when released (pulling away from device) allow the end used to adjust the height of the device. Once the desired height is obtained the levers must be locked (pressing towards the device) to support the weight of the patient's arm and laser heads. To adjust tension, rotate lever in a counter clockwise direction to tighten and clockwise direction to loosen.

Ensure to control the upper portion of the device when lowering by placing your hand under the arm rest to support the weight and slowly lower to desired height before locking levers in place. To adjust tension, rotate lever in a counter clockwise direction to tighten and clockwise direction to loosen. Over rotating may cause damage to the device

2) ***Angle Adjustment Lever*** – On both sides below the arm rest, there are two levers that when rotated counter clockwise will allow the end user to adjust the angle of the laser heads and arm rest.

 Ensure to control the upper portion of the device when tilting by holding the arm rest raising/lowering slowly to desired angle before tightening levers. Rotate levers clockwise until tension is snug. Over rotating may cause damage to the device

3) ***Touch Screen*** – The touch screen functions as a display screen and an input panel, providing information to the end user and a means to operate the device by touching the appropriate icon.

4) ***Key Switch*** – The key switch is the ON/OFF mechanism, shown as "O" = off and "I" = on. After insertion turn it to the right to turn on. Because the device has 2 computers when you first turn it on it will take a few moments to initialize up before use. The unit will not operate unless key is in the ON position. Turning the key to the OFF position satisfies the FDA requirement for mechanical lock out, ensuring the safety of non-authorized users.

5) ***Laser Output Head*** – Each one of the five laser output heads emits a 635nm red laser light. Each laser contains electronic diodes, with patented optics. These diodes when activated generate laser energy thereby emitting red beam(s). This specially designed and patented laser diode was created to ensure the laser beam is focused and directed for the most optimal use.

 The MLS, ZERONA device is classified as a Class 2 Laser. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 device is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging. To ensure there is no possible instance of residual effect, we have included a pair of specialty patient glasses for use by the patient during treatment.

6) ***Arm Rest Pad*** – The padded platform, in which the patient lays the arm on to be treated.

 This is the only portion of the device that comes into physical contact with the patient. This pad can be removed for ease of cleaning. For cleaning, use a disinfectant wipe.

7) ***Power Inlet Module/Fuse Holder*** – the power cord, which plugs into mains, is detachable. This is the place 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. Fuses to be rated a T2A 250V with an input to cover 100 – 240V~ 1.5-.5A, 50-60 Hz. Ref: Maintenance section for replacement instructions.

Labeling

This 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.

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

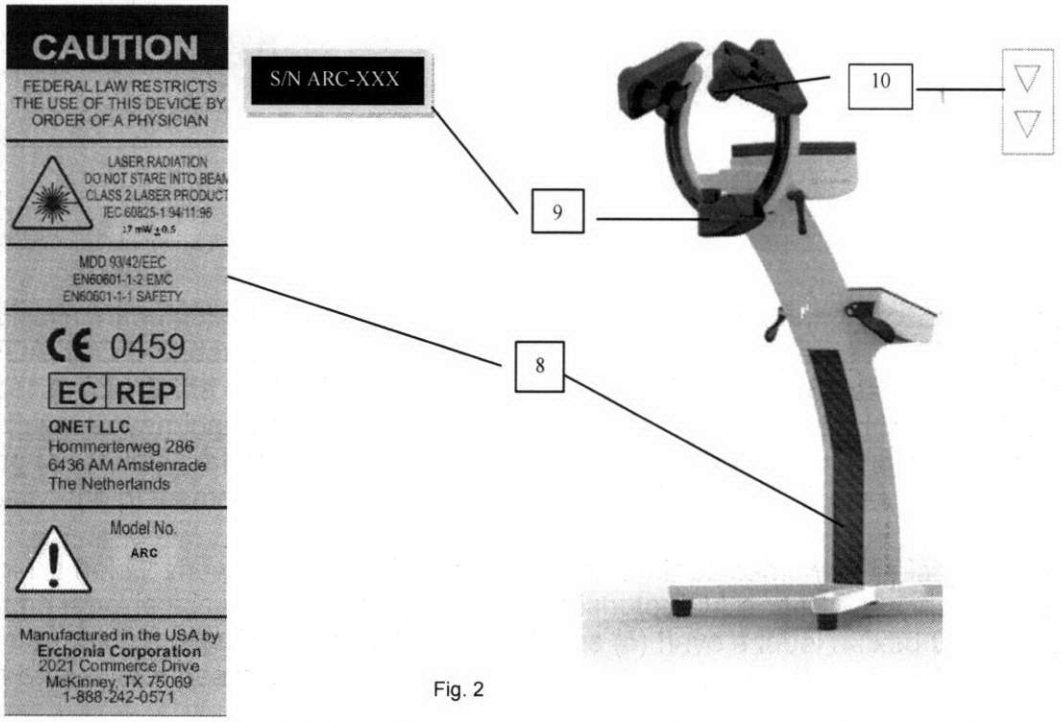


Fig. 2

8) ***Compliance Label*** – Contains all the governing agencies required information regarding the device, including but not limited to the US FDA device classification, EU classification, output information and power inlet symbols. Also includes the manufacturer name and address.

9) ***Serial Number*** – The unique identifier for the device. All information regarding this unit is associated with the serial number.

10) ***Laser Output*** – Each of the laser diodes (5) have a label affixed that show the direction of the laser beam output.

Visual Inspection

This completes the listing and the description of the parts of the Erchonia® MLS, ZERONA™ device. Once you are familiar with each part and you are sure that each part is in good working order, read the next section.

Protocol -- Non-invasive Dermatological Aesthetic Protocol for the Reduction of Circumference of the Upper Arms

1. Each patient receives six total procedures administered across a two-week time frame; three procedures per week; each one at least two days, but no more than three days, apart.
2. Each procedure administration will take a total of 40 minutes; 20 minutes per arm.
3. The procedure administration protocol for each session is as follows:
    a. The patient lies comfortably on his or her stomach on the treatment table, extending his or her right arm to rest on the arm rest of the device.
    b. The patient is correctly fitted with the laser safety glasses.
    c. The fixed center diode of the device is positioned at a distance of 6.00 inches above the skin and directed on the patient's mid upper arm.
    d. The other four rotating diodes are positioned 120 degrees apart and tilted 30 degrees off the centerline (mid upper arm) of the center scanner.
    e. The device is activated for 20 minutes. Each of the 5 rotating diodes emit a laser beam of approximately 17 mW with a wavelength of 635 nm red light for a total output of 85 mW for all 5 diodes. Each diode 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.
    f. This process is repeated for the patient's left arm.
    g. The patient removes the laser safety glasses and the session is over.

Mechanical Instructions for Use: How to Use the Device

To turn the device ON, place the key in the key lock and turn to the ON position. **NOTE:** The device 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 manufactures logo.

Press ">>Touch Here to Enter Treatment Screen<<" button, this will take you to the pre-set protocol screen. Press "PRESS TO START" button to begin the non-invasive arm reduction 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.

The device is preprogrammed to treat for a total of twenty minutes. Therefore in twenty minutes you will need to position the device on the second arm, manipulate the laser heads, and then press "PRESS TO START" button to continue with the remainder of the application. When done return the key to the OFF position.

Manufacturer Information

The manufacturer's name, address and telephone number, as shown below.

Manufacturer Information

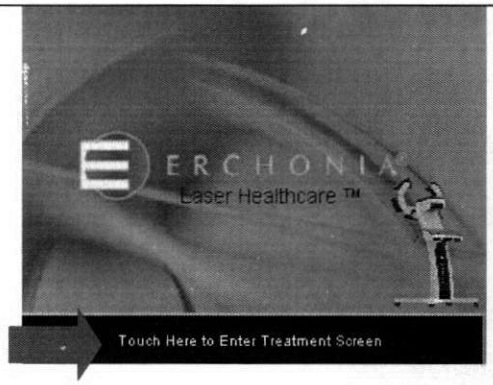
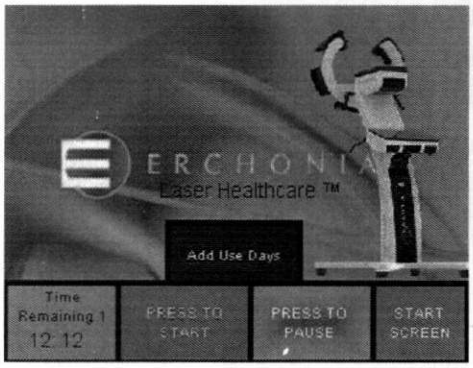
Erchonia ® Corporation
2021 Commerce Drive
McKinney, Texas 75069 USA
+1 888-242-0571
www.Erchonia.com

Distributor Information

Erchonia ® Corporation
2021 Commerce Drive
McKinney, Texas 75069 USA
+1 888-242-0571
www.Erchonia.com

Section 3

Activate Treatment Protocol

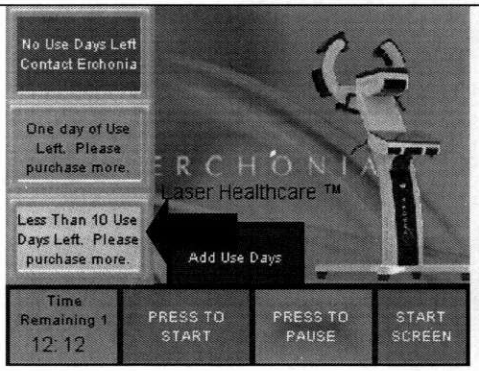
Operating the Device Press "Touch Here to Enter Treatment Screen" button, this will take you to the Erchonia Preset Protocol (Mode) Selection screen.	
Press "PRESS TO START" button to begin the non-invasive arm reduction protocol. If for any reason you need to pause, press the "PRESS TO PAUSE" button. 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.	

Device Update

This device requires an update every 30 days from software installation. You are required to contact your distributor for an update code

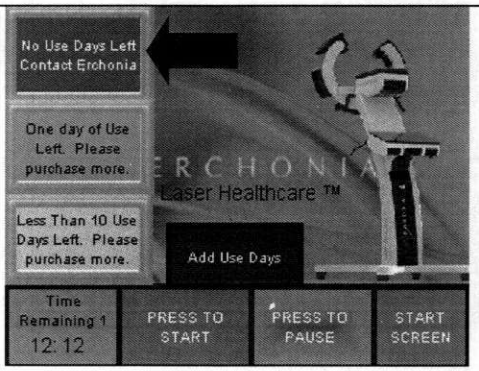
NOTE: Notification will start to display on the protocol screen to inform you that you have 10 calendar days until the device will lockout any further treatments.

You must contact the distributor for a device update code and will only unlock once the code is imputed into the device.

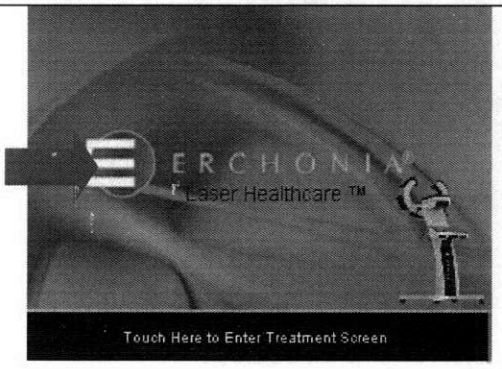


Once the UPDATE DUE screen appears, it will remain until an update code is entered or the 10 days expire.

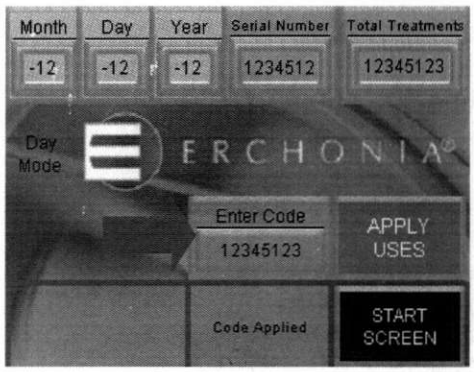
NOTE: Once the 10 days expire, the machine will stop operating and a notification will display on the touchscreen to advise you to CONTACT ERCHONIA FOR DEVICE UPDATE.



To enter the update code, tap the circled E of the Erchonia logo on the Introductory Splash Screen. The "Add Use Days" button will appear also displaying the device Serial Number.



Tap the "Add Use Days" button. This will take you to the "Day Mode" screen. To enter the update code, tap the "Enter Code" box, an entry screen will appear.



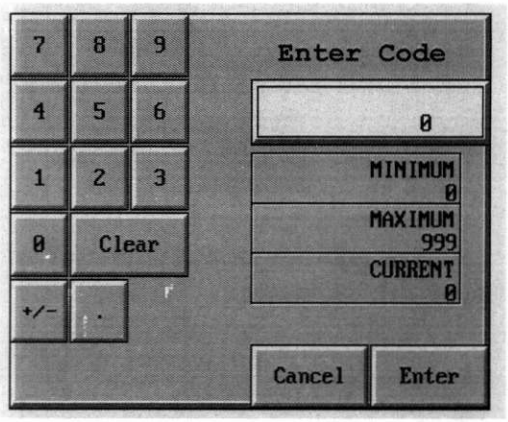
Enter the code received from the Distributor by selecting one number at a time, reading left to right. When the number in total appears in the field under ENTER CODE, tap enter.

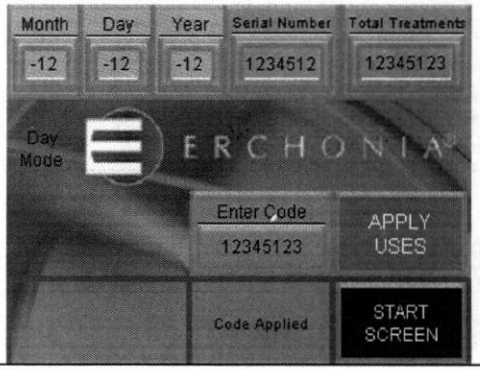
Code entered will display in the "Enter Code" icon

Tap the "APPLY USES" icon

A green flashing icon reading 'Code Applied" will appear under the "Update Code" box.

NOTE: If Code is entered incorrectly, a flashing red icon will appear under the "Update Code" box displaying "Incorrect Code". Repeat code entry process.





(b)(4) Test Data

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(b)(4) Test Data

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

February 7, 2012

FDA CDRH DMC
FEB - 8 2012
Received K120257

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: Addendum to 510(k) #K120257 for the MLS-ZERONA-AD

Dear Sir or Madam,

This document is being submitted as an addendum to 510(k) #K120257 for the MLS-ZERONA-AD. The purpose of this addendum is to change the indications for use to the more general indications of non-invasive dermatological aesthetic treatment for body contouring. The change of the indications for use is predicated on email communications with Mr. Neil Ogden, Chief, General Surgery Devices Branch, in which it was determined that this more general indication for use may be possible due to clinical data that was presented in K082609 regarding the results with hips, waists and thighs, along with the data presented in this 510(k) regarding the results with arms.

Please refer to the following changes to K120257 provided below.

Please replace the CDRH Premarket Review Submission Cover Sheet, Form FDA 3514, submitted in the original 510(k) application with the one that is contained in **Appendix A** of this addendum.

On Page 1 of the original 510(k) application, please replace the Trade Name with Erchonia® MLS, Zerona

On Page 2 of the original 510(k) application, please replace the Indications for Use statement with the following:

The MLS, Zerona™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring.

The new Indications for Use Statement is contained in **Appendix B** of this addendum.

On Page 4 of the original 510(k) application, please replace the Substantial Equivalence table with the following:

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

Comparison of the New and Predicate Devices

Device	Erchonia® MLS, Zerona™	Erchonia MLS Laser
510(k)	N/A	K082609
Indications for Use	The MLS, Zerona™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring.	The Erchonia® ML Scanner (MLS) is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs
Power	1 mw	1 mw
Wavelength	Red 630 nm – 640 nm (near infrared)	Red 630 nm – 640 nm (near infrared)
Waveform	Pulsed	Pulsed
Energy Source	Five diodes, each collected then line dispersed and rotated	Five diodes, each collected then line dispersed and rotated
Power Supply	AC	AC
Energy Delivery	Machine mounted probe	Machine mounted probe
Treatment Time	0 – 9.9 minutes	0 – 9.9 minutes
Target Size	Line pattern, mechanically rotated to form circles and scanned over treatment area.	Line pattern, 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.

Please refer to the new Operation & Maintenance Manual contained in **Appendix C**.

We hope the information contained in the original 510(k) premarket notification, along with the information enclosed in this addendum is sufficient for finding the MLS, Zerona™ substantially equivalent. Please let me know whether you have any questions or concerns or you require any additional information.

Respectfully yours,

Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.

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

February 7, 2012

Food and Drug Administration
Center for Devices and Radiological Health
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Device	Erchonia® MLS, Zerona™	Erchonia MLS Laser
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Indications for Use	The MLS, Zerona™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring.	The Erchonia® ML Scanner (MLS) is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs
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Please refer to the new Operation & Maintenance Manual contained in **Appendix C**.

We hope the information contained in the original 510(k) premarket notification, along with the information enclosed in this addendum is sufficient for finding the MLS, Zerona™ substantially equivalent. Please let me know whether you have any questions or concerns or you require any additional information.

Respectfully yours,

Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.

Indications for Use

510(k) Number (if known): _____

Device Name: Erchonia® MLS, Zerona™

Indications for Use: The MLS, Zerona™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring.

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)

Acknowledgements & Accreditations

We at Erchonia ® Corporation would like to thank you for purchasing the Erchonia® MLS, Zerona™ device.

Erchonia ® Corporation is an ISO certified company and is audited from time to time by outside governing agencies, including the FDA, to be sure to stay in compliance with the highest quality standards. Our company operates according to and our devices are manufactured according with:

- FDA Good Manufacturing Practices
- ISO 9001 :2000 - Quality
- ISO 13485:2003 – Medical
- ISO 60825-1 - Laser Safety
- FDA Laser Class 2
- FDA Device Class II
- IEC Laser Class 2
- IEC Device Class 1
- MDD 93/42/EEC
- EN/IEC 60601-1-2 EMC
- EN/IEC EN60601-1-1 Safety
- Model Number: ARC
- Software Version ARM-E Rev A (1-9-12)
  - **ARM-E-TS Rev A**
  - **ARM-E-PLC Rev A**

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

Doc. No.	Issue Date	CR #	Revision	Rev Date
MLS-O&M MLS Zerona	1/11/2012	510(k) Release	0	1/11/2012

Legend:
The following symbols are used throughout this manual to show areas of concern. For your safety, and for the care of the device, please read and take note of these warnings and cautions.

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

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

Refers to the part of the medical device which comes into physical contact with the patient in order for the device to carry out its intended function.

US National Consideration:
When using in the US, the equipment is intended to be powered by a 120V source. If powered by a 240V source in the US, then the power source must be a center-tapped, 240V single phase circuit.

Erchonia® Corporation
2021 Commerce Dr. McKinney, TX 75069
Phone +1 888-242-0571 • Fax +1 214.544.2228
www.Erchonia.com
Patent(s): US – 6,013,096, Patent Pending

CAUTION: FEDERAL LAW RESTRICTS THE USE OF THIS DEVICE BY ORDER OF PHYSICIAN

MLS, Zerona Components

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

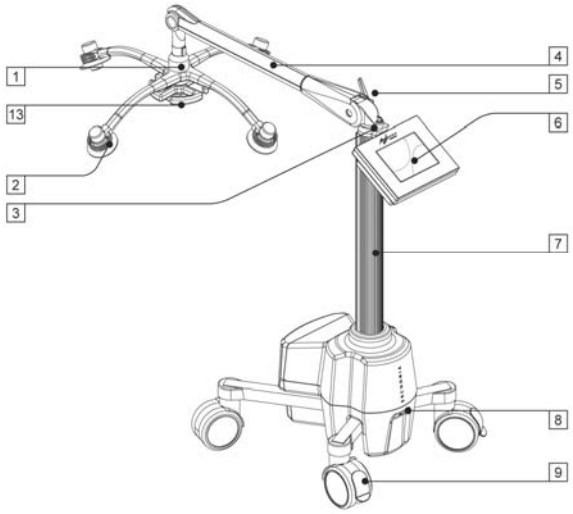


Fig. 1

1. Laser Head Assembly
2. Laser Output Head
3. Power Safety Lockout Key
4. Laser Arm
5. Arm Lock
6. Touch screen Control Surface
7. Main Upright of Base
8. Power Inlet
9. Rear Wheel Lock
10. Electrical Connector – (Page 4)
11. Locking Nut – (Page 4)
12. Power Cord – not shown
13. Handle

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].

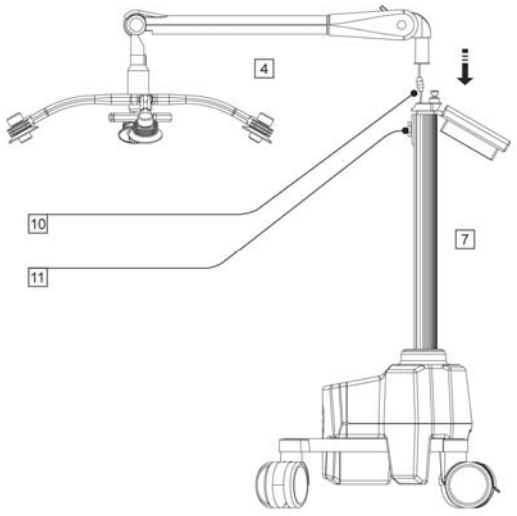
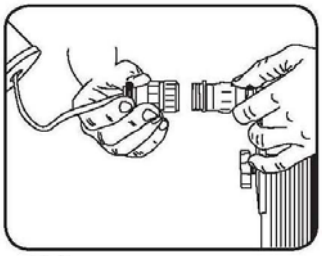
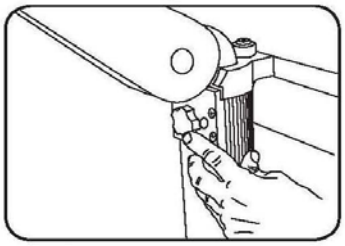
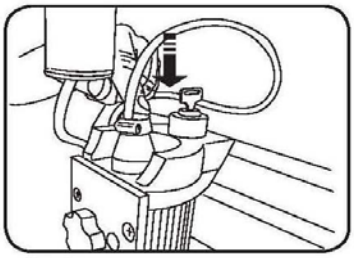
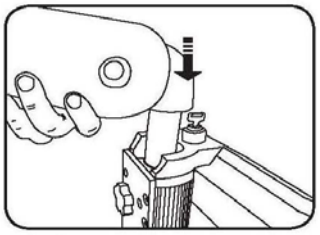
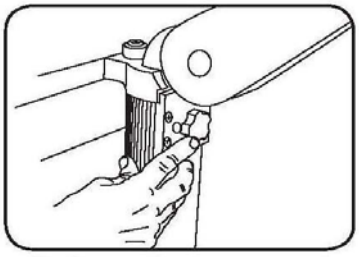


Fig. 2

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.** **This is important so the two halves do not separate over time.**	 Fig. 3
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 treaded 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.

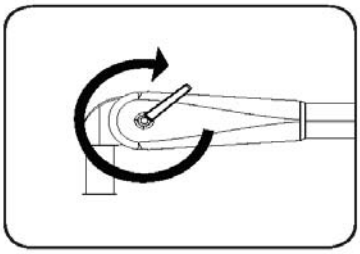


Fig. 8

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.

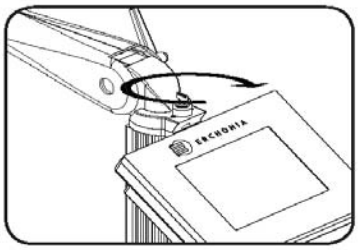


Fig. 9

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.

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.

When moving the head assembly into the desired position, make sure to use the handle on the side of the head assembly (fig 1, #13) 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.

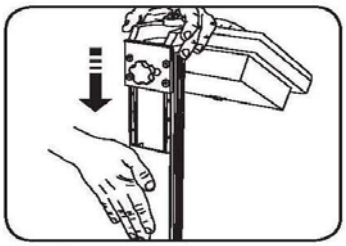


Fig. 10

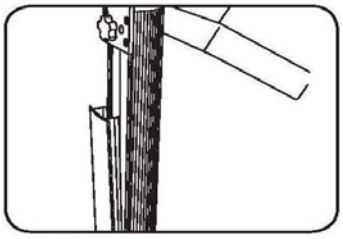


Fig. 11

Introduction to Contents

The Erchonia® MLS, Zerona™ laser package is comprised of (1) MLS, Zerona, (1) pair of patient protective eyewear, (1) Power Cord, (2) Keys, and this user guide. The components of this package are detailed below.

Erchonia® MLS, Zerona ™

The Erchonia® MLS, Zerona™ is made up of five independent 635 nanometer diodes. Laser devices are typically constructed to emit a "spot" of light. The Erchonia® MLS, Zerona™ laser utilizes internal mechanics that collects the light emitted from the diode and processes through a proprietary patented lens which redirects the beam with a line refractor. The lines generated by each head are rotated via a patented rotation device that operates independent of each other to ensure thorough coverage. The target area is approximately 8" x 10" inches or 80 square inches, approximately 516 square centimeters.

Power

The power switch is the key switch on top of the Touch screen, ref Item 3, FIG 1. The unit will not operate unless key is in the ON position. Turning the key to the OFF position satisfies the FDA requirement for mechanical lock out, ensuring the safety of non-authorized users. The power switch has a fail-safe system which ensures the 110/240 voltage from a wall socket can never come in contact with the user. The system uses a 2 amp fuse, which will only require replacement if there is an issue. To replace, locate fuse holder in back of base unit, pull fuse holder out of enclosure, replace fuses and reinsert. Use only rated T2A 250V. The device includes a transformer which converts AC power to match the power output i.e. 110V or 240V. Only a plug prong adaptor is required (available at any retail electronics store). Once the adaptor is affixed to the plug end, put into wall socket. Input: 100-240V-0.5-1.5A 50-60 Hz.

NOTE: Make sure the power cord is plugged into device 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. Fuses to be rated a T2A 250V with an input to cover 100 – 240V~ 1.5-.5A, 50-60 Hz.

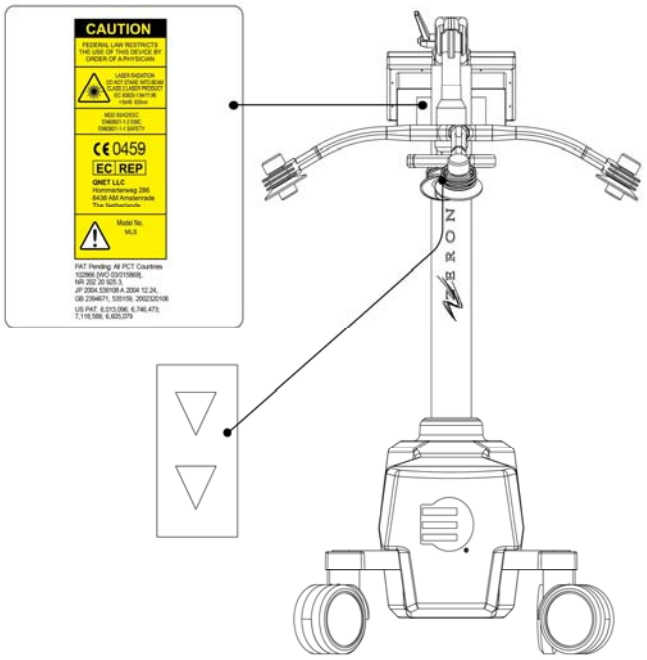
Protective Eyewear

The Erchonia® MLS, Zerona™ is classified as a Class 2 laser. This designation represents a current standard for use in order to ensure the safety of the patient.

The MLS, Zerona™ device is classified as a Class 2 Laser. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 device is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging. To ensure there is no possible instance of residual effect, we have included a pair of specialty patient glasses for use by the patient during treatment

Labeling

The 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 2 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.



Manufacturer and Distributor Information

Manufacturer's Information

Erchonia Corporation
2021 Commerce Dr.
McKinney, TX. USA 75069
+1.214.544.2227

Distributor Information

Erchonia Corporation
2021 Commerce Dr.
McKinney, TX. USA 75069
+1.214.544.2227

The Erchonia® MLS, Zerona™ Device

The Erchonia® MLS, Zerona™ device is a self-contained device created for use of non-invasive dermatological aesthetic treatment for body contouring. It is easy to use, compact, all in one, mains powered unit.

The Erchonia® MLS, Zerona™ device has been classified by the FDA as a Class 2 Laser product and a Class 2 in accordance to IEC 60825-1 (EU). These are the current standards for use that ensures the safety of the user.

Technical Information

Technical documentation required by international end-users, in case of necessary reparations, will be provided by our EU agent. These documents will be supplied once the manufacturer, working with the EU agent, makes the determination that the requested documents do not constitute a disclosure of priority or patent protected information and are a part of the filed and documented technical file.

Transportation and Storage

The unit must be stored and/or transported in conditions not to exceed -30 to +70ºC (-22 to +158ºF) @ 0-100% Relative Humidity Non-Condensing.

Intended Use

The MLS, Zerona™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring.

Visual Inspection

This completes the listing and the description of the parts of the Erchonia® MLS, Zerona™ device. Once you are familiar with each part and you are sure that each part is in good working order, read the next section.

Protocol -- Non-invasive Dermatological Aesthetic Protocol for the Upper Arms

1. Each patient receives six total procedures administered across a two-week time frame; three procedures per week; each one at least two days, but no more than three days, apart.
2. Each procedure administration will take a total of 40 minutes; 20 minutes per arm.
3. The procedure administration protocol for each session is as follows:
    a. The patient lies comfortably on his or her stomach on the treatment table, extending his or her right arm to rest at a 90 degree angle to his or her body flat on the treatment table, palm down.
    b. The patient is correctly fitted with the laser safety glasses.
    c. The fixed center diode of the device is positioned at a distance of 6.00 inches above the skin and directed on the patient's mid upper arm.
    d. The other four rotating diodes are positioned 120 degrees apart and tilted 30 degrees off the centerline (mid upper arm) of the center scanner.
    e. The device is activated for 20 minutes. The 5 rotating diodes emit a laser beam of approximately 17 mW with a wavelength of 635 nm red light. Each diode 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.
    f. This process is repeated for the patient's left arm.
    g. The patient removes the laser safety glasses and the session is over.

Protocol -- Non-invasive Dermatological Aesthetic Protocol for the Front of the Body

1. The patient lies comfortably flat on his or her back on the table such that the front area of the patient's body encompassing the region spanning from the patient's stomach (abdomen) down through the hips and frontal aspect of both thighs, is facing upwards.

2. The center diode of the Erchonia® MLS, Zerona™ is positioned at a distance of 6.00 inches above the patient, centered along the body's midline (the "line" that vertically "dissects" the body into two equal halves).
3. The Erchonia® MLS, Zerona™ is activated for 20 minutes. Each scanner emits to the patient a laser beam of approximately 17mW with a wavelength of 635 nm, and creates a spiraling circle pattern that is totally random and independent from the others. These patterns overlap each other to guarantee total coverage within the target area of approximately 516 square centimeters.

Protocol -- Non-invasive Dermatological Aesthetic Protocol for the Back of the Body

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

Clinical Trial Summary

A DOUBLE-BLIND, PLACEBO-CONTROLLED RANDOMIZED EVALUATION OF THE EFFECT OF THE ERCHONIA® ML SCANNER (MLS) ON BODY CONTOURING OF THE WAIST, HIPS AND THIGHS.
Erchonia Medical. Inc.

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

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

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

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

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

Table 1: Table of Subject Demographics

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

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

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

Table 2: Mean Baseline measurements

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

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

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

STUDY RESULTS

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

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

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

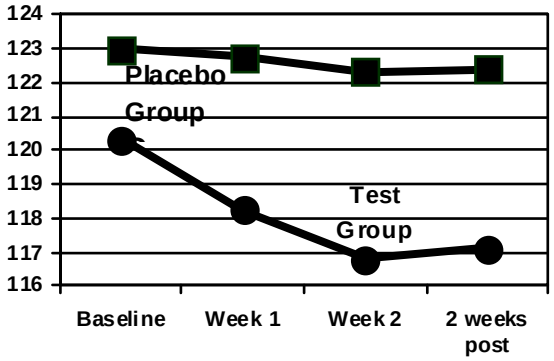
The magnitude of the mean change in total circumference measurement was a decrease of 3.521 inches for subjects who received the study procedures with the actual Erchonia® MLS and a decrease of 0.684 inches for subjects who received the study procedures with a 'fake' (placebo) laser device. A t-test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

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

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

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

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



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

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

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

Table 4: Mean individual body area circumference measurements.

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

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

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

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

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

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

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

AN EVALUATION OF THE EFFECTIVENESS OF THE ERCHONIA® ML SCANNER (MLS) AS A NON-INVASIVE DERMATOLOGICAL AESTHETIC TREATMENT FOR THE REDUCTION OF CIRCUMFERENCE OF THE UPPER ARMS
Erchonia Corporation

BACKGROUND: The purpose of this clinical study was to demonstrate the effectiveness of the Erchonia® MLS, Zerona™ for non-invasive body contouring of the upper arms by applying the MLS, Zerona™ to the upper arms 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 two (62) subjects completed this study. Of the 62 participating subjects, 31 were randomized to the active procedure group and 31 were randomized to the placebo group.

Subjects were those aged 18 to 65 years who were deemed suitable for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that had failed

to respond to diet and exercise; specifically for the indication of body contouring of the bilateral upper arms, as per the American Academy of Cosmetic Surgery's 2006 Guidelines for Liposuction Surgery developed by a joint Ad Hoc Committee of the American Society of Liposuction Surgery (ASLSS) and the American Academy of Cosmetic Surgery (AACS), and/or for the procedure of brachioplasty (upper arm lift).

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

Table 1: Table of Subject Demographics

Gender	**Female**		**Male**	
n=62	*number*	*%*	*number*	*%*
	60	97%	2	3%
Ethnicity	**Caucasian**		**Hispanic**	
n=62	*number*	*%*	*number*	*%*
	37	60%	21	34%
	African American		**Caucasian/African American**	
	number	*%*	*number*	*%*
	2	3%	2	3%

STUDY MEASURES: Circumference measurements at three points on the upper arms, and body mass index (BMI) were recorded at baseline, study mid-point (week 1), study endpoint (week 2), and study follow-up two weeks later. Subject satisfaction with the procedure outcome was recorded at study endpoint.

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

Table 2: Mean Baseline measurements

	Test Group n=31	**Placebo Group n=31**
Body Mass Index (BMI)	29.57	30.57
Right Upper Arm Circumference (cms.)	95.67	94.66
Left Upper Arm Circumference (cms.)	95.81	94.92

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

STUDY PROCEDURE: Subjects received six procedure administrations with the Erchonia® MLS, Zerona™ to the right and left upper arms, across a consecutive two-week period: three procedures per week, each procedure two to three days apart.

STUDY RESULTS

(i) Total Circumference Measurements: The study primary outcome measure was based on individual circumference measurements taken at 3 points along each of the subject's upper arms combined to attain a single circumference measurement for each of the right arm and the left arm, separately.

It was pre-determined that a subject would be considered a study success if he or she attained a 1.25 cm or greater reduction in combined circumference measurement for each of the right and left upper arms, separately, from baseline to study endpoint (after completion of the two-week procedure phase).

58% of subjects who received the study procedures with the actual Erchonia® MLS, Zerona™ attained a decrease in combined circumference measurement of 1.25 cms or greater for each of the right and left upper arms, separately, compared with 3% 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 55% to be statistically significant at $p<0.000005$.

The mean change in total circumference for subjects who received the study procedures with the actual Erchonia® MLS, Zerona™ was a decrease of 1.85 cms for the right upper arm, a decrease of 1.84 cms for the left upper arm and decrease of 3.70 cms for both upper arms combined. The mean change in total circumference for subjects who received the study procedures with the 'fake' (placebo) laser device was a decrease of 0.08 cms for the right upper arm, a decrease of 0.23 cms for the left upper arm and decrease of 0.31 cms for both upper arms combined.

Paired samples t-tests found the changes in upper arm circumference measurements for subjects in the test group to be statistically significant, as shown in Table 3 below. The changes in upper arm circumference measurements for subjects in the placebo group were not found to be statistically significant, as shown in Table 4 below.

Table 3: Paired samples t-tests for test group subjects

Test Group	μa-μb	t	df	p(two-tailed)	significance
Right Arm	1.855	+9.61	30	<0.0001	p<0.0001
Left Arm	1.842	+8.98	30	<0.0001	p<0.0001
Right & Left Arms	3.70	+10.65	30	<0.0001	p<0.0001

Table 4: Paired samples t-tests for placebo group subjects

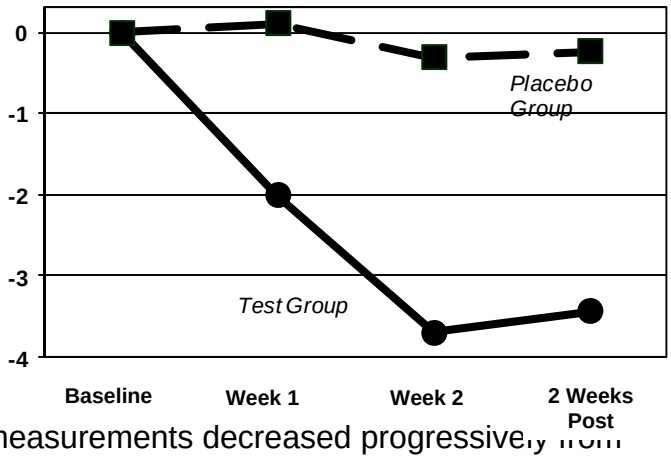
Placebo Group	μa-μb	t	df	p(two-tailed)	p	significance
Right Arm	0.0806	+0.83	30	0.413	p>0.05	Not significant
Left Arm	0.23	+1.95	30	0.061	p>0.05	Not significant
Right & Left Arms	0.31	+1.67	30	0.105	p>0.05	Not significant

Table 5 and Chart 1 below show the mean change in total upper arm circumference measurements (right and left arms combined) across the four study measurement time points.

Table 5: Mean total circumference measurements (cms) across evaluation points

	Test Group	Placebo Group
Baseline	191.48	189.58
Midpoint (week 1)	189.47	189.69
Endpoint (week 2)	187.78	189.27
Follow-up (week 4)	188.04	189.34

Chart 1: Mean change in total upper arm circumference measurements (cms) at each study evaluation point relative to baseline



For test group subjects, total circumference measurements decreased progressively from baseline across the procedure administration phase, indicating a progressive and cumulative treatment effect of the laser. However, for placebo group subjects, total circumference measurements were unchanged across the procedure administration phase relative to baseline.

Total circumference measurements stabilized for test group subjects across the subsequent 2-week follow-up assessment period during which time no laser procedures were administered, indicating duration of the treatment effect up to at least 2 weeks following the end of laser procedure administration.

(ii) Change in body mass index (BMI): BMI measurements did not change significantly across and between any of the evaluation time points for either test or placebo subject groups. However, upper arm circumference measurements did change significantly across and between evaluation points for test group subjects but not for placebo group subjects. This combined finding further supports the effectiveness of the Erchonia® MLS, Zerona™ device as it demonstrates that the change in body shape (reduction in cms for the upper arms) attained for test group subjects in this study at this test site resulted from the Erchonia® MLS, Zerona™ device applications and not from change in body mass index as a result of incidental weight loss.

(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 upper arms attained using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied.

65% of test group subjects reported being ‘Satisfied’ (Very or Somewhat Satisfied) with the outcome of the study procedures compared with 22% 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® MLS, Zerona™ is an effective tool for body contouring, significantly reducing circumference measurements when applied to the bilateral upper arms over a 2-week period.

Mechanical Instructions for Use: How to Use the Device

Operating the Device

Press “Touch Here to Enter Treatment Screen” button, this will take you to the Erchonia Preset Protocol (Mode) Selection screen.

Press “PRESS TO START” button to begin the non-invasive arm reduction 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.

This device requires an update every 30 days from software installation. You are required to contact your distributor for an update code

NOTE: Notification will start to display on the protocol screen to inform you that you have 10 calendar days until the device will lockout any further treatments.

You must contact the distributor for a device update code and will only unlock once the code is imputed into the device.

Once the UPDATE DUE screen appears, it will remain until an update code is entered or the 10 days expire.

NOTE: Once the 10 days expire, the machine will stop operating and a notification will display on the touchscreen to advise you to CONTACT ERCHONIA FOR DEVICE UPDATE.

Warnings

1) The long-term effects of prolonged use of non-thermal laser exposure are not known.
2) The device should not be used over, or near, cancerous lesions, as conclusive tests have not been done.
3) The device should not be used when you are in the bath or shower because electrical shock may occur.
4) To avoid any possible danger to the eyes, do not shine the laser light directly into your eyes.
5) Keep the device out of the reach of children at all times.
6) Changes to the use of the laser controls or to the performance of treatments other than those specified in this manual may cause hazardous radiation exposure.

Cautions

1) Safety of non-thermal laser for use during pregnancy has not been shown.
2) Caution should be used over areas of skin that lack normal sensation (feeling).
3) The device should be used only with the parts recommended for use by the manufacturer.
4) Avoid any liquid getting into the device.
5) Avoid contact with flammable products, or with air with oxygen or nitrous oxide.
6) To ensure proper use and to mitigate the possibility of interference, avoid placing in close proximity to other electromagnetic devices.

NOTE: If due to misuse, failure to follow cautions or unforeseen circumstances the device is damaged, contact the manufacturer.

Maintenance & Cleaning

The Erchonia® MLS, Zerona™ device, if used according to the instructions in this manual will work well for years. For proper care, it is best to:

1. Do regular visual checks for signs of damage to the device other than normal wear and tear. If you are concerned about damage, please contact the manufacturer to see if action needs to be taken.

2. If you see a change in how the device works while in the ON position, please contact the manufacturer to see if action needs to be taken.

3. The inside parts of the device should not need any maintenance; however, if you think there is a problem because the device is not working well or is working differently than before, the device must be sent to the manufacturer.

4. Since the MLS, Zerona™ is placed on the floor and designed to be in conjunction with a table or chair for ease of the patient. The platform in which the patient's arm rests is to be cleaned using disinfectant wipes.

5. If during treatment any part of the device touches the skin, follow the cleaning process defined in step #4, to correct.

6. Fuses can be replaced by the end-user. The fuse holder is part of the power inlet module, see item #7, Device Description. To replace, pull open fuse drawer, remove spent fuse, insert new fuse rated at T2A 250V 100-240V~.5 – 1.5A, 50 – 60 Hz.

Disposal

The Erchonia® MLS, Zerona™ is a self-contained unit that gives out light energy and as such creates no byproducts that require control. However, as a courtesy Erchonia offers disposal services. To take advantage of the offer, when the device cannot be used properly and/or cannot be repaired, send to manufacturer for disposal.

Warranty Information

Detailed description of the Terms and Condition for warranty of the Erchonia® MLS, Zerona™ device.

Limited Warranty

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

Terms and Conditions

- Shipping for warranty repair and / or maintenance within the first 90 days will be paid for by the manufacturer.
- Shipping for warranty repair and / or maintenance after 90 days will be paid for by the consumer.
- 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 repair to damage caused by:

Accident, misuse or abuse
Lack of responsible care
Use of an unapproved power cord
Alteration to or disassembly of the device
Loss of parts
Exposure to the elements
Ingress of liquid (liquid entering the device)

Point of Contact

If for any reason, you are not satisfied with this product or have warranty concerns or questions about how to use the device, please call +1 888-242-0571 for immediate help.

K120257/A1

Regulatory Insight, Inc.

Worldwide Medical Device Submissions and Quality Systems

February 7, 2012

FDA CDRH DMC
FEB - 8 2012
Received

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: Addendum to 510(k) #K120257 for the MLS-ZERONA-AD

Dear Sir or Madam,

This document is being submitted as an addendum to 510(k) #K120257 for the MLS-ZERONA-AD. The purpose of this addendum is to change the indications for use to the more general indications of non-invasive dermatological aesthetic treatment for body contouring. The change of the indications for use is predicated on email communications with Mr. Neil Ogden, Chief, General Surgery Devices Branch, in which it was determined that this more general indication for use may be possible due to clinical data that was presented in K082609 regarding the results with hips, waists and thighs, along with the data presented in this 510(k) regarding the results with arms.

Please refer to the following changes to K120257 provided below.

Please replace the CDRH Premarket Review Submission Cover Sheet, Form FDA 3514, submitted in the original 510(k) application with the one that is contained in **Appendix A** of this addendum.

On Page 1 of the original 510(k) application, please replace the Trade Name with Erchonia® MLS, Zerona

On Page 2 of the original 510(k) application, please replace the Indications for Use statement with the following:

The MLS, Zerona™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring.

The new Indications for Use Statement is contained in **Appendix B** of this addendum.

On Page 4 of the original 510(k) application, please replace the Substantial Equivalence table with the following:

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

Comparison of the New and Predicate Devices

Device	Erchonia® MLS, Zerona™	Erchonia MLS Laser
510(k)	N/A	K082609
Indications for Use	The MLS, Zerona™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring.	The Erchonia® ML Scanner (MLS) is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs
Power	1 mw	1 mw
Wavelength	Red 630 nm – 640 nm (near infrared)	Red 630 nm – 640 nm (near infrared)
Waveform	Pulsed	Pulsed
Energy Source	Five diodes, each collected then line dispersed and rotated	Five diodes, each collected then line dispersed and rotated
Power Supply	AC	AC
Energy Delivery	Machine mounted probe	Machine mounted probe
Treatment Time	0 – 9.9 minutes	0 – 9.9 minutes
Target Size	Line pattern, mechanically rotated to form circles and scanned over treatment area.	Line pattern, 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.

Please refer to the new Operation & Maintenance Manual contained in **Appendix C**.

We hope the information contained in the original 510(k) premarket notification, along with the information enclosed in this addendum is sufficient for finding the MLS, Zerona™ substantially equivalent. Please let me know whether you have any questions or concerns or you require any additional information.

Respectfully yours,

Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
01/24/2012	(b) (4)	K120257

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

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

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

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

PSC Publishing Services (301) 443-6740 EF

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

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

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

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

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

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

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

- ☐ Response to FDA correspondence:

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

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

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

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	OLI	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*
1	K082609	ML Scanner	Erchonia
2			
3			
4			
5			
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	MLS, Zerona™	
2		
3		
4		
5		

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

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

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☒ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
OLI	878.5400	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

General & Plastic Surgery

Indications *(from labeling)*

The Erchonia® The MLS ZERONA™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring.

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

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Erchonia Medical, Inc.		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: Steven Shanks	Contact Title: President	Contact E-mail Address: SShanks@erchonia.com	

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

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

SECTION I — UTILIZATION OF STANDARDS

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

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

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

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

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

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

Indications for Use

510(k) Number (if known): _____

Device Name: Erchonia® MLS, Zerona™

Indications for Use: The MLS, Zerona™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring.

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)

Acknowledgements & Accreditations

We at Erchonia ® Corporation would like to thank you for purchasing the Erchonia® MLS, Zerona™ device.

Erchonia ® Corporation is an ISO certified company and is audited from time to time by outside governing agencies, including the FDA, to be sure to stay in compliance with the highest quality standards. Our company operates according to and our devices are manufactured according with:

- FDA Good Manufacturing Practices
- ISO 9001 :2000 - Quality
- ISO 13485:2003 – Medical
- ISO 60825-1 - Laser Safety
- FDA Laser Class 2
- FDA Device Class II
- IEC Laser Class 2
- IEC Device Class 1
- MDD 93/42/EEC
- EN/IEC 60601-1-2 EMC
- EN/IEC EN60601-1-1 Safety
- Model Number: ARC
- Software Version ARM-E Rev A (1-9-12)
  - **ARM-E-TS Rev A**
  - **ARM-E-PLC Rev A**

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

Doc. No.	Issue Date	CR #	Revision	Rev Date
MLS-O&M MLS Zerona	1/11/2012	510(k) Release	0	1/11/2012

Legend:
The following symbols are used throughout this manual to show areas of concern. For your safety, and for the care of the device, please read and take note of these warnings and cautions.

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

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

Refers to the part of the medical device which comes into physical contact with the patient in order for the device to carry out its intended function.

US National Consideration:
When using in the US, the equipment is intended to be powered by a 120V source. If powered by a 240V source in the US, then the power source must be a center-tapped, 240V single phase circuit.

Erchonia® Corporation
2021 Commerce Dr. McKinney, TX 75069
Phone +1 888-242-0571 • Fax +1 214.544.2228
www.Erchonia.com
Patent(s): US – 6,013,096, Patent Pending

CAUTION: FEDERAL LAW RESTRICTS THE USE OF THIS DEVICE BY ORDER OF PHYSICIAN

MLS, Zerona Components

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

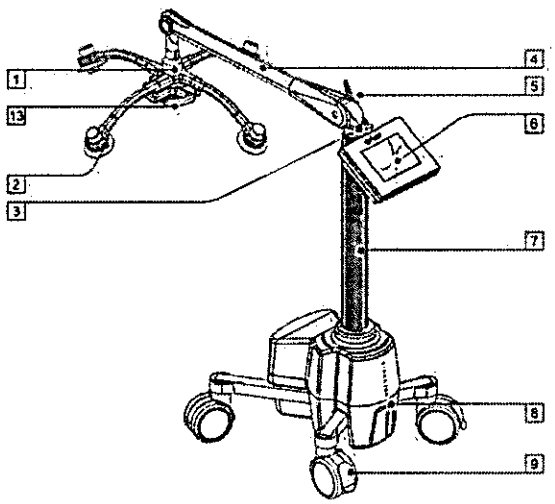


Fig. 1

1. Laser Head Assembly
2. Laser Output Head
3. Power Safety Lockout Key
4. Laser Arm
5. Arm Lock
6. Touch screen Control Surface
7. Main Upright of Base
8. Power Inlet
9. Rear Wheel Lock
10. Electrical Connector – (Page 4)
11. Locking Nut – (Page 4)
12. Power Cord – not shown
13. Handle

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].

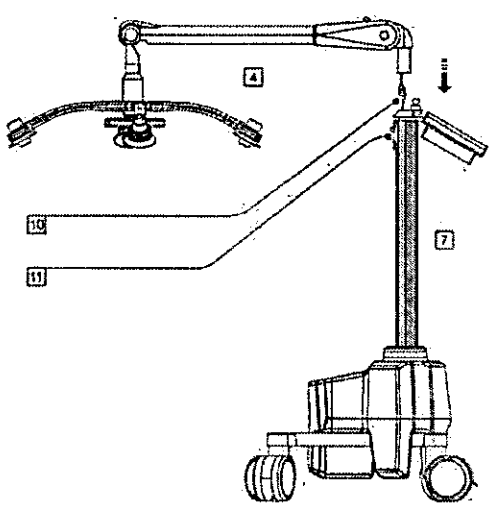


Fig. 2

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

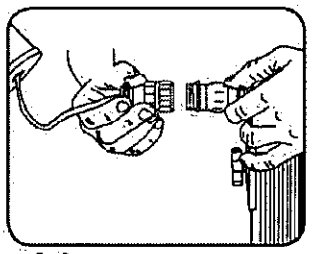


Fig. 3

Step 2:

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

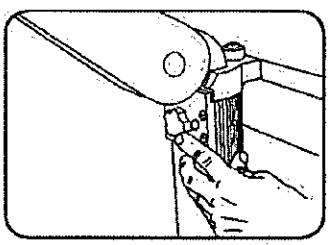


Fig. 4

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

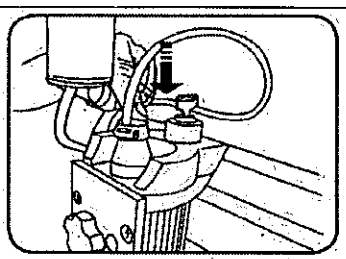


Fig. 5

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.

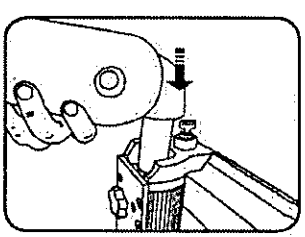


Fig. 6

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 treaded 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.

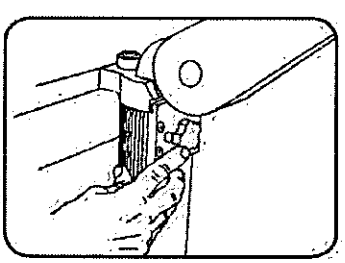


Fig. 7

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.

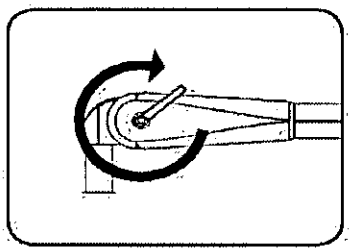


Fig. 8

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.

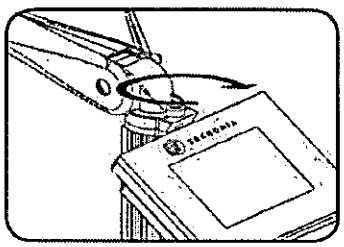


Fig. 9

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.

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.

When moving the head assembly into the desired position, make sure to use the handle on the side of the head assembly (fig 1, #13) 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.

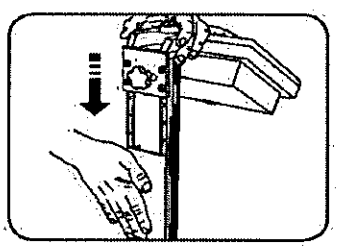


Fig. 10

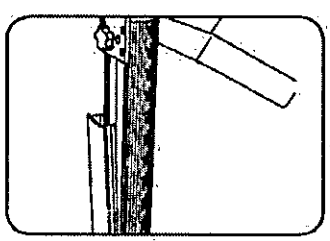


Fig. 11

Introduction to Contents

The Erchonia® MLS, Zerona™ laser package is comprised of (1) MLS, Zerona, (1) pair of patient protective eyewear, (1) Power Cord, (2) Keys, and this user guide. The components of this package are detailed below.

Erchonia® MLS, Zerona ™

The Erchonia® MLS, Zerona™ is made up of five independent 635 nanometer diodes. Laser devices are typically constructed to emit a "spot" of light. The Erchonia® MLS, Zerona™ laser utilizes internal mechanics that collects the light emitted from the diode and processes through a proprietary patented lens which redirects the beam with a line refractor. The lines generated by each head are rotated via a patented rotation device that operates independent of each other to ensure thorough coverage. The target area is approximately 8" x 10" inches or 80 square inches, approximately 516 square centimeters.

Power

The power switch is the key switch on top of the Touch screen, ref Item 3, FIG 1. The unit will not operate unless key is in the ON position. Turning the key to the OFF position satisfies the FDA requirement for mechanical lock out, ensuring the safety of non-authorized users. The power switch has a fail-safe system which ensures the 110/240 voltage from a wall socket can never come in contact with the user. The system uses a 2 amp fuse, which will only require replacement if there is an issue. To replace, locate fuse holder in back of base unit, pull fuse holder out of enclosure, replace fuses and reinsert. Use only rated T2A 250V. The device includes a transformer which converts AC power to match the power output i.e. 110V or 240V. Only a plug prong adaptor is required (available at any retail electronics store). Once the adaptor is affixed to the plug end, put into wall socket. Input: 100-240V-0.5-1.5A 50-60 Hz.

NOTE: Make sure the power cord is plugged into device 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. Fuses to be rated a T2A 250V with an input to cover 100 – 240V~ 1.5-.5A, 50-60 Hz.

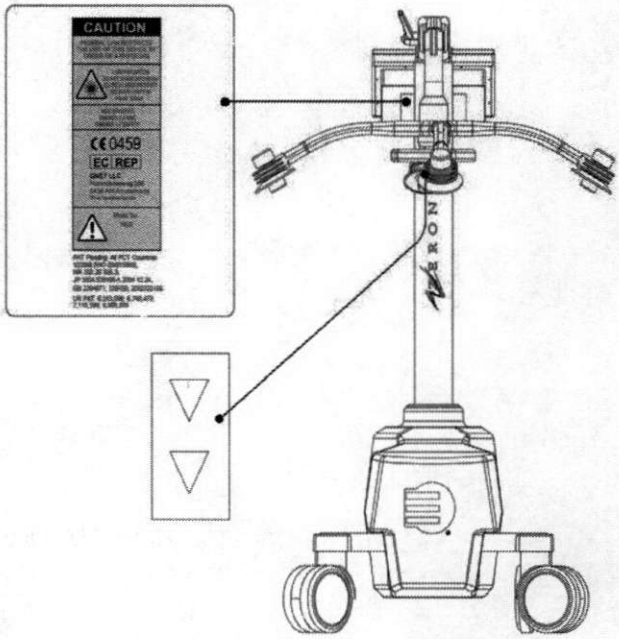
Protective Eyewear

The Erchonia® MLS, Zerona™ is classified as a Class 2 laser. This designation represents a current standard for use in order to ensure the safety of the patient.

 The MLS, Zerona™ device is classified as a Class 2 Laser. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 device is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging. To ensure there is no possible instance of residual effect, we have included a pair of specialty patient glasses for use by the patient during treatment

Labeling

The 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 2 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.



Manufacturer and Distributor Information

Manufacturer's Information
Erchonia Corporation
2021 Commerce Dr.
McKinney, TX. USA 75069
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Distributor Information
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McKinney, TX. USA 75069
+1.214.544.2227

The Erchonia® MLS, Zerona™ Device

The Erchonia® MLS, Zerona™ device is a self-contained device created for use of non-invasive dermatological aesthetic treatment for body contouring. It is easy to use, compact, all in one, mains powered unit.

The Erchonia® MLS, Zerona™ device has been classified by the FDA as a Class 2 Laser product and a Class 2 in accordance to IEC 60825-1 (EU). These are the current standards for use that ensures the safety of the user.

Technical Information

Technical documentation required by international end-users, in case of necessary reparations, will be provided by our EU agent. These documents will be supplied once the manufacturer, working with the EU agent, makes the determination that the requested documents do not constitute a disclosure of priority or patent protected information and are a part of the filed and documented technical file.

Transportation and Storage

The unit must be stored and/or transported in conditions not to exceed -30 to +70ºC (-22 to +158ºF) @ 0-100% Relative Humidity Non-Condensing.

Intended Use

The MLS, Zerona™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring.

Visual Inspection

This completes the listing and the description of the parts of the Erchonia® MLS, Zerona™ device. Once you are familiar with each part and you are sure that each part is in good working order, read the next section.

Protocol -- Non-invasive Dermatological Aesthetic Protocol for the Upper Arms

1. Each patient receives six total procedures administered across a two-week time frame; three procedures per week; each one at least two days, but no more than three days, apart.
2. Each procedure administration will take a total of 40 minutes; 20 minutes per arm.
3. The procedure administration protocol for each session is as follows:
    a. The patient lies comfortably on his or her stomach on the treatment table, extending his or her right arm to rest at a 90 degree angle to his or her body flat on the treatment table, palm down.
    b. The patient is correctly fitted with the laser safety glasses.
    c. The fixed center diode of the device is positioned at a distance of 6.00 inches above the skin and directed on the patient's mid upper arm.
    d. The other four rotating diodes are positioned 120 degrees apart and tilted 30 degrees off the centerline (mid upper arm) of the center scanner.
    e. The device is activated for 20 minutes. The 5 rotating diodes emit a laser beam of approximately 17 mW with a wavelength of 635 nm red light. Each diode 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.
    f. This process is repeated for the patient's left arm.
    g. The patient removes the laser safety glasses and the session is over.

Protocol -- Non-invasive Dermatological Aesthetic Protocol for the Front of the Body

1. The patient lies comfortably flat on his or her back on the table such that the front area of the patient's body encompassing the region spanning from the patient's stomach (abdomen) down through the hips and frontal aspect of both thighs, is facing upwards.

2. The center diode of the Erchonia® MLS, Zerona™ is positioned at a distance of 6.00 inches above the patient, centered along the body's midline (the "line" that vertically "dissects" the body into two equal halves).
3. The Erchonia® MLS, Zerona™ is activated for 20 minutes. Each scanner emits to the patient a laser beam of approximately 17mW with a wavelength of 635 nm, and creates a spiraling circle pattern that is totally random and independent from the others. These patterns overlap each other to guarantee total coverage within the target area of approximately 516 square centimeters.

Protocol -- Non-invasive Dermatological Aesthetic Protocol for the Back of the Body

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

Clinical Trial Summary

A DOUBLE-BLIND, PLACEBO-CONTROLLED RANDOMIZED EVALUATION OF THE EFFECT OF THE ERCHONIA® ML SCANNER (MLS) ON BODY CONTOURING OF THE WAIST, HIPS AND THIGHS.
Erchonia Medical. Inc.

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

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

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

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

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

Table 1: Table of Subject Demographics

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

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

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

Table 2: Mean Baseline measurements

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

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

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

STUDY RESULTS

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

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

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

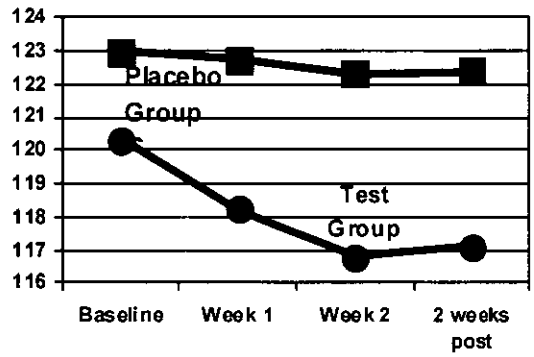
The magnitude of the mean change in total circumference measurement was a decrease of 3.521 inches for subjects who received the study procedures with the actual Erchonia® MLS and a decrease of 0.684 inches for subjects who received the study procedures with a 'fake' (placebo) laser device. A t-test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

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

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

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

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



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

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

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

Table 4: Mean individual body area circumference measurements.

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

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

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

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

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

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

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

AN EVALUATION OF THE EFFECTIVENESS OF THE ERCHONIA® ML SCANNER (MLS) AS A NON-INVASIVE DERMATOLOGICAL AESTHETIC TREATMENT FOR THE REDUCTION OF CIRCUMFERENCE OF THE UPPER ARMS
Erchonia Corporation

BACKGROUND: The purpose of this clinical study was to demonstrate the effectiveness of the Erchonia® MLS, Zerona™ for non-invasive body contouring of the upper arms by applying the MLS, Zerona™ to the upper arms 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 two (62) subjects completed this study. Of the 62 participating subjects, 31 were randomized to the active procedure group and 31 were randomized to the placebo group.

Subjects were those aged 18 to 65 years who were deemed suitable for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that had failed

to respond to diet and exercise; specifically for the indication of body contouring of the bilateral upper arms, as per the American Academy of Cosmetic Surgery's 2006 Guidelines for Liposuction Surgery developed by a joint Ad Hoc Committee of the American Society of Liposuction Surgery (ASLSS) and the American Academy of Cosmetic Surgery (AACS), and/or for the procedure of brachioplasty (upper arm lift).

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

Table 1: Table of Subject Demographics

Gender	**Female**		**Male**	
n=62	*number*	*%*	*number*	*%*
	60	97%	2	3%
Ethnicity	**Caucasian**		**Hispanic**	
n=62	*number*	*%*	*number*	*%*
	37	60%	21	34%
	African American		**Caucasian/African American**	
	number	*%*	*number*	*%*
	2	3%	2	3%

STUDY MEASURES: Circumference measurements at three points on the upper arms, and body mass index (BMI) were recorded at baseline, study mid-point (week 1), study endpoint (week 2), and study follow-up two weeks later. Subject satisfaction with the procedure outcome was recorded at study endpoint.

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

Table 2: Mean Baseline measurements

	Test Group n=31	**Placebo Group n=31**
Body Mass Index (BMI)	29.57	30.57
Right Upper Arm Circumference (cms.)	95.67	94.66
Left Upper Arm Circumference (cms.)	95.81	94.92

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

STUDY PROCEDURE: Subjects received six procedure administrations with the Erchonia® MLS, Zerona™ to the right and left upper arms, across a consecutive two-week period: three procedures per week, each procedure two to three days apart.

STUDY RESULTS

(i) **Total Circumference Measurements**: The study primary outcome measure was based on individual circumference measurements taken at 3 points along each of the subject's upper arms combined to attain a single circumference measurement for each of the right arm and the left arm, separately.

It was pre-determined that a subject would be considered a study success if he or she attained a 1.25 cm or greater reduction in combined circumference measurement for each of the right and left upper arms, separately, from baseline to study endpoint (after completion of the two-week procedure phase).

58% of subjects who received the study procedures with the actual Erchonia® MLS, Zerona™ attained a decrease in combined circumference measurement of 1.25 cms or greater for each of the right and left upper arms, separately, compared with 3% 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 55% to be statistically significant at $p<0.000005$.

The mean change in total circumference for subjects who received the study procedures with the actual Erchonia® MLS, Zerona™ was a decrease of 1.85 cms for the right upper arm, a decrease of 1.84 cms for the left upper arm and decrease of 3.70 cms for both upper arms combined. The mean change in total circumference for subjects who received the study procedures with the 'fake' (placebo) laser device was a decrease of 0.08 cms for the right upper arm, a decrease of 0.23 cms for the left upper arm and decrease of 0.31 cms for both upper arms combined.

Paired samples t-tests found the changes in upper arm circumference measurements for subjects in the test group to be statistically significant, as shown in Table 3 below. The changes in upper arm circumference measurements for subjects in the placebo group were not found to be statistically significant, as shown in Table 4 below.

Table 3: Paired samples t-tests for test group subjects

Test Group	μa-μb	t	df	p(two-tailed)	significance
Right Arm	1.855	+9.61	30	<0.0001	p<0.0001
Left Arm	1.842	+8.98	30	<0.0001	p<0.0001
Right & Left Arms	3.70	+10.65	30	<0.0001	p<0.0001

Table 4: Paired samples t-tests for placebo group subjects

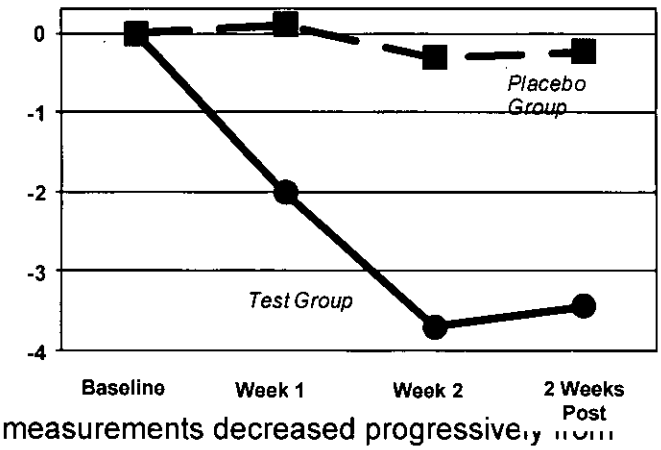
Placebo Group	μa-μb	t	df	p(two-tailed)	p	significance
Right Arm	0.0806	+0.83	30	0.413	p>0.05	Not significant
Left Arm	0.23	+1.95	30	0.061	p>0.05	Not significant
Right & Left Arms	0.31	+1.67	30	0.105	p>0.05	Not significant

Table 5 and Chart 1 below show the mean change in total upper arm circumference measurements (right and left arms combined) across the four study measurement time points.

Table 5: Mean total circumference measurements (cms) across evaluation points

	Test Group	Placebo Group
Baseline	191.48	189.58
Midpoint (week 1)	189.47	189.69
Endpoint (week 2)	187.78	189.27
Follow-up (week 4)	188.04	189.34

Chart 1: Mean change in total upper arm circumference measurements (cms) at each study evaluation point relative to baseline



For test group subjects, total circumference measurements decreased progressively from baseline across the procedure administration phase, indicating a progressive and cumulative treatment effect of the laser. However, for placebo group subjects, total circumference measurements were unchanged across the procedure administration phase relative to baseline.

Total circumference measurements stabilized for test group subjects across the subsequent 2-week follow-up assessment period during which time no laser procedures were administered, indicating duration of the treatment effect up to at least 2 weeks following the end of laser procedure administration.

(ii) Change in body mass index (BMI): BMI measurements did not change significantly across and between any of the evaluation time points for either test or placebo subject groups. However, upper arm circumference measurements did change significantly across and between evaluation points for test group subjects but not for placebo group subjects. This combined finding further supports the effectiveness of the Erchonia® MLS, Zerona™ device as it demonstrates that the change in body shape (reduction in cms for the upper arms) attained for test group subjects in this study at this test site resulted from the Erchonia® MLS, Zerona™ device applications and not from change in body mass index as a result of incidental weight loss.

(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 upper arms attained using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied.

65% of test group subjects reported being 'Satisfied' (Very or Somewhat Satisfied) with the outcome of the study procedures compared with 22% 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

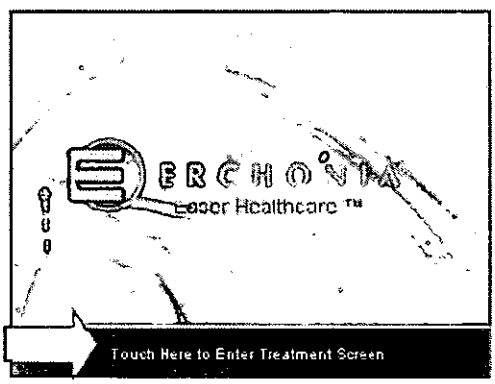
subject.

CONCLUSION: The Erchonia® MLS, Zerona™ is an effective tool for body contouring, significantly reducing circumference measurements when applied to the bilateral upper arms over a 2-week period.

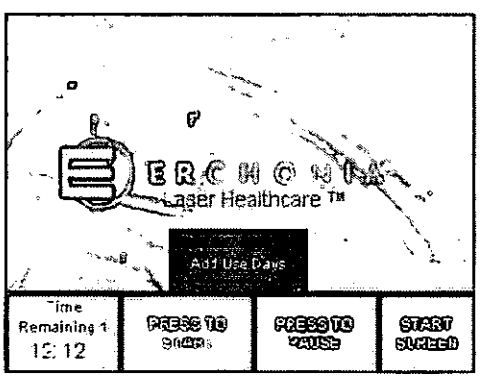
Mechanical Instructions for Use: How to Use the Device

Operating the Device

Press "Touch Here to Enter Treatment Screen" button, this will take you to the Erchonia Preset Protocol (Mode) Selection screen.

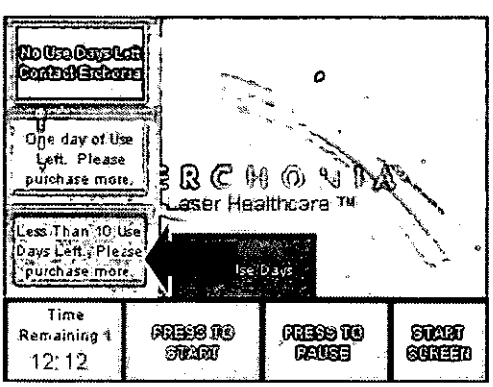


Press "PRESS TO START" button to begin the non-invasive arm reduction protocol. If for any reason you need to pause, press the "PRESS TO PAUSE" button. To restart, press the "PRESS TO RESUME" button. The "Time Remaining" display shows the elapsed time. When done return the key to the OFF position.



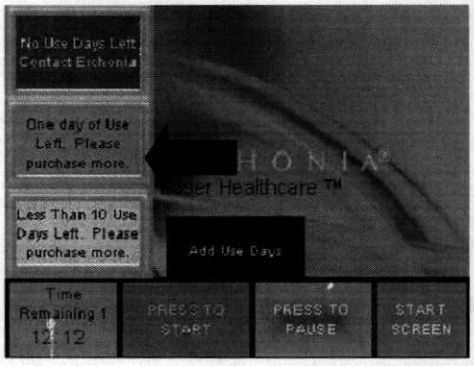
This device requires an update every 30 days from software installation. You are required to contact your distributor for an update code

NOTE: Notification will start to display on the protocol screen to inform you that you have 10 calendar days until the device will lockout any further treatments.



You must contact the distributor for a device update code and will only unlock once the code is imputed into the device.

Once the UPDATE DUE screen appears, it will remain until an update code is entered or the 10 days expire.



NOTE: Once the 10 days expire, the machine will stop operating and a notification will display on the touchscreen to advise you to CONTACT ERCHONIA FOR DEVICE UPDATE.

Warnings

1) The long-term effects of prolonged use of non-thermal laser exposure are not known.
2) The device should not be used over, or near, cancerous lesions, as conclusive tests have not been done.
3) The device should not be used when you are in the bath or shower because electrical shock may occur.
4) To avoid any possible danger to the eyes, do not shine the laser light directly into your eyes.
5) Keep the device out of the reach of children at all times.
6) Changes to the use of the laser controls or to the performance of treatments other than those specified in this manual may cause hazardous radiation exposure.

Cautions

1) Safety of non-thermal laser for use during pregnancy has not been shown.
2) Caution should be used over areas of skin that lack normal sensation (feeling).
3) The device should be used only with the parts recommended for use by the manufacturer.
4) Avoid any liquid getting into the device.
5) Avoid contact with flammable products, or with air with oxygen or nitrous oxide.
6) To ensure proper use and to mitigate the possibility of interference, avoid placing in close proximity to other electromagnetic devices.

NOTE: If due to misuse, failure to follow cautions or unforeseen circumstances the device is damaged, contact the manufacturer.

Maintenance & Cleaning

The Erchonia® MLS, Zerona™ device, if used according to the instructions in this manual will work well for years. For proper care, it is best to:

1. Do regular visual checks for signs of damage to the device other than normal wear and tear. If you are concerned about damage, please contact the manufacturer to see if action needs to be taken.

2. If you see a change in how the device works while in the ON position, please contact the manufacturer to see if action needs to be taken.

3. The inside parts of the device should not need any maintenance; however, if you think there is a problem because the device is not working well or is working differently than before, the device must be sent to the manufacturer.

4. Since the MLS, Zerona™ is placed on the floor and designed to be in conjunction with a table or chair for ease of the patient. The platform in which the patient's arm rests is to be cleaned using disinfectant wipes.

5. If during treatment any part of the device touches the skin, follow the cleaning process defined in step #4, to correct.

6. Fuses can be replaced by the end-user. The fuse holder is part of the power inlet module, see item #7, Device Description. To replace, pull open fuse drawer, remove spent fuse, insert new fuse rated at T2A 250V 100-240V~.5 – 1.5A, 50 – 60 Hz.

Disposal

The Erchonia® MLS, Zerona™ is a self-contained unit that gives out light energy and as such creates no byproducts that require control. However, as a courtesy Erchonia offers disposal services. To take advantage of the offer, when the device cannot be used properly and/or cannot be repaired, send to manufacturer for disposal.

Warranty Information

Detailed description of the Terms and Condition for warranty of the Erchonia® MLS, Zerona™ device.

Limited Warranty

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

Terms and Conditions

- Shipping for warranty repair and / or maintenance within the first 90 days will be paid for by the manufacturer.
- Shipping for warranty repair and / or maintenance after 90 days will be paid for by the consumer.
- 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 repair to damage caused by:

Accident, misuse or abuse
Lack of responsible care
Use of an unapproved power cord
Alteration to or disassembly of the device
Loss of parts
Exposure to the elements
Ingress of liquid (liquid entering the device)

Point of Contact

If for any reason, you are not satisfied with this product or have warranty concerns or questions about how to use the device, please call +1 888-242-0571 for immediate help.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

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

MAY 14 2012

Re: K120257
Trade/Device Name: Erchonia MLS, Zerona™
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Lever Laser System for Aesthetic Use
Regulatory Class: II
Product Code: OLI, GEX
Dated: May 8, 2012
Received: May 9, 2012

Dear Mr. Walls:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K120257

Device Name: Erchonia® MLS, Zerona™

Indications for Use: The Erchonia® MLS, Zerona™ is indicated for non-invasive dermatological aesthetic treatment for the reduction of the circumference of the upper arms.

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. P. Ogden for mtm

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

510(k) Number K120257

Page 1 of 1

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

May 09, 2012

ERCHONIA MEDICAL, INC.
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT
GREENWOOD VILLAGE, COLORADO 80127
ATTN: KEVIN WALLS

510k Number: K120257

Product: MLS, ZERONA-AD

The additional information you have submitted has been received.

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

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

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

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

Sincerely,

510(k) Staff

Mcdonald, Lisa *

From: Microsoft Outlook
To: 'kevin@reginsight.com'
Sent: Wednesday, May 09, 2012 1:10 PM
Subject: Relayed: K120257 AI Letter

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

'kevin@reginsight.com'

Subject: K120257 AI Letter

Sent by Microsoft Exchange Server 2007

* * * COMMUNICATION RESULT REPORT (MAY. 7. 2012 11:18AM) * * *

FAX HEADER 1:
FAX HEADER 2:

T[illegible]SMITTED/STORED : MAY. 7. 2012 11:17AM

[illegible] MODE	OPTION	ADDRESS	RESULT	PAGE
4907 MEMORY TX		17209625413	OK	2/2

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

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

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

May 07, 2012

ERCHONIA MEDICAL, INC.
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT
GREENWOOD VILLAGE, COLORADO 80127
ATTN: KEVIN WALLS

510k Number: K120257
Product: MLS, ZERONA-AD
On Hold As of 5/4/2012

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

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

May 07, 2012

ERCHONIA MEDICAL, INC.
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT
GREENWOOD VILLAGE, COLORADO 80127
ATTN: KEVIN WALLS

510k Number: K120257
Product: MLS, ZERONA-AD
On Hold As of 5/4/2012

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.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

April 26, 2012

ERCHONIA MEDICAL, INC.
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT
GREENWOOD VILLAGE, COLORADO 80127
ATTN: KEVIN WALLS

510k Number: K120257
Product: MLS, ZERONA-AD
On Hold As of 4/23/2012

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.

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

Please remember that the Safe Medical Devices Act 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
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Mcdonald, Lisa *

From: Microsoft Outlook
To: 'kevin@reginsight.com'
Sent: Thursday, April 26, 2012 9:11 AM
Subject: Relayed: K120257 Hold Letter

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

'kevin@reginsight.com'

Subject: K120257 Hold Letter

Sent by Microsoft Exchange Server 2007

51

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

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

March 20, 2012

ERCHONIA MEDICAL, INC.
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT
GREENWOOD VILLAGE, COLORADO 80127
ATTN: KEVIN WALLS

510k Number: K120257
Product: MLS, ZERONA-AD
On Hold As of 3/19/2012

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.

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

Sincerely yours,

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

Grayson, Giovanna *

From: Microsoft Outlook
To: 'kevin@reginsight.com'
Sent: Tuesday, March 20, 2012 11:20 AM
Subject: Relayed: Hold Letter

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

'kevin@reginsight.com'

Subject: Hold Letter

Sent by Microsoft Exchange Server 2007

99

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Tuesday, March 20, 2012 11:20 AM
To: 'kevin@reginsight.com'
Subject: Hold Letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

March 20, 2012
WALLS
KEVIN
ERCHONIA MEDICAL, INC.
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT
GREENWOOD VILLAGE, COLORADO 80127
ATTN: KEVIN WALLS

510k Number: K120257

Product: MLS, ZERONA-AD

On Hold As of 3/19/2012

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

Please remember that the Safe Medical Devices Act 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
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Nichols, Karl *

From: Microsoft Outlook
To: 'Kevin Walls'
Sent: Friday, January 27, 2012 3:45 PM
Subject: Relayed: K120257- Acknowledgement Letter

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

'Kevin Walls'

Subject: K120257- Acknowledgement Letter

Sent by Microsoft Exchange Server 2007

166

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

January 27, 2012

ERCHONIA MEDICAL, INC.
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT
GREENWOOD VILLAGE, COLORADO 80127
ATTN: KEVIN WALLS

510k Number: K120257
Received: 1/27/2012
Product: MLS, ZERONA-AD

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

K120257
SU/DSURD

Regulatory Insight, Inc.

Worldwide Medical Device Submissions and Quality Systems

January 24, 2012

FDA CDRH DMC
JAN 27 2012
Received

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

RE: 510(k) Notification for the Erchonia® MLS, Zerona-AD™

Dear Sir or Madam:

Please find enclosed a 510(k) premarket notification for the Erchonia® MLS, Zerona-AD™ manufactured by Erchonia Medical Inc. The Erchonia® MLS, Zerona-AD™ is indicated for a non-invasive dermatological aesthetic treatment for the reduction of circumference of the arm.

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

Sincerely,

Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)
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
5401 S. Cottonwood Ct.
Greenwood Village CO 80121
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

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

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

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b) (4)
20-Jan-2012

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

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

January 24, 2012

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

RE: 510(k) Notification for the Erchonia® MLS, Zerona-AD™

Dear Sir or Madam:

Please find enclosed a 510(k) premarket notification for the Erchonia® MLS, Zerona-AD™ manufactured by Erchonia Medical Inc. The Erchonia® MLS, Zerona-AD™ is indicated for a non-invasive dermatological aesthetic treatment for the reduction of circumference of the arm.

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

Sincerely,

Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.

5401 S. Cottonwood Court • Greenwood Village, Colorado 80121 • U.S.A.
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Erchonia® MLS, Zerona-AD™ 510(k)
Table of Contents

Name and Address of Sponsor

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McKinney, TX 75069
Phone: 214-544-2227
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Name and Address of Manufacturer

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Establishment Registration Number

2032513

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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® MLS, Zerona-AD™
Common Name: Fat reducing low level laser
Classification Name: Low level laser system for aesthetic use

Classification, Panel and Product Code

Class II, General & Plastic Surgery, OLI

Previous Submission

This same device was submitted and subsequently cleared under 510(k) #K082609 for the indications for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs.

Indications for Use

The Erchonia® MLS, Zerona-AD™ is indicated for a non-invasive dermatological aesthetic treatment for the reduction of circumference of the arm.

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

Device Description

The Erchonia® MLS, Zerona-AD™ (Figure 1.) is for a non-invasive dermatological aesthetic treatment for the reduction of circumference of the arm.

The Erchonia® MLS, Zerona-AD™ is a mains powered device, the specifications of which are:

- Height – Retracted 24", Extended 39"
- Width – Retracted 13", Extended 39"
- Depth – Retracted 20", Extended 40"
- Weight – Wall Unit 20 lbs., Head Unit 6.1 lbs.

The Erchonia® MLS, Zerona-AD™ device is made up of five independent diodes, 635 nanometer variable frequency device. The variable frequency feature of the MLS, Zerona-AD™ is a pulsed wave, defined as containing a selected series of breaks, variances that are preprogrammed.

The Erchonia® MLS, Zerona-AD™ 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, approximately 516 square centimeters.

The Erchonia® MLS, Zerona-AD™ contains 5 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 diode is positioned at the centerline. Each scanner emits 17mW, 635 nm of red laser light.

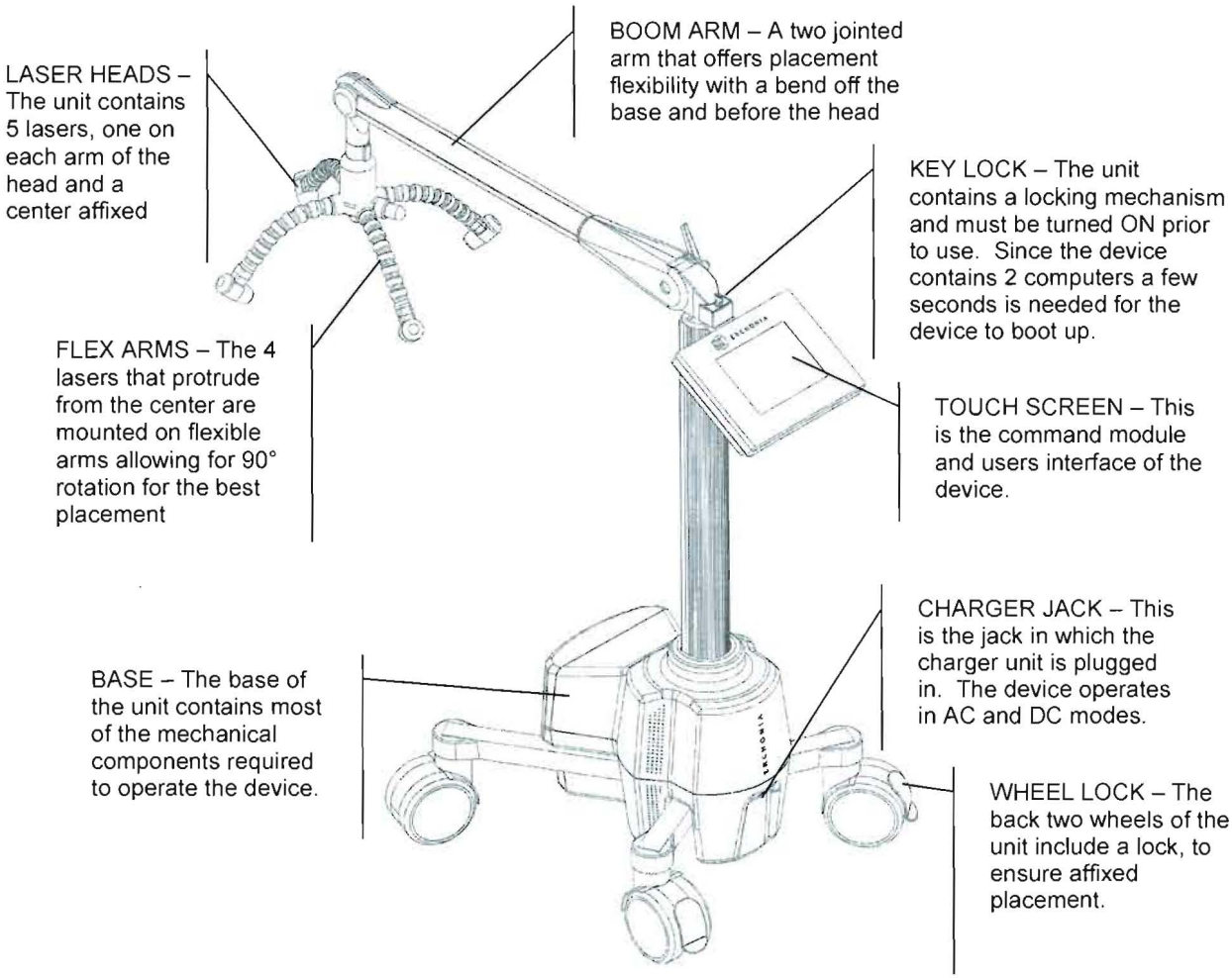


Figure 1.

The Erchonia® MLS, Zerona-AD™ is a Class II laser device and as such protective eyewear is provided for both the clinician and the patient (Figure 2). The eyewear is specialty glasses that are medium grade blue Laser LineGuard, which blocks a good portion of the laser light. These protective glasses are 6" long, 2" wide (arms folded), 5.5" (earpieces extended), 2.5 high, weighing 2 ounces.

Figure 2.

Labeling

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

Performance Standards

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

Substantial Equivalence

Comparison of the New and Predicate Devices

Device	Erchonia® MLS, Zerona-AD™	Erchonia MLS Laser
510(k)	N/A	K082609
Indications for Use	The Erchonia® MLS, Zerona-AD™ is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of the arm.	The Erchonia® ML Scanner (MLS) is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs
Power	1 mw	1 mw
Wavelength	Red 630 nm – 640 nm (near infrared)	Red 630 nm – 640 nm (near infrared)
Waveform	Pulsed	Pulsed
Energy Source	Five diodes, each collected then line dispersed and rotated	Five diodes, each collected then line dispersed and rotated
Power Supply	AC	AC
Energy Delivery	Machine mounted probe	Machine mounted probe
Treatment Time	0 – 9.9 minutes	0 – 9.9 minutes
Target Size	Line pattern, mechanically rotated to form circles and scanned over treatment area.	Line pattern, mechanically rotated to form circles and scanned over treatment area.
Target Population	Individuals intending to undergo liposuction procedure.	Individuals intending to undergo liposuction procedure.
Locations for Use	Hospital, health care provider office.	Hospital, health care provider office.

Clinical Study Results

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 is 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, along with the applicable Forms FDA 3654.

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.

1-10-2012
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.

1-10-2012

Steven Shanks
President
Erchonia Medical, Inc.

Date

Indications for Use

510(k) Number (if known): _____

Device Name: Erchonia® MLS, Zerona-AD™

Indications for Use: The Erchonia® MLS, Zerona-AD™ is indicated for a non-invasive dermatological aesthetic treatment for the reduction of circumference of the arm.

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)

Acknowledgements & Accreditations

We at Erchonia ® Corporation would like to thank you for purchasing the Erchonia® Zerona-AD™ device.

Erchonia ® Corporation is an ISO certified company and is audited from time to time by outside governing agencies, including the FDA, to be sure to stay in compliance with the highest quality standards. Our company operates according to and our devices are manufactured according with:

- FDA Good Manufacturing Practices
- ISO 9001 :2000 - Quality
- ISO 13485:2003 – Medical
- ISO 60825-1 - Laser Safety
- FDA Laser Class 2
- FDA Device Class II
- IEC Laser Class 2
- IEC Device Class 1
- MDD 93/42/EEC
- EN/IEC 60601-1-2 EMC
- EN/IEC EN60601-1-1 Safety
- Model Number: ARC
- Software Version ARM-E Rev A (1-9-12)
  - **ARM-E-TS Rev A**
  - **ARM-E-PLC Rev A**

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

Doc. No.	Issue Date	CR #	Revision	Rev Date
MLS-O&M Zerona-AD	1/11/2012	510(k) Release	0	1/11/2012

Legend:
The following symbols are used throughout this manual to show areas of concern. For your safety, and for the care of the device, please read and take note of these warnings and cautions.

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

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

Refers to the part of the medical device which comes into physical contact with the patient in order for the device to carry out its intended function.

US National Consideration:
When using in the US, the equipment is intended to be powered by a 120V source. If powered by a 240V source in the US, then the power source must be a center-tapped, 240V single phase circuit.

Erchonia® Corporation
2021 Commerce Dr. McKinney, TX 75069
Phone +1 888-242-0571 • Fax +1 214.544.2228
www.Erchonia.com
Patent(s): US – 6,013,096, Patent Pending

CAUTION: FEDERAL LAW RESTRICTS THE USE OF THIS DEVICE BY ORDER OF PHYSICIAN

Zerona-AD Components

The Zerona-AD (Zerona™) model has been shipped to you with some assembly required. This section is included to familiarize you with the components of the unit ensuring the remainder of this manual is clearly communicated.

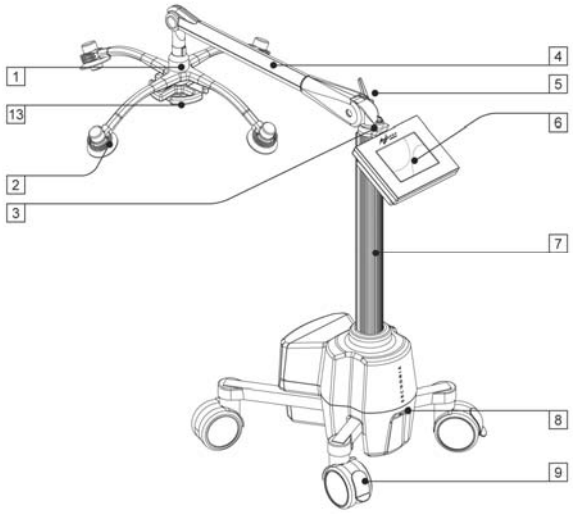


Fig. 1

1. Laser Head Assembly
2. Laser Output Head
3. Power Safety Lockout Key
4. Laser Arm
5. Arm Lock
6. Touch screen Control Surface
7. Main Upright of Base
8. Power Inlet
9. Rear Wheel Lock
10. Electrical Connector – (Page 4)
11. Locking Nut – (Page 4)
12. Power Cord – not shown
13. Handle

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].

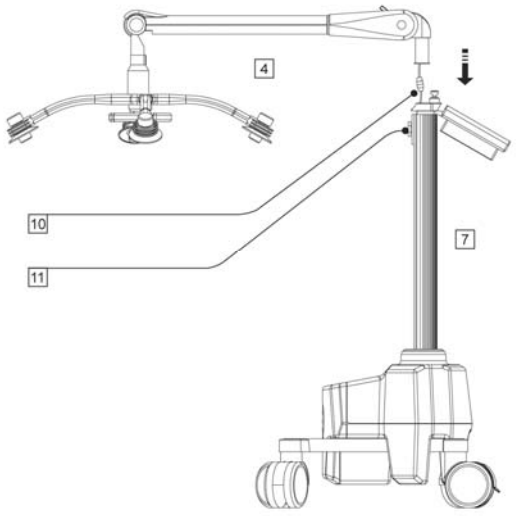
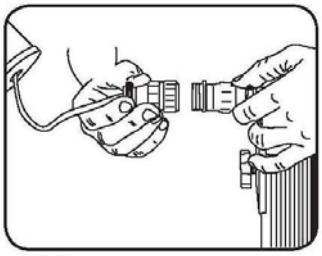
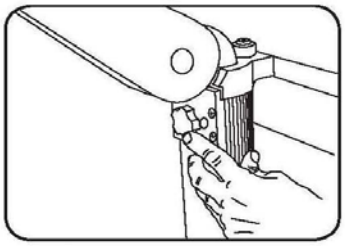
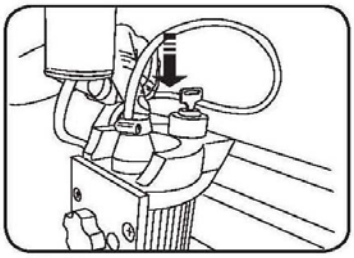
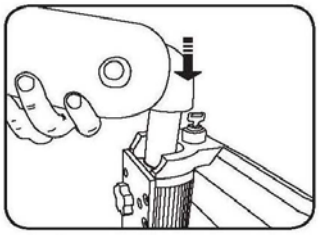
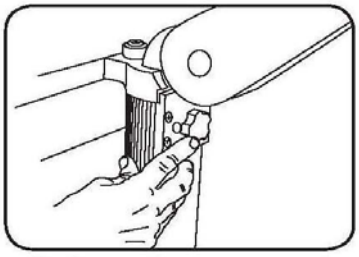


Fig. 2

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.** **This is important so the two halves do not separate over time.**	 Fig. 3
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 treaded 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.

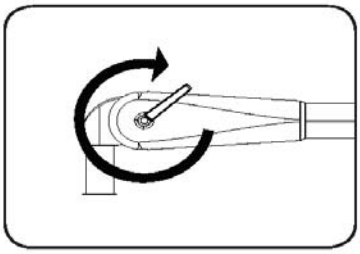


Fig. 8

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.

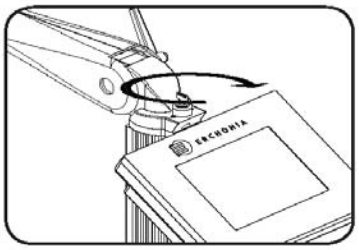


Fig. 9

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.
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.

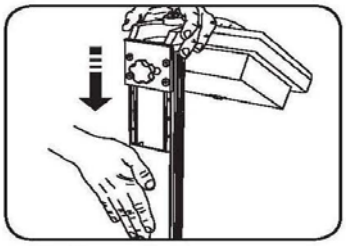


Fig. 10

When moving the head assembly into the desired position, make sure to use the handle on the side of the head assembly (fig 1, #13) to avoid the possibility of pinching.

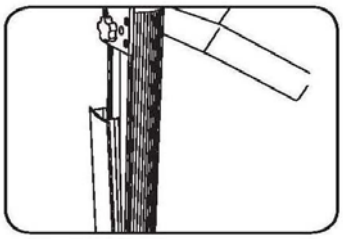


Fig. 11

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

Introduction to Contents

The Erchonia® laser package is comprised of (1) Zerona-AD, (1) pair of patient protective eyewear, (1) Power Cord, (2) Keys, and this user guide. The components of this package are detailed below.

Erchonia® MLS, Zerona-AD™

The Erchonia® Zerona-AD is made up of five independent 635 nanometer diodes. Laser devices are typically constructed to emit a "spot" of light. The Erchonia® laser utilizes internal mechanics that collects the light emitted from the diode and processes through a proprietary patented lens which redirects the beam with a line refractor. The lines generated by each head are rotated via a patented rotation device that operates independent of each other to ensure thorough coverage. The target area is approximately 8" x 10" inches or 80 square inches, approximately 516 square centimeters.

Power

The power switch is the key switch on top of the Touch screen, ref Item 3, FIG 1. The unit will not operate unless key is in the ON position. Turning the key to the OFF position satisfies the FDA requirement for mechanical lock out, ensuring the safety of non-authorized users. The power switch has a fail-safe system which ensures the 110/240 voltage from a wall socket can never come in contact with the user. The system uses a 2 amp fuse, which will only require replacement if there is an issue. To replace, locate fuse holder in back of base unit, pull fuse holder out of enclosure, replace fuses and reinsert. Use only rated T2A 250V. The device includes a transformer which converts AC power to match the power output i.e. 110V or 240V. Only a plug prong adaptor is required (available at any retail electronics store). Once the adaptor is affixed to the plug end, put into wall socket. Input: 100-240V-0.5-1.5A 50-60 Hz.

NOTE: Make sure the power cord is plugged into device 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. Fuses to be rated a T2A 250V with an input to cover 100 – 240V~ 1.5-.5A, 50-60 Hz.

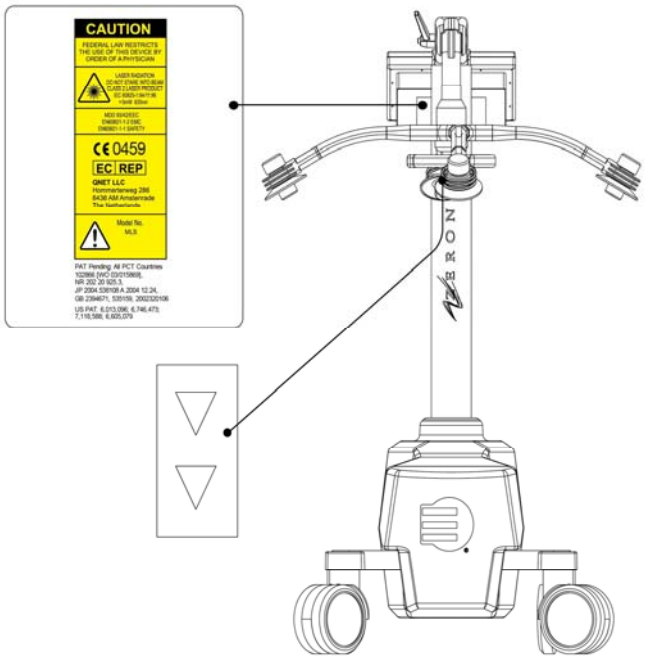
Protective Eyewear

The Erchonia® Zerona-AD is classified as a Class 2 laser. This designation represents a current standard for use in order to ensure the safety of the patient.

The ZERONA-AD device is classified as a Class 2 Laser. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 device is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging. To ensure there is no possible instance of residual effect, we have included a pair of specialty patient glasses for use by the patient during treatment

Labeling

The 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 2 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.



Manufacturer and Distributor Information

Manufacturer's Information

Erchonia Corporation
2021 Commerce Dr.
McKinney, TX. USA 75069
+1.214.544.2227

Distributor Information

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+1.214.544.2227

The Erchonia® ZERONA-AD Device

The Erchonia® ZERONA-AD™ device is a self-contained device created for use of the reduction of circumference of the upper arms. It is easy to use, compact, all in one, mains powered unit.

The Erchonia® ZERONA-AD™ device has been classified by the FDA as a Class 2 Laser product and a Class 2 in accordance to IEC 60825-1 (EU). These are the current standards for use that ensures the safety of the user.

Technical Information

Technical documentation required by international end-users, in case of necessary reparations, will be provided by our EU agent. These documents will be supplied once the manufacturer, working with the EU agent, makes the determination that the requested documents do not constitute a disclosure of priority or patent protected information and are a part of the filed and documented technical file.

Transportation and Storage

The unit must be stored and/or transported in conditions not to exceed -30 to +70ºC (-22 to +158ºF) @ 0-100% Relative Humidity Non-Condensing.

Intended Use

The ZERONA-AD™ is indicated for a non-invasive dermatological aesthetic treatment for the reduction of circumference of the arm.

Visual Inspection

This completes the listing and the description of the parts of the Erchonia® ZERONA-AD™ device. Once you are familiar with each part and you are sure that each part is in good working order, read the next section.

Protocol -- Non-invasive Dermatological Aesthetic Protocol for the Reduction of Circumference of the Upper Arms

1. Each patient receives six total procedures administered across a two-week time frame; three procedures per week; each one at least two days, but no more than three days, apart.
2. Each procedure administration will take a total of 40 minutes; 20 minutes per arm.
3. The procedure administration protocol for each session is as follows:
    a. The patient lies comfortably on his or her stomach on the treatment table, extending his or her right arm to rest at a 90 degree angle to his or her body flat on the treatment table, palm down.
    b. The patient is correctly fitted with the laser safety glasses.
    c. The fixed center diode of the device is positioned at a distance of 6.00 inches above the skin and directed on the patient's mid upper arm.
    d. The other four rotating diodes are positioned 120 degrees apart and tilted 30 degrees off the centerline (mid upper arm) of the center scanner.
    e. The device is activated for 20 minutes. The 5 rotating diodes emit a laser beam of approximately 17 mW with a wavelength of 635 nm red light. Each diode 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.
    f. This process is repeated for the patient's left arm.
    g. The patient removes the laser safety glasses and the session is over.

Clinical Trial Summary

AN EVALUATION OF THE EFFECTIVENESS OF THE ERCHONIA® ML SCANNER (MLS) AS A NON-INVASIVE DERMATOLOGICAL AESTHETIC TREATMENT FOR THE REDUCTION OF CIRCUMFERENCE OF THE UPPER ARMS
Erchonia Corporation

BACKGROUND: The purpose of this clinical study was to demonstrate the effectiveness of the Erchonia® ML Scanner (MLS) for non-invasive body contouring of the upper arms by

applying the MLS to the upper arms 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 two (62) subjects completed this study. Of the 62 participating subjects, 31 were randomized to the active procedure group and 31 were randomized to the placebo group.

Subjects were those aged 18 to 65 years who were deemed suitable for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that had failed to respond to diet and exercise; specifically for the indication of body contouring of the bilateral upper arms, as per the American Academy of Cosmetic Surgery's 2006 Guidelines for Liposuction Surgery developed by a joint Ad Hoc Committee of the American Society of Liposuction Surgery (ASLSS) and the American Academy of Cosmetic Surgery (AACS), and/or for the procedure of brachioplasty (upper arm lift).

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

Table 1: Table of Subject Demographics

Gender	**Female**		**Male**	
n=62	*number*	*%*	*number*	*%*
	60	97%	2	3%
Ethnicity	**Caucasian**		**Hispanic**	
n=62	*number*	*%*	*number*	*%*
	37	60%	21	34%
	African American		**Caucasian/African American**	
	number	*%*	*number*	*%*
	2	3%	2	3%

STUDY MEASURES: Circumference measurements at three points on the upper arms, and body mass index (BMI) were recorded at baseline, study mid-point (week 1), study endpoint (week 2), and study follow-up two weeks later. Subject satisfaction with the procedure outcome was recorded at study endpoint.

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

Table 2: Mean Baseline measurements

	Test Group n=31	**Placebo Group n=31**
Body Mass Index (BMI)	29.57	30.57
Right Upper Arm Circumference (cms.)	95.67	94.66
Left Upper Arm Circumference (cms.)	95.81	94.92

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

STUDY PROCEDURE: Subjects received six procedure administrations with the Erchonia® MLS to the right and left upper arms, across a consecutive two-week period: three procedures per week, each procedure two to three days apart.

STUDY RESULTS

(i) Total Circumference Measurements: The study primary outcome measure was based on individual circumference measurements taken at 3 points along each of the subject's upper arms combined to attain a single circumference measurement for each of the right arm and the left arm, separately.

It was pre-determined that a subject would be considered a study success if he or she attained a 1.25 cm or greater reduction in combined circumference measurement for each of the right and left upper arms, separately, from baseline to study endpoint (after completion of the two-week procedure phase).

58% of subjects who received the study procedures with the actual Erchonia® MLS attained a decrease in combined circumference measurement of 1.25 cms or greater for each of the right and left upper arms, separately, compared with 3% 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 55% to be statistically significant at $p<0.000005$.

The mean change in total circumference for subjects who received the study procedures with the actual Erchonia® MLS was a decrease of 1.85 cms for the right upper arm, a decrease of 1.84 cms for the left upper arm and decrease of 3.70 cms for both upper arms combined. The mean change in total circumference for subjects who received the study procedures with the 'fake' (placebo) laser device was a decrease of 0.08 cms for the right upper arm, a decrease of 0.23 cms for the left upper arm and decrease of 0.31 cms for both upper arms combined.

Paired samples t-tests found the changes in upper arm circumference measurements for subjects in the test group to be statistically significant, as shown in Table 3 below. The changes in upper arm circumference measurements for subjects in the placebo group were not found to be statistically significant, as shown in Table 4 below.

Table 3: Paired samples t-tests for test group subjects

Test Group	μa-μb	t	df	p(two-tailed)	significance
Right Arm	1.855	+9.61	30	<0.0001	p<0.0001
Left Arm	1.842	+8.98	30	<0.0001	p<0.0001
Right & Left Arms	3.70	+10.65	30	<0.0001	p<0.0001

Table 4: Paired samples t-tests for placebo group subjects

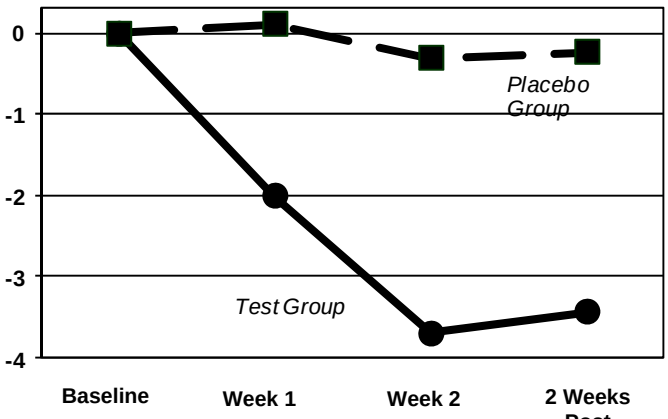
Placebo Group	μa-μb	t	df	p(two-tailed)	p	significance
Right Arm	0.0806	+0.83	30	0.413	p>0.05	Not significant
Left Arm	0.23	+1.95	30	0.061	p>0.05	Not significant
Right & Left Arms	0.31	+1.67	30	0.105	p>0.05	Not significant

Table 5 and Chart 1 below show the mean change in total upper arm circumference measurements (right and left arms combined) across the four study measurement time points.

Table 5: Mean total circumference measurements (cms) across evaluation points

	Test Group	Placebo Group
Baseline	191.48	189.58
Midpoint (week 1)	189.47	189.69
Endpoint (week 2)	187.78	189.27
Follow-up (week 4)	188.04	189.34

Chart 1: Mean change in total upper arm circumference measurements (cms) at each study evaluation point relative to baseline



For test group subjects, total circumference measurements decreased progressively from baseline across the procedure administration phase, indicating a progressive and cumulative treatment effect of the laser. However, for placebo group subjects, total circumference measurements were unchanged across the procedure administration phase relative to baseline.

Total circumference measurements stabilized for test group subjects across the subsequent 2-week follow-up assessment period during which time no laser procedures were administered, indicating duration of the treatment effect up to at least 2 weeks following the end of laser procedure administration.

(ii) Change in body mass index (BMI): BMI measurements did not change significantly across and between any of the evaluation time points for either test or placebo subject groups. However, upper arm circumference measurements did change significantly across and between evaluation points for test group subjects but not for placebo group subjects. This combined finding further supports the effectiveness of the Erchonia® MLS device as it demonstrates that the change in body shape (reduction in cms for the upper arms) attained for test group subjects in this study at this test site resulted from the Erchonia® MLS device applications and not from change in body mass index as a result of incidental weight loss.

(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 upper arms attained using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied.

65% of test group subjects reported being 'Satisfied' (Very or Somewhat Satisfied) with the outcome of the study procedures compared with 22% 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® MLS is an effective tool for body contouring, significantly reducing circumference measurements when applied to the bilateral upper arms over a 2-week period.

Mechanical Instructions for Use: How to Use the Device

Operating the Device

Press "Touch Here to Enter Treatment Screen" button, this will take you to the Erchonia Preset Protocol (Mode) Selection screen.

Press "PRESS TO START" button to begin the non-invasive arm reduction 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.

This device requires an update every 30 days from software installation. You are required to contact your distributor for an update code

NOTE: Notification will start to display on the protocol screen to inform you that you have 10 calendar days until the device will lockout any further treatments.

You must contact the distributor for a device update code and will only unlock once the code is imputed into the device.

Once the UPDATE DUE screen appears, it will remain until an update code is entered or the 10 days expire.

NOTE: Once the 10 days expire, the machine will stop operating and a notification will display on the touchscreen to advise you to CONTACT ERCHONIA FOR DEVICE UPDATE.

Warnings

1) The long-term effects of prolonged use of non-thermal laser exposure are not known.
2) The device should not be used over, or near, cancerous lesions, as conclusive tests have not been done.
3) The device should not be used when you are in the bath or shower because electrical shock may occur.
4) To avoid any possible danger to the eyes, do not shine the laser light directly into your eyes.
5) Keep the device out of the reach of children at all times.
6) Changes to the use of the laser controls or to the performance of treatments other than those specified in this manual may cause hazardous radiation exposure.

Cautions

1) Safety of non-thermal laser for use during pregnancy has not been shown.
2) Caution should be used over areas of skin that lack normal sensation (feeling).

3) The device should be used only with the parts recommended for use by the manufacturer.
4) Avoid any liquid getting into the device.
5) Avoid contact with flammable products, or with air with oxygen or nitrous oxide.
6) To ensure proper use and to mitigate the possibility of interference, avoid placing in close proximity to other electromagnetic devices.

NOTE: If due to misuse, failure to follow cautions or unforeseen circumstances the device is damaged, contact the manufacturer.

Maintenance & Cleaning

The Erchonia® ZERONA-AD™ device, if used according to the instructions in this manual will work well for years. For proper care, it is best to:

1. Do regular visual checks for signs of damage to the device other than normal wear and tear. If you are concerned about damage, please contact the manufacturer to see if action needs to be taken.

2. If you see a change in how the device works while in the ON position, please contact the manufacturer to see if action needs to be taken.

3. The inside parts of the device should not need any maintenance; however, if you think there is a problem because the device is not working well or is working differently than before, the device must be sent to the manufacturer.

4. Since the ZERONA-AD™ is placed on the floor and designed to be in conjunction with a table or chair for ease of the patient. The platform in which the patient's arm rests is to be cleaned using disinfectant wipes.

5. If during treatment any part of the device touches the skin, follow the cleaning process defined in step #4, to correct.

6. Fuses can be replaced by the end-user. The fuse holder is part of the power inlet module, see item #7, Device Description. To replace, pull open fuse drawer, remove spent fuse, insert new fuse rated at T2A 250V 100-240V~.5 – 1.5A, 50 – 60 Hz.

Disposal

The Erchonia® ZERONA-AD™ is a self-contained unit that gives out light energy and as such creates no byproducts that require control. However, as a courtesy Erchonia offers disposal services. To take advantage of the offer, when the device cannot be used properly and/or cannot be repaired, send to manufacturer for disposal.

Warranty Information

Detailed description of the Terms and Condition for warranty of the Erchonia® ZERONA-AD™ device.

Limited Warranty

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

Terms and Conditions

- Shipping for warranty repair and / or maintenance within the first 90 days will be paid for by the manufacturer.
- Shipping for warranty repair and / or maintenance after 90 days will be paid for by the consumer.
- 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 repair to damage caused by:

Accident, misuse or abuse
Lack of responsible care
Use of an unapproved power cord
Alteration to or disassembly of the device
Loss of parts
Exposure to the elements
Ingress of liquid (liquid entering the device)

Point of Contact

If for any reason, you are not satisfied with this product or have warranty concerns or questions about how to use the device, please call +1 888-242-0571 for immediate help.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616. Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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
Jan 23, 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)

Erchonia® ML Scanner (MLS)

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): NCT01376037

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)*
5401 S. Cottonwood Ct.
Greenwood Village, CO 80121

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 720-962-5412
(Fax) 720-962-5413

15. DATE OF CERTIFICATION
Jan 23, 2012

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

ERCHONIA® ML Scanner (MLS)

An evaluation of the effectiveness of the Erchonia® ML Scanner (MLS) as a non-invasive dermatological aesthetic treatment for the reduction of circumference of the upper arms clinical study protocol

ERCHONIA CORPORATION

Version 1.1
January 4, 2011

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ERCHONIA® ML Scanner (MLS)

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Version 1.1; January 4, 2011

Clinical Study Results Report

ERCHONIA CORPORATION

January 18, 2011

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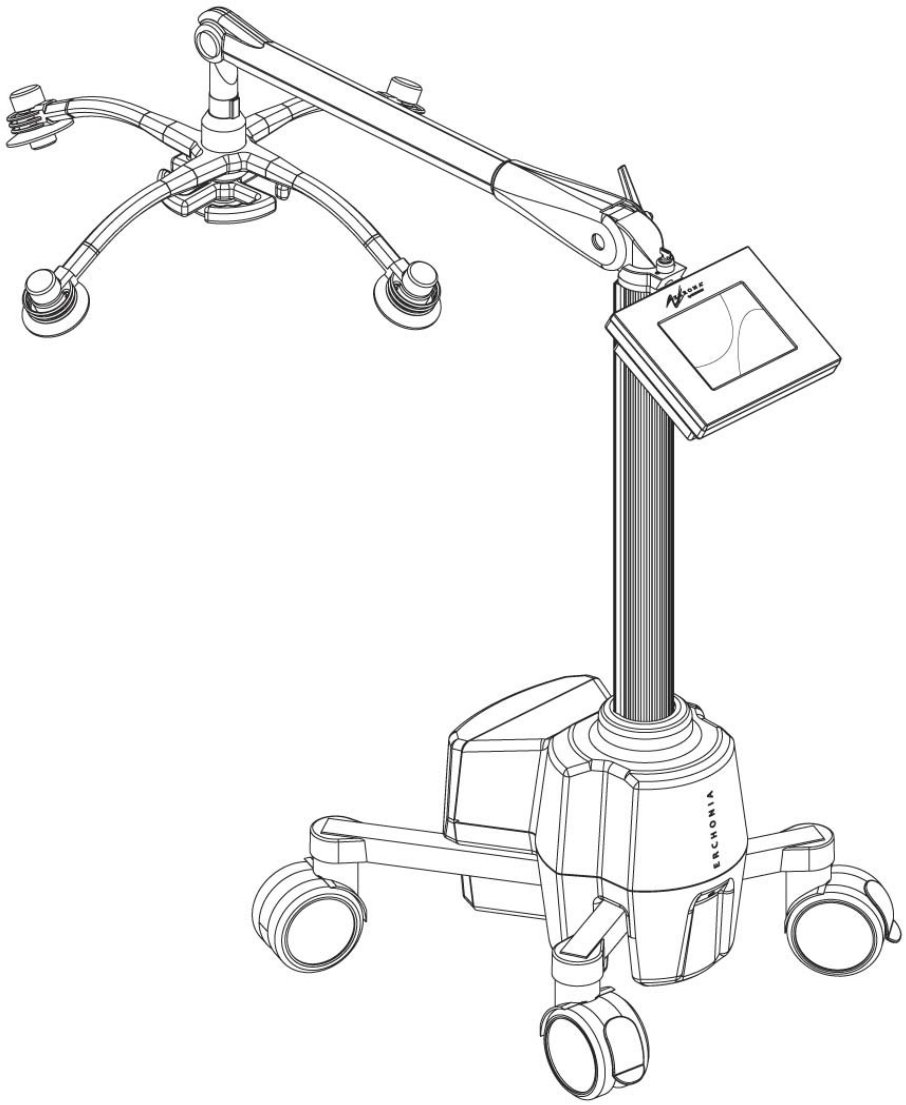
ZERONA™
By ERCHONIA®



ZERONA™ LASER SCANNER

Operation & Maintenance Manual

Acknowledgements and Accreditations

We at Erchonia® Medical would like to thank you for purchasing the Erchonia® laser unit.

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

- FDA Good Manufacturing Practices
- ISO 9001 :2000 - Quality
- ISO 13485:2003 – Medical
- ISO 60825-1 - Laser Safety
- FDA Laser Class IIIb
- IEC Laser Class 2
- MDD 93/42/EEC
- EN/IEC 60601-1-2 EMC
- EN/IEC EN60601-1-1 Safety
- CE Mark
- CB Certified
- Model Number: MLS, MLS-AC

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-MLS-E*	7/12/07	**57.08.MLS**	2	4/28/09
O&M-MLS-E*	7/12/07	**95/09 ADM**	3	10/27/09
O&M-MLS-E*	7/12/07		4	12/16/09

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

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

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

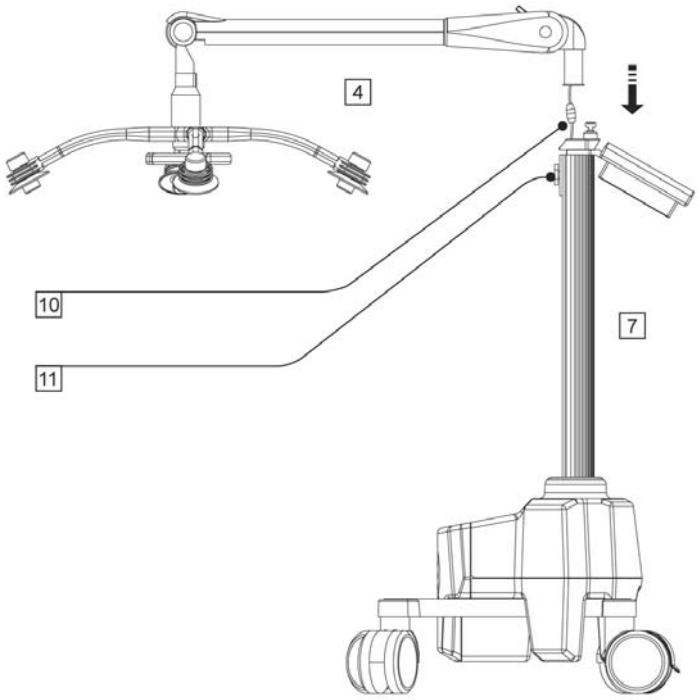
Erchonia® Medical
2021 Commerce Drive McKinney, TX 75069
Phone 214.544.2227 • Fax 214.544.2228
www.erchonia.com

*Erchonia Version

Table of Contents

ML Scanner Components

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

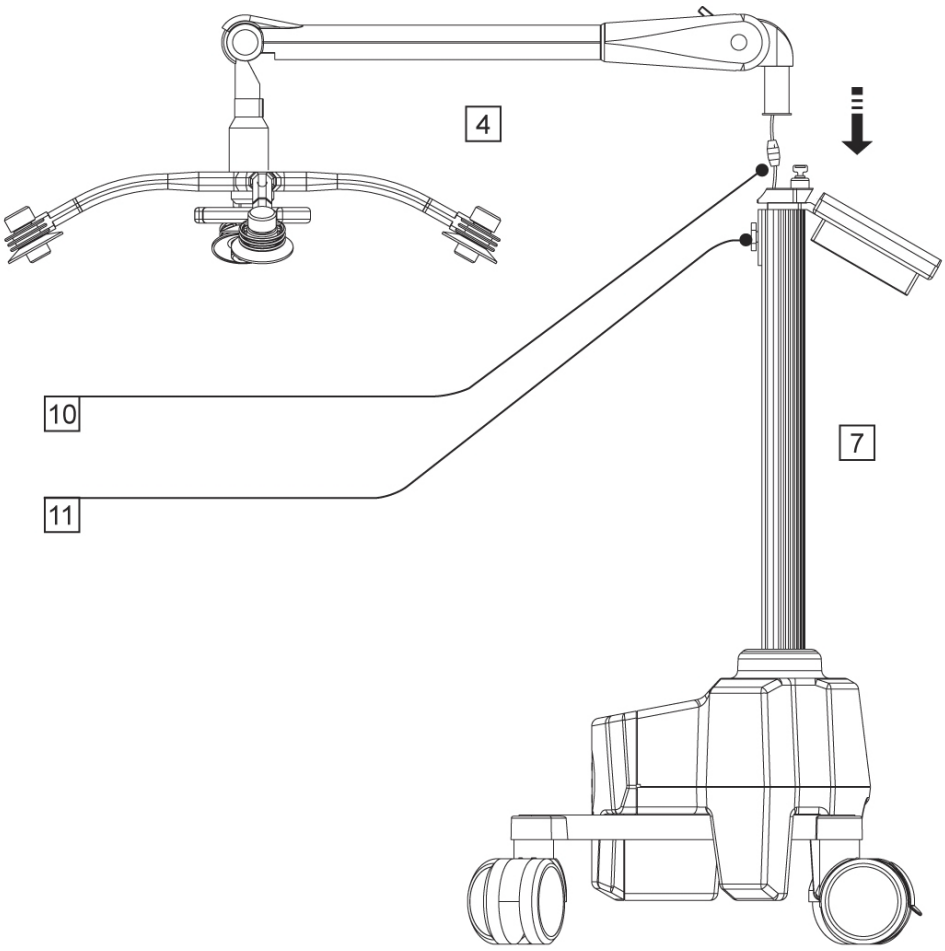


1. Laser Head Assembly
2. Laser Output Head
3. Power Safety Lockout Key
4. Laser Arm
5. Arm Lock
6. Touchscreen Control Surface
7. Main Upright of Base
8. Power Inlet
9. Rear Wheel Lock
10. Power Cord – not shown
11. Locking Nut – not shown
12. Electrical Connector
13. Handle

Assembly Instructions

This is a pictorial look at the simple 1 piece assembly of the scanner. The scanner only has one piece to assemble. This assembly is best done with 2 people.

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



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

Simply insert the 2 halves of the electrical connection [21] (fig 3) together slightly pushing the outlet into the inlet. Twist until secure. (The connector can only be connected one way)

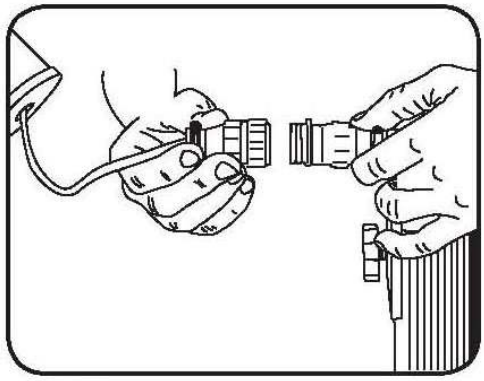


Fig. 3

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

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

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

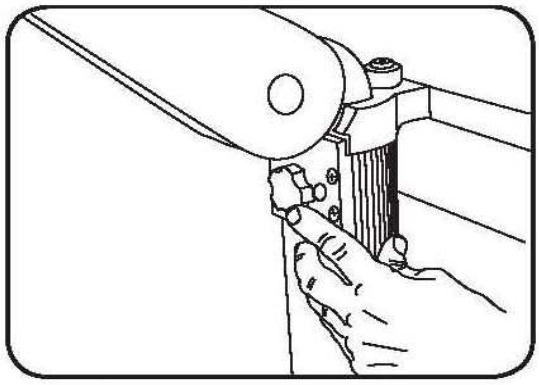


Fig. 4

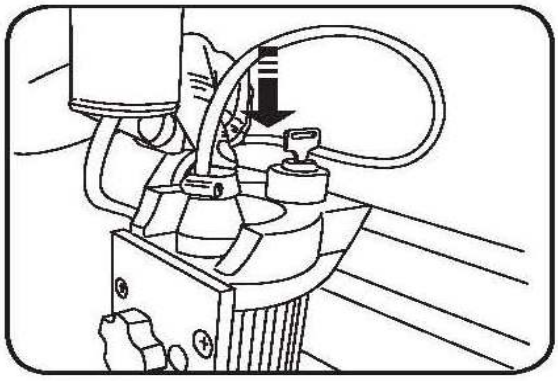


Fig. 5

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

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

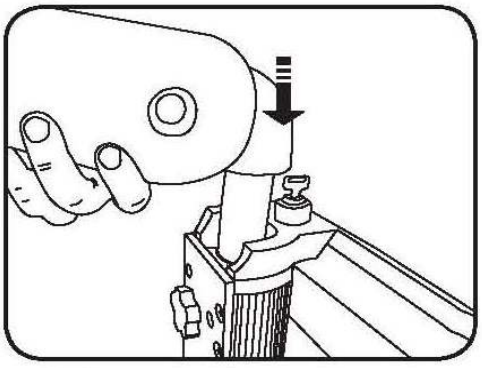


Fig. 6

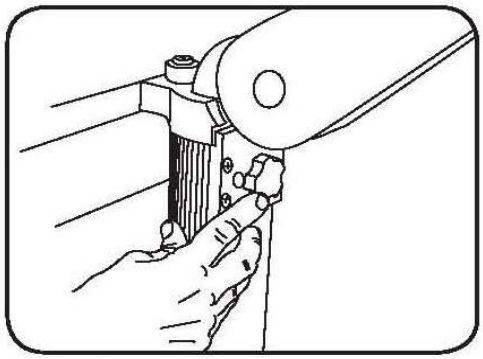


Fig. 7

Additional Information

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

To activate your 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 warm up before use.

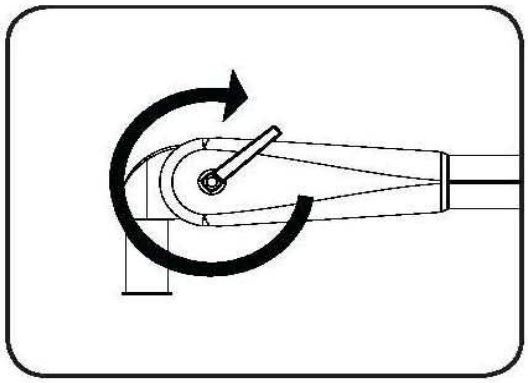


Fig. 8

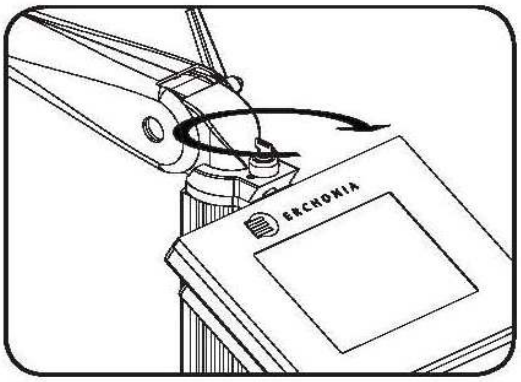


Fig. 9

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

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

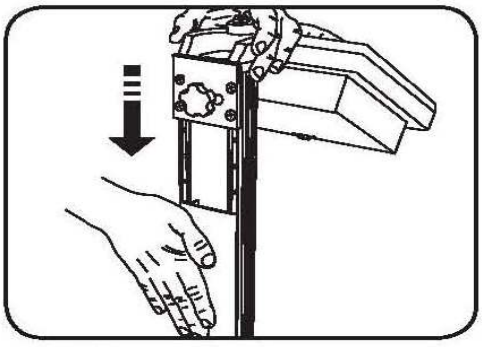


Fig. 10

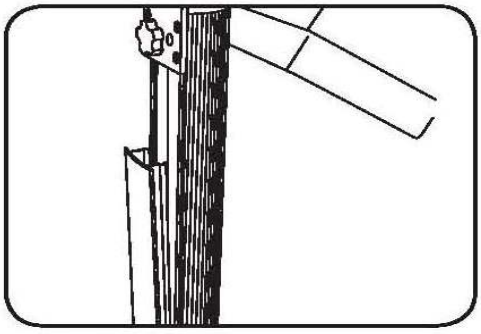


Fig. 11

Introduction to Contents

The Erchonia® laser package is comprised of (1) ML Scanner, (1) pair of patient protective eyewear, (1) Power Cord, this user guide and a warranty card. The components of this package are detailed below.

Erchonia® Laser - ML Scanner

The Erchonia® ML Scanner is made up of five independent 635 nanometer diodes each with variable frequency that can be set by the end-user, via the touch screen. The variable frequency feature of the MLS is a pulsed wave, defined as containing a selected series of breaks, variances that are pre-programmed. Clinical studies have shown that pulse wave is the most effective method of laser use.

Laser devices are typically constructed to emit a "spot" of light. The Erchonia® laser utilizes internal mechanics that collects the light emitted from the diode and processes through a proprietary patented lens which redirects the beam with a line refractor. The lines generated by each head are rotated via a patented rotation device that operates independent of each other to ensure thorough coverage. The target area is approximately 8" x 10" inches or 80 square inches, approximately 516 square centimeters, per head. The optimum operating environment is 0% - 80% humidity.

Power

The power switch is the key switch on top of the Touch screen, ref Item 3, FIG 1. The unit will not operate unless key is in the ON position. Turning the key to the OFF position satisfies the FDA requirement for mechanical lock out, ensuring the safety of non-authorized users. The mains power disconnect is the power inlet module at the back of the device. The pull the plug from the module.

The mains power switch has a fail safe system which ensures the 100/240V~ 1.5 – 0.5A 50-60Hz voltage from a wall socket can never come in contact with the user. The system uses a 2 amp fuse, (T2A 250V) which will only requires replacement if there is an issue. To replace, locate fuse holder in back of base unit, pull fuse holder out of enclosure, replace fuses and reinsert. Device should be connected to a reliable protective earth connection through a standard wall socket.

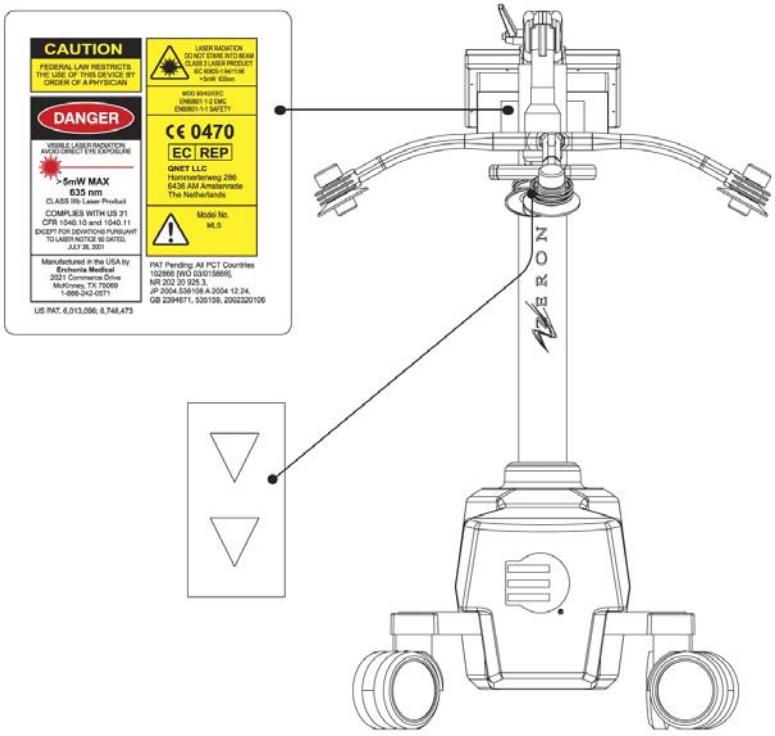
Protective Eyewear

The Erchonia® ML Scanner is classified by the FDA as a Class IIIb Laser Product. This designation represents a current standard for use in order to ensure the safety of the patient. A Class IIIb hazard class device is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging. To ensure there is no possible instance of residual effect, we have included a pair of specialty patient glasses for use by the patient during treatment.

Labeling

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

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



Manufacturer and Distributor Information

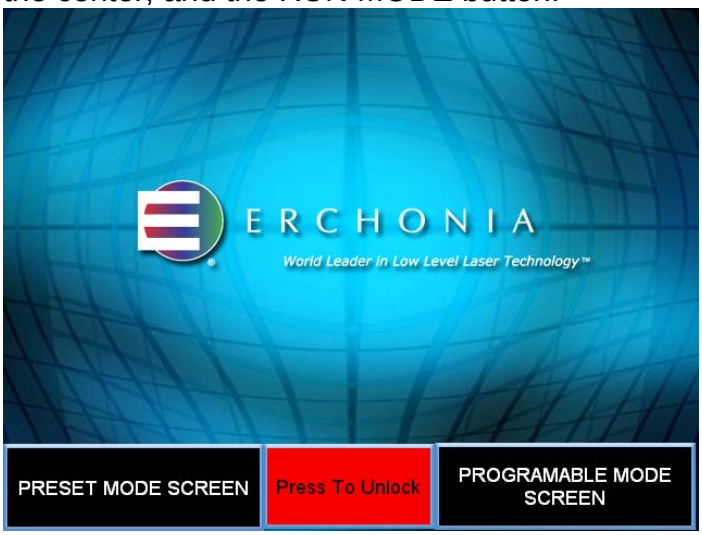
Manufacturer's Information
Erchonia Medical
2021 Commerce Dr.
McKinney, TX 75069
214.544.2227

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

Instructions for Use

Operating

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 company logo in the center, and the RUN MODE button.

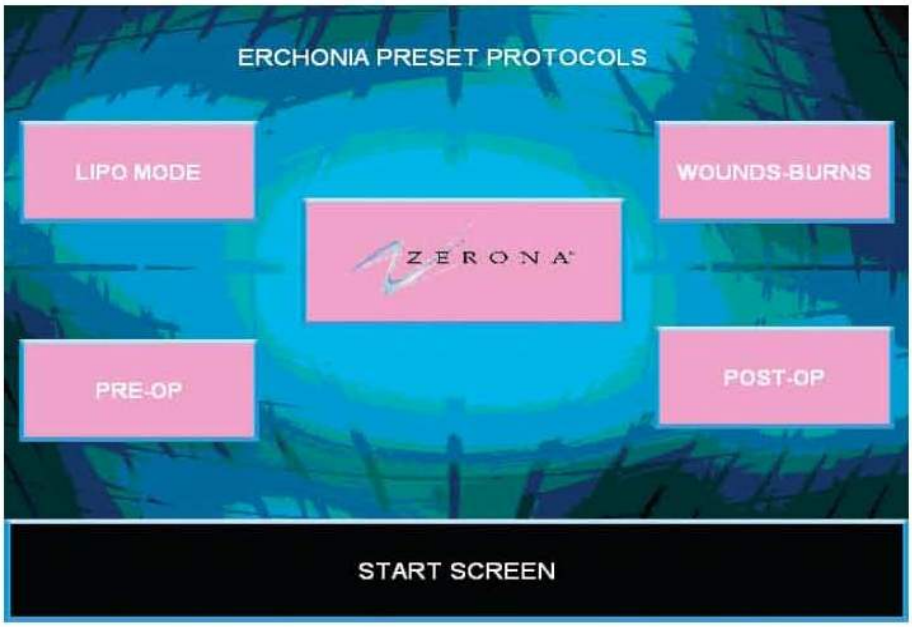


1. Press the PRESS TO UNLOCK button in the lower center of the screen
2. There are both PRESET and PROGRAMMABLE features to the ML Scanner (Zerona™) Press the appropriate section of the touch screen

PRESET MODE

This screen shows the Erchonia preset protocols. The options are:

a) Lipo
b) Pre-op
c) Zerona™
d) Wound/Burns
e) Post-Op



For instance, when you press the Zerona button in the middle of the PRESET screen, the following screen is displayed.

All preset screens follow the same pattern. All control keys are located on the bottom of each screen. Starting on the left, pressing the preset mode will return you to the preset selection screen. To the right of that is the treatment count down timer display. This is a visual indicator of how much time remains for the current treatment. Next to that, located in the center, is the start/stop key. Pressing this will start or stop a treatment. The **"PRESS TO PAUSE"** stops the treatment. When you are ready to restart the treatment press the paused key as it will be flashing **"PAUSED"** to continue the treatment where it was left off. The last key located on the bottom far right will return to the first or start screen. Each of the PRESET, START screens is pictured below.

PROGRAMMABLE MODE

This is the user settable screen selector. This screen allows the user to select between 5 custom treatment protocols. To return to the start screen press the start bar located on the bottom.

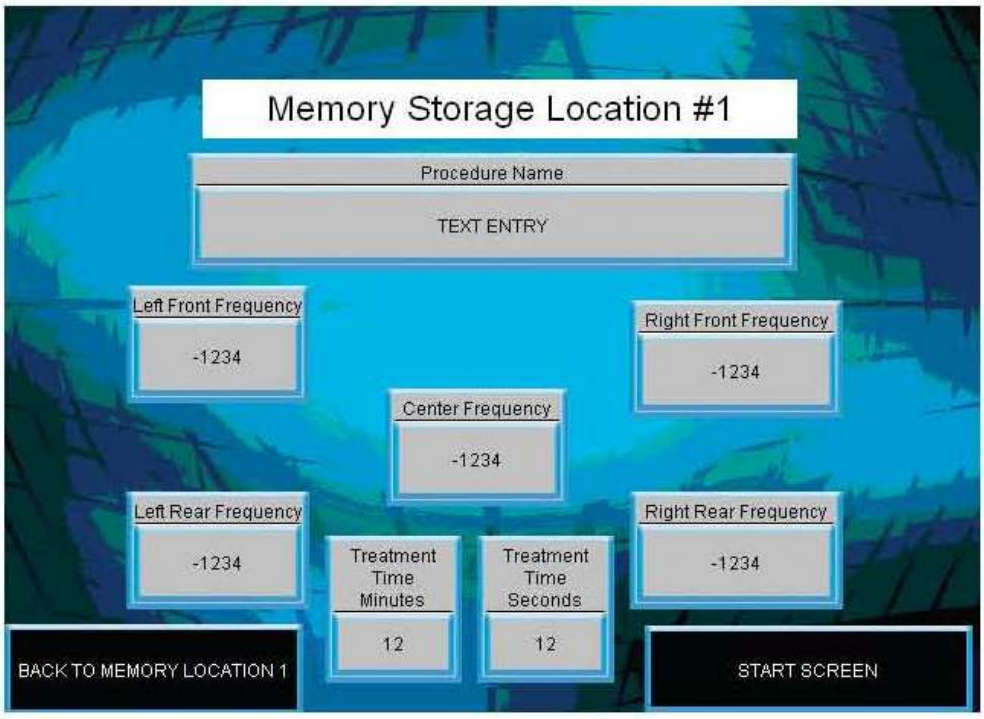
To begin programming, select a memory location, identified as Preset, meaning preset by physician. The following screen will display.

All 5 of the user settable screens look and work exactly the same except located at the extreme top center the specific memory location will be indicated, example **"MEMORY LOCATION 1".** As with all the run mode screens all the basic control keys are located on the bottom of the screen. The switch bars in each of the preset mode starts with the **PRESET MODE** screen button located on the bottom extreme left.

Next to that located on the bottom left is the setup screen, **"PRESET MODE 1 SETUP",** for its corresponding screen. By pressing this key a screen will appear allowing the user to set specific frequencies and treatment time as well as insert user text instructions and information that will display on this page in the dynamic text window. Next to that located in the center is the **START/STOP** key. Pressing this will start or stop a treatment.

The **"PRESS TO PAUSE"** key to stop the treatment. Then when you are ready to restart the treatment press the pause key as it will be flashing **"PAUSED"** to continue the treatment where it left off. The key located at the extreme right **START SCREEN** will return to the start screen.

The window display area, located above the basic control keys, is an image of the laser head with green windows displaying user settable information about all 5 laser scanner heads. This information includes treatment time remaining, the frequency of each scanner head, as well as the settable text. To set the parameters for each user settable mode; on each location press the **PRESET MODE SETUP** key located on the bottom left. Each laser head can be turned off during treatment by pressing the flashing red circle displaying **"ON",** on each head. The circle will turn green and say **"OFF".** In that state the treatment will continue, the timer will count down, the motors will run and all other lasers will fire except those turned off.



This screen will appear once the setup key is pressed. To program the treatment protocol press each gray window. There are 8 areas of data input available for entry:

> **1.) Procedure name;** Located top center. By pressing this window any information the doctor determines needs to be displayed can be entered via a keypad that will appear.(Note: the text area has limited display area)

2.) Left rear frequency; Located bottom left in the display area. This window will only program the bottom left scanner head frequency. This laser is located on the bottom left side when looking from the keypad toward the scanner head.

3.) Left front frequency; Located center left in the display area. This window will only program the top left scanner head frequency. This laser is located on the top left side when looking from the keypad toward the scanner head.

4.) Center frequency; Located center in the display area. This window will on~ program the center scanner head frequency. This laser is located in the center when looking from the keypad toward the scanner head.

5.) Right front frequency; Located center right in the display area. This window will only program the top right scanner head frequency. This laser is located on the top right side when looking from the keypad toward the scanner head.

6.) Right rear frequency; Located bottom right in the display area. This window will only program the bottom right scanner head frequency. This laser is located on the bottom right side when looking from the keypad toward the scanner head.

7.) Treatment time minutes; Will program the number of minutes the treatment will last (30 minute maximum].

8.) Treatment time seconds; Will program the number of seconds the treatment will last (59 second maximum].

Application *I* Administration

The ML Scanner device is intended for use by health care professionals for the treatment of the symptoms of pain associated with cosmetic and plastic surgeries, such as Laser Assisted Liposuction and Zerona™. The treatment protocols that are hard coded into the device have been developed in conjunction with Medical Doctors and where first used in in-office observations, implemented in an IRB approved clinical trial or are pending launch of trial. Inclusion of the process screens in this manual does not necessarily indicate an approval but are hard coded as the frequencies are proprietary. Medical professional in receipt of this device are to use the preset as their medical training and experience dictate.

Warnings

1. The long term effects of prolonged use of non-thermal laser exposure are unknown
2. Laser treatment should not be applied over, or in proximity to, cancerous lesions as conclusive tests have not been conducted.
3. Laser treatment should not be applied when in the bath or shower in fear of electrical shock.

4. To eliminate any possible danger to the eyes safety glasses must be worn by the patient during treatment
5. Keep out of reach of children at all times

Cautions

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

Maintenance and Cleaning

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

1. Regular visual inspection to make sure there is not external damage other than normal wear and tear. If during these inspections you identify an area of concern, please contact the manufacturer
2. If you notice a change in the performance of the device while in the ON position, please contact the manufacturer.
3. The internal components should not require any maintenance, however if an issue arises, which will show itself in the form of altered performance, the device must be sent to the manufacturer.
4. Since the device contains a touchscreen interface, periodic cleaning of the touchscreen will be necessary. To clean the touchscreen, use warm soapy water only, applied with a clean cloth that has been wrung out to ensure there is NOT an excess of fluid.
5. The touchscreen back up battery must be replaced every five years. This must be done by manufacturer.
6. The unit must be stored, shipped and used at temperatures not to exceed 40C/104ºF

Disposal

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

Warranty Information

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

Terms and Conditions
• This product contains a 30 day money back guarantee, which covers purchase price only. If for any reason, the end-user is unsatisfied with the product and/or it's performance, it can be returned for full refund of purchase price.
• Shipping required facilitating warranty repair and or maintenance issues within the first 90 days will be paid by the manufacturer.
• Shipping required facilitating warranty repair and or maintenance issues after 90 days is the financial responsibility of the end-user.

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

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

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

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

ERCHONIA

World Leader in Low Level Laser Technology™

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

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

COVER SHEET MEMORANDUM

From: Reviewer Name Richard P. Fenton

Subject: 510(k) Number K120857/S3

To: The Record

Please list CTS decision code SE

- ☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- ☐ Hold (Additional Information or Telephone Hold).
- ☑ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

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

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):	YES	NO
Indications for Use Page *Attach IFU*	X	
510(k) Summary /510(k) Statement *Attach Summary*	X	
Truthful and Accurate Statement *Must be present for a Final Decision*	X	
Is the device Class III?		X
If yes, does firm include Class III Summary? *Must be present for a Final Decision*		Y
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 1/, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC		X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		X
Is this device intended for pediatric use only?	X	
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?	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		

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
§78.5400	II	OLI

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

Additional Product Codes:

Review: _____ (Branch Chief) GSDB (Branch Code) 5/14/12 (Date)

Final Review: _____ (Division Director) 5/14/12 (Date)

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

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

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

K120257/S3_____

Date: May 14, 2012
To: The Record
From: Richard P. Felten

Office: ODE
Division: DSORD

510(k) Holder: Regulatory Insight, Inc.
for Erchonia Medical, Inc.
Device Name: Erchonia MLS, Zerona-AD Scanner
Contact: Mr. Kevin Walls
Phone: 720-962-5412
Fax: 720-962-5413
Email: kevin@reginsight.com

I. Purpose and Submission Summary

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

II. Administrative Requirements

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

III. Device Description

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

IV. Indications for Use

The Erchonia MLS, Zerona is indicated for the non-invasive reduction of circumference of the upper arm.

V. Predicate Device Comparison

The technological predicate is the device itself. This application is a request to expand the indications for use from reduction of waist, hip, and thigh circumference to now include reduction of upper arm circumference.

VI. Labeling

The application does contain a User Manual. The manual does contain clear instructions for device assembly, recommended treatment procedures, a summary of the clinical data supporting this application and a specifications table for the device. The information provided is acceptable.

VII. Sterilization/Shelf Life/Reuse

This is not applicable since the device is not sold sterile and self life is not an important factor for this device.

VIII. Biocompatibility

The only part of the device that comes in contact with the patient is the arm rest and it is made of biocompatible materials

IX. Software

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:	X	
Unresolved anomalies:		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

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

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

IEC 60601-1-2, (Second edition, 2001), Medical Electrical Equipment – Part 1-2: General Requirements for Safety, Electromagnetic

XI. Performance Testing – Bench

N/A

XII. Performance Testing – Animal

N/A

XIII. Performance Testing – Clinical

The company has provided clinical data from a 62 subject study that was a randomized, placebo control; double blinded study. The primary endpoint was the difference in number of subjects between treated and placebo control showing a reduction in upper arm circumference. The success criteria for individual patients was at least 1.25 cm or greater reduction in arm circumference at the 2 week treatment time point. Study success required that there be a 35% difference between the number of treated successes versus placebo control successes. The company also evaluated success as a secondary endpoint two weeks after the last treatment.

The company was requested to clarify how the upper arm measurements were accomplished and this information has been provided.

The company was requested on April 20, 2012 to provide any long term follow-up data they had for this study. This information has been provided and included 14 treated subjects and 20 placebo control subjects who had measurement data from 5-9 months post last treatment. This data does show continued effectiveness at these time points compared to their baseline circumference measurements.

There were no adverse events reported for the study.

(see attached review for Supplement 3 for a more detailed discussion of the clinical data provided)

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?		X	If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

1. This application is requesting an expanded indication for use for this cleared device.
2. There are no new types of safety questions since the mechanism of action for the new indication for use is the same as for the already cleared indication for use for this device.
3. This is the same device as previously cleared for reduction of waist, hip and thigh circumference.
4. Descriptive characteristics are not adequate since this is a new location for treatment and you can not assume success from a different location insure success at the new location.
5. Company has provided clinical data demonstrating that the treatment regime will produce a reduction in upper arm circumference.

XV. Deficiencies

XVI. Contact History

Ms. Elvira Walls, Regulatory Insight was contacted by telephone on May 4, 2012 and requested to clarify the number of subjects in the long term follow-up study and that the indication for use for the device would limited to upper arm circumference reduction.

Mr. Kevin Walls, Regulatory Insight was contacted by electronic mail on May 13, 2012 requesting clarification of a number of issues related to information in the User Manual. These issues included clarifying the actual laser energy output of the diodes used in the device; clarification of the positioning of the subject for treatment; and correction of the device comparison tables.

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

Richard P. Felton — Reviewer — May 14, 2012 — Date

Neil R. Ogden — Branch Chief — 5/14/12 — Date

I concur with SE.

May 14, 2012

Review of K120257/S3

Submitted by Regulatory Insight
for Erchonia Medical

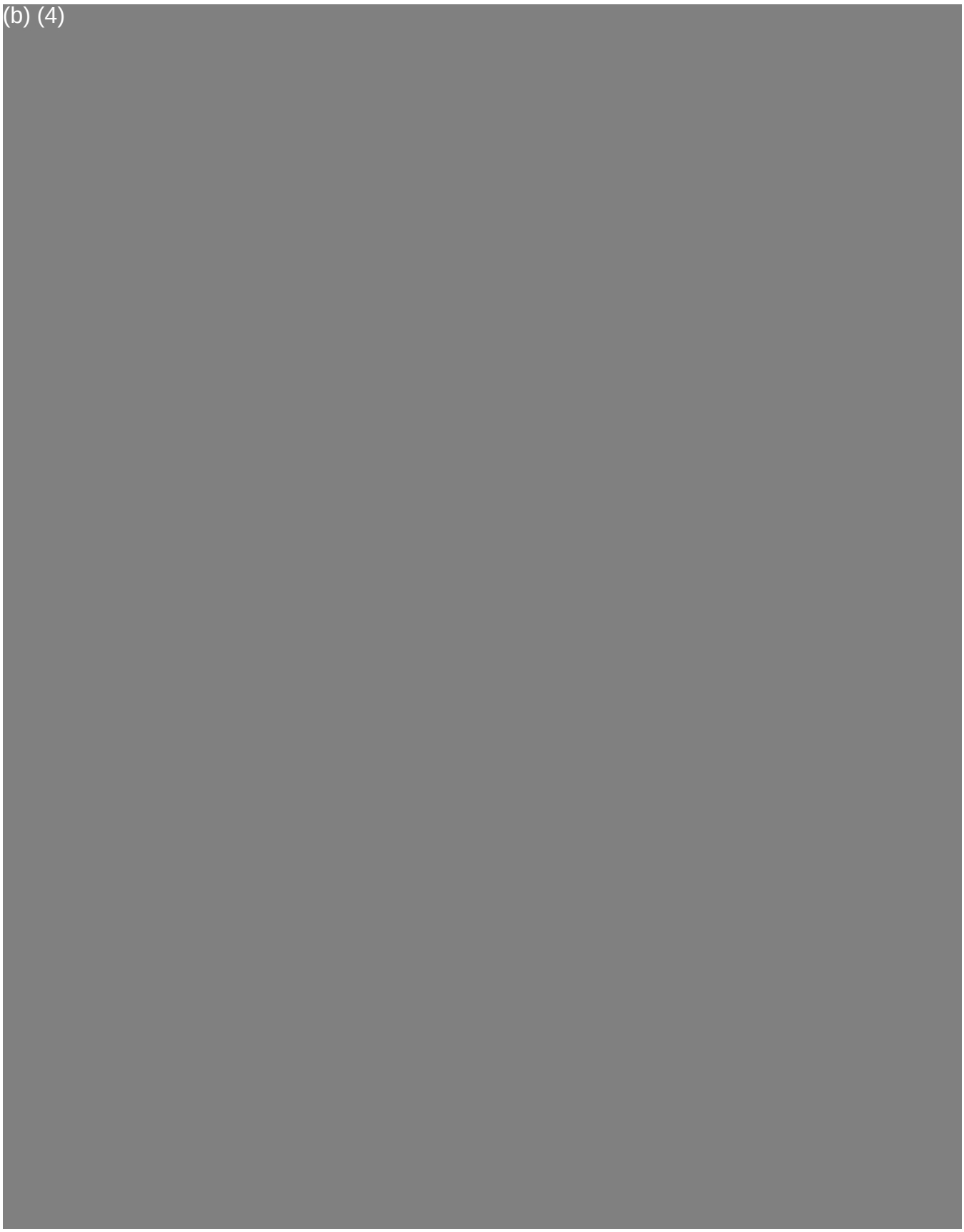
Reviewed by Richard P. Felten, DSORD, GSDB

Richard P. Felten

(b) (4)

[redacted]

(b) (4)



(b) (4)

Based on the original two week follow-up data and the long-term data provided in Supplement 2, I recommend that a determination of Substantial Equivalence be made for this application limiting the indication to use to "non-invasive dermatological aesthetic treatment for the reduction of the circumference of the upper arms".

I concur with SE.

5/14/12

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

COVER SHEET MEMORANDUM

From: Reviewer Name Richard P. Felton

Subject: 510(k) Number K120257|S2

To: The Record

Please list CTS decision code AF

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

☑ Hold (Additional Information or Telephone Hold). Telephone 5-4-2012

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

Not Substantially Equivalent (NSE) Codes

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

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

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

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

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

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

Nanotechnology

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

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

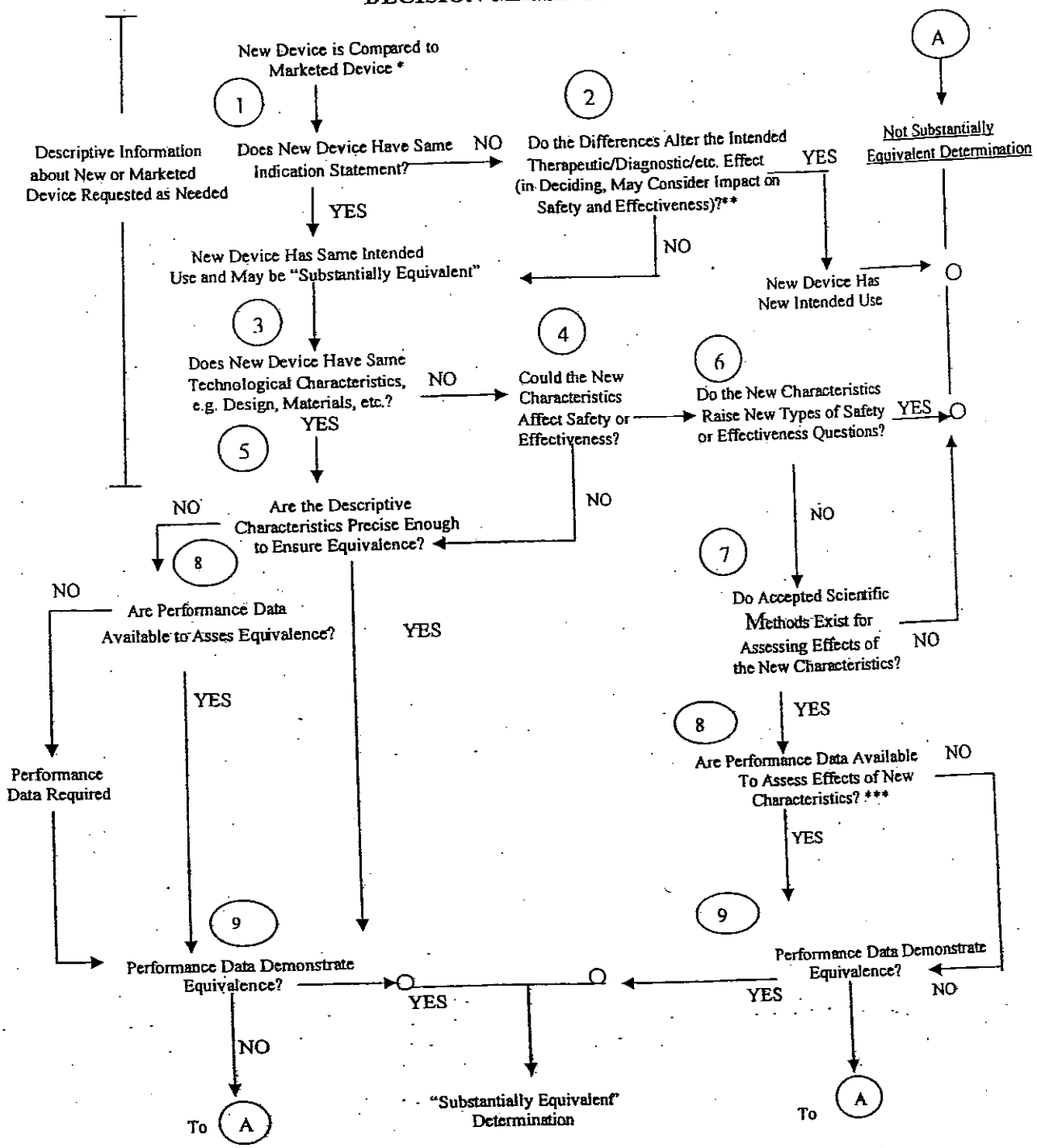
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

eview: _____ (Branch Chief) GSDB (Branch Code) 5/4/12 (Date)

Final Review: _____ (Division Director) (Date)

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



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

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

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

May 4, 2012

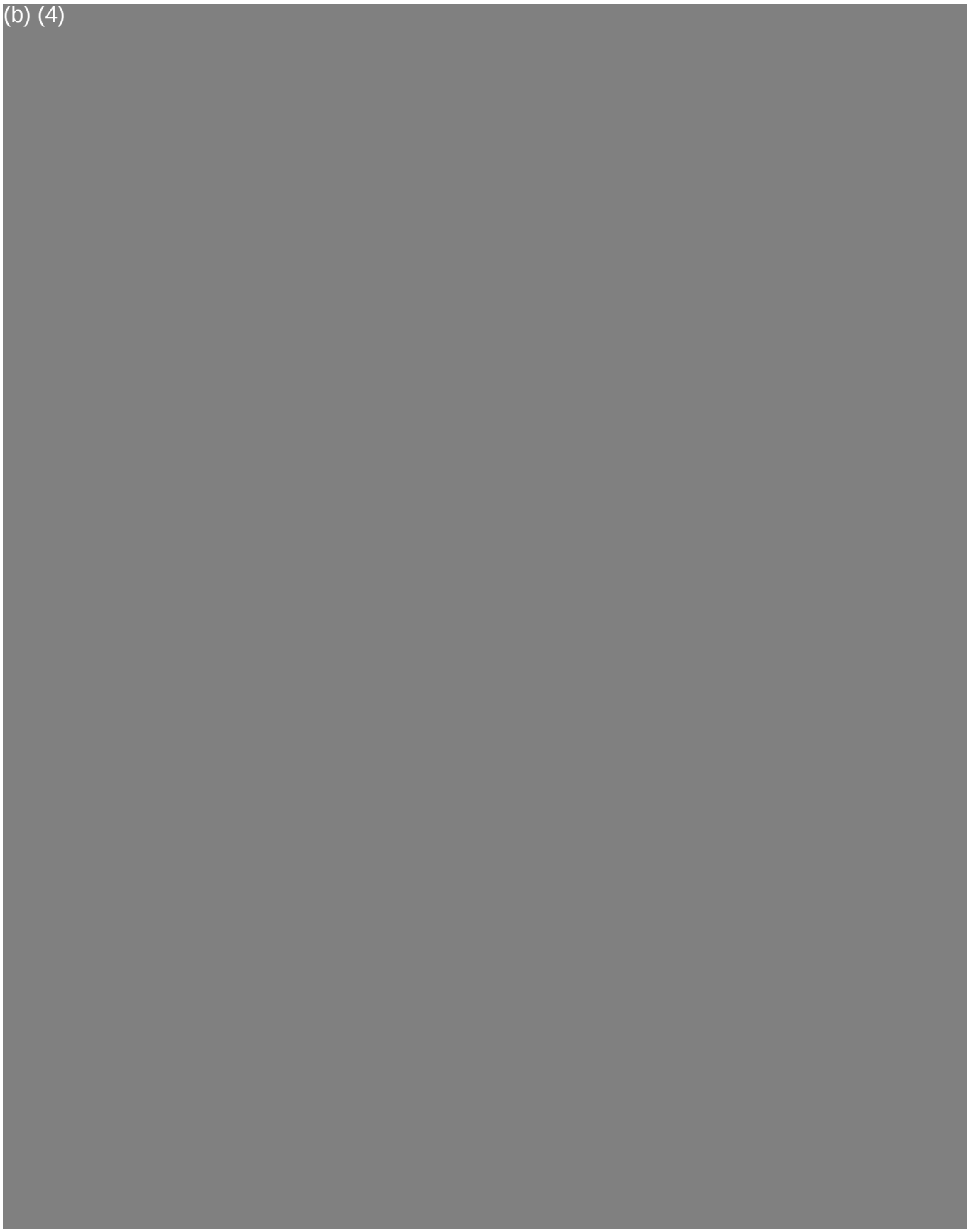
Review of K120257/S2

Submitted by Regulatory Insight
For Erchonia Medical, Inc.

Reviewed by Richard P. Felten, DSORD, GSDB

(b) (4)

(b) (4)



(b) (4)

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

COVER SHEET MEMORANDUM

From: Reviewer Name Richard P. Felten

Subject: 510(k) Number K120257|S1

To: The Record

Please list CTS decision code AT

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

☑ Hold (Additional Information or Telephone Hold).

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

Not Substantially Equivalent (NSE) Codes

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

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

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

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

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

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

Nanotechnology

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

Regulation Number **Class*** **Product Code**

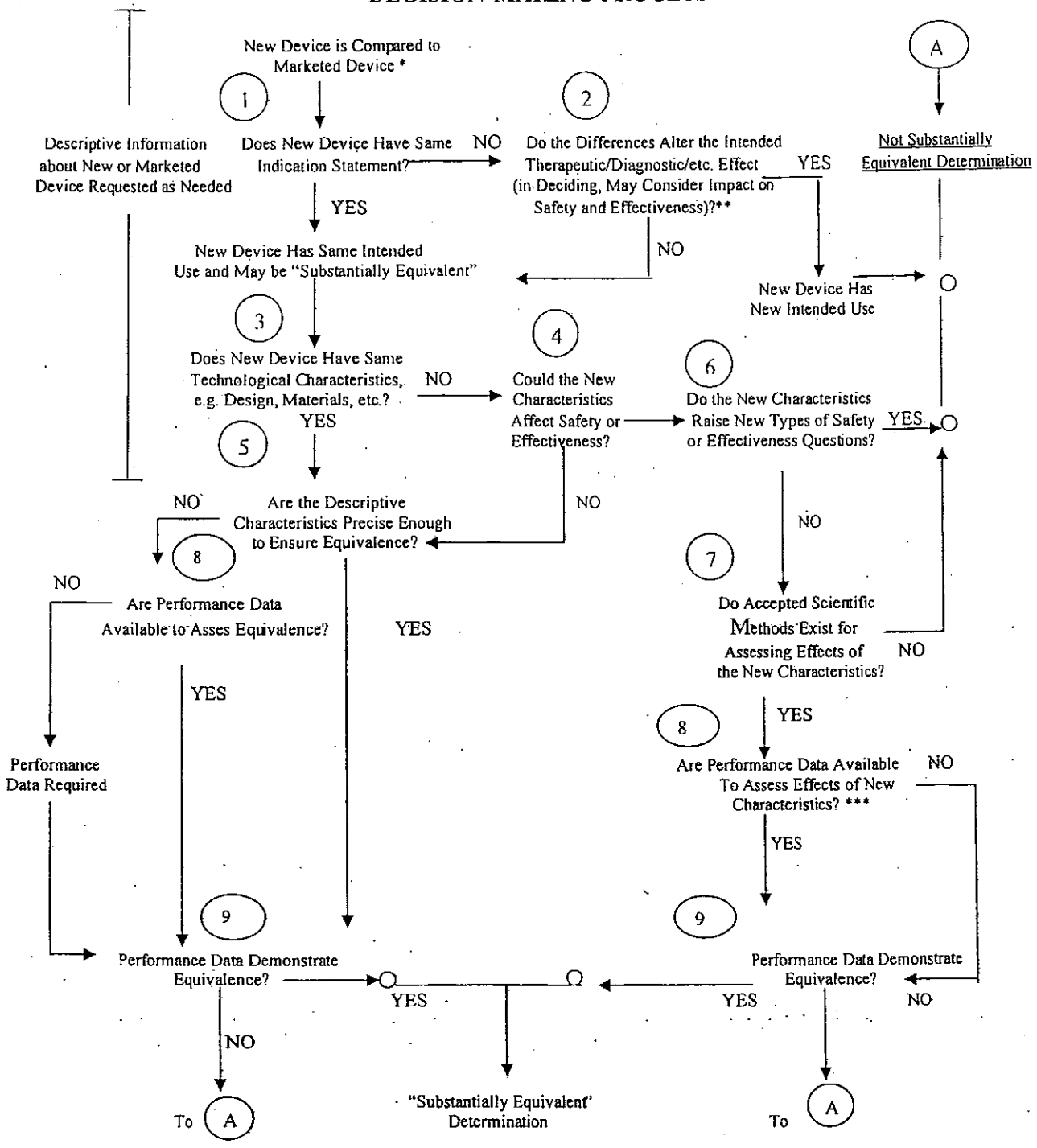
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: _____ GSDB 4/23/12
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

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



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

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required. Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Ogden, Neil

From: Felten, Richard P.
Sent: Friday, April 20, 2012 6:10 PM
To: Ogden, Neil
Subject: RE: Erchonia

Neil:

Could you do this for me. Even if it is done on Monday it will save some time at the end since it is close to 90 days. I have not yet seen anything from Harry Bushar who is doing the statistical but it may be in earlier e-mails I have not yet read.

I'll tell Steve that we put it on HOLD and for him to send me the information by e-mail so I can look at it first and then have the hard copy sent after we are done.

I talked with the people from TRIA and they were working on my request for decrease in hair count data. I did tell them that we may have issues with the data if we see non-symmetrical effects with one side of the lip showing hair loss and the other showing hair gain. They were planning on showing that the average loss was statistical and I said we look at the number of individual subjects showing 30% loss and that we may have issues with asymmetry. I think we are going to need to discuss this also given we are going to have a short review time left on this file also.

Some really great work being done on scars. Very good presentation on the etiology of scars and why they form.

The doctor from Army showed some really interesting slides where following fractional treatment scars seemed to convert back to normal skin with normal hair growth and he even had a case where following fractional treatment a person redeveloped the ability to sweat. Neat stuff here but we are really going to be faced with this whole issue of drug and stuff delivered through fraxel channels.

[redacted] you Wednesday.

[redacted] ould be able to read e-mails the rest of the weekend and on Monday.

Starting reading and had forgotten that today was Friday and everyone is already home for the weekend.

Richard

From: Ogden, Neil
Sent: Friday, April 20, 2012 8:48 AM
To: Felten, Richard P.
Subject: RE: Erchonia

Hi RPF, Sure we should get that additional data. Placing on hold works for me. Have fun there in FL.
Neil

More follow-up data requested.. Full review to be added later.

From: Felten, Richard P.
Sent: Friday, April 20, 2012 6:36 AM
To: Ogden, Neil
Subject: Erchonia

Neil:

[redacted] talked with Steve Shanks yesterday about the data we have for his arm circumference study and the fact we only have 2 week follow-up and this may be an issue given we have several month follow-up for the other body contouring indications from LipoSonix and Ulthera. He stated he does have some longer term follow-up for a subset of these patients, I think he said 2-5 months depending and maybe 35 subjects. I was wondering if maybe we should place the application on HOLD and ask for this, he has not problem giving it to us, so we would have at least some additional

data even if it isn't necessarily statistically solid.

I have not be able to get my system to down load any messages this morning and need to leave here to get to Gaylord.

If you think putting them on HOLD makes sense the document is in my room and just let me know by e-mail.

I may try to call you today to check on this idea, possibly after the Plenary session.

So you know it is me, my cell phone number should come up on the phone and it is 301-793-0965.

So far things have gone pretty good.

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

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

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

COVER SHEET MEMORANDUM

From: Reviewer Name Richard P. Forlaw

Subject: 510(k) Number K120257

To: The Record

Please list CTS decision code AF

☐ 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). Elaine MacDonald Phone 3/16/2012

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

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NM	NSE requires PMA
☐	NS	NSE no response
☐	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	X	
510(k) Summary /510(k) Statement	*Attach Summary*	X	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age < 21			

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

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 878.5460 **Class*** II **Product Code** OLT

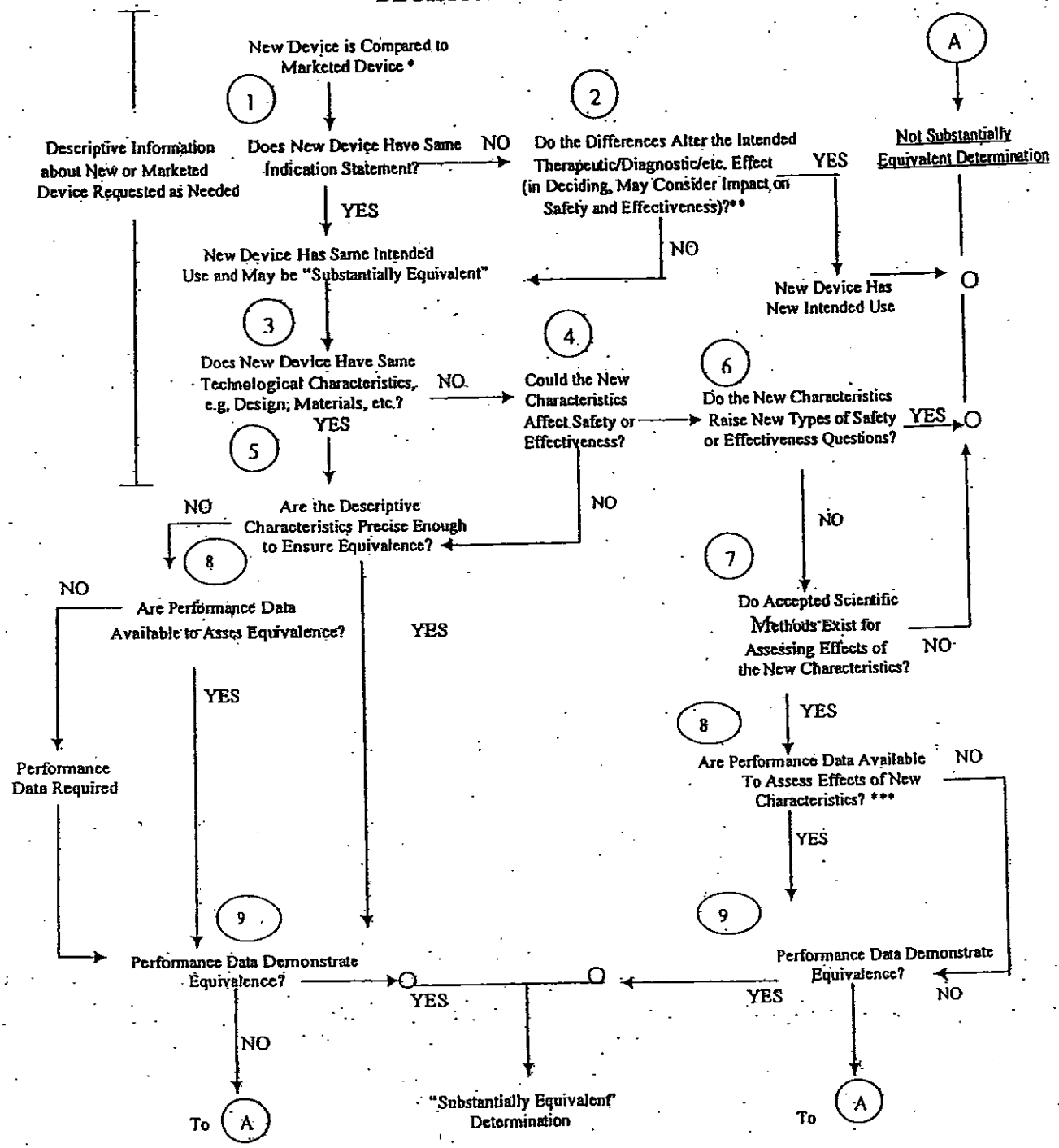
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: [signature] (Branch Chief) GSDB (Branch Code) 3/19/12 (Date)

Final Review: (Division Director) (Date)

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



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

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

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

Felten, Richard P.

om: Felten, Richard P.
ent: Friday, March 16, 2012 1:28 PM
To: Kevin Walls (kevin@reginsight.com)
Subject: K120257 Arm Circumference

Attachments: Erchonia MLS Scanner Arms Deficiencies K120257.doc

Mr. Walls:

I have completed my review of the application and there are a number of items that need to be addressed. The major issue is that we would need a copy of the individual patient data on a CD that we can give to the statisticians for their review. This should be either in SAS or Excel and should include a description of the statistical analysis that the company has performed.

There are a number of other items that do need to be addressed also.

I am placing the application on HOLD as of today.

I'll try to call later to make sure you did receive the electronic message and if you have any questions.

Erchonia MLS Scanner Arms Defi...

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

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

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March 16, 2012

Deficiencies for K120257

Submitted by Erchonia Medical, Inc.

(b) (4)

(b) (4)

[redacted]

O.K.
3/19/12

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

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

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

K120257

Date: March 16, 2012
To: The Record
From: Richard P. Felten

Office: ODE
Division: DSORD

510(k) Holder: Regulatory Insight, Inc.
for Erchonia Medical, Inc.
Device Name: Erchonia MLS, Zerona-AD Scanner
Contact: Mr. Kevin Walls
Phone: 720-962-5412
Fax: 720-962-5413
Email: kevin@reginsight.com

I. Purpose and Submission Summary

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

II. Administrative Requirements

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

III. Device Description

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

IV. Indications for Use

For the non-invasive reduction of circumference of the arm.

V. Predicate Device Comparison

The technological predicate is the device itself. This application is a request to expand the indications for use from reduction of waist, hip, and thigh circumference to now include reduction of arm circumference.

VI. Labeling

The application does contain what appears to be an Operator Manual, although at this time this manual is not clearly intended or identified as an Operator Manual. This manual has not been reviewed in detail since review of the clinical data has not been completed at this time. The company has not provided the individual subject data and without this a complete review of the Operator Manual can not be made.

VII. Sterilization/Shelf Life/Reuse

This is not applicable since the device is not sold sterile and self life is not an important factor for this device.

VIII. Biocompatibility

Not applicable since the device does not come into contact with the patient.

IX. Software

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:	X	
Unresolved anomalies:		

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

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

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

IEC 60601-1-2, (Second edition, 2001), Medical Electrical Equipment – Part 1-2: General Requirements for Safety, Electromagnetic

XI. Performance Testing – Bench

N/A

XII. Performance Testing – Animal

N/A

XIII. Performance Testing – Clinical

The company has provided clinical data from a 62 subject study that was a randomized, placebo control;

double blinded study. The primary endpoint was the difference in number of subjects between treated and placebo control who did show arm reduction. Success criteria for individual patients was at least 1.25 cm or greater reduction in arm circumference at the 2 week treatment time point. Study success required that there be a 35% difference between individual treated success versus placebo control success rate. The company also evaluated success as a secondary endpoint two weeks after the last treatment.

The company will be asked to clarify how the actual measurements of the upper arm are made and how repeatability is insured. They will also be asked to provide the individual data for each subject so that our statistical staff can independently verify the statistical conclusions.

There were no adverse events reported for the study.

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:

(b) (4)

(b) (4)

XVI. Contact History

Mr. Kevin Walls, Regulatory Insight, who is the official contact, will be sent an electronic mail message containing the above deficiencies. He will be informed that the application is being placed on HOLD based on this message. An attempt will be made to contact him by telephone in case there is need to clarify any of the issues.

XVII. Recommendation

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

Reviewer — Date: Mar 16, 2012

Branch Chief — Date: 3/19/12

March 16, 2012

Review of K120257

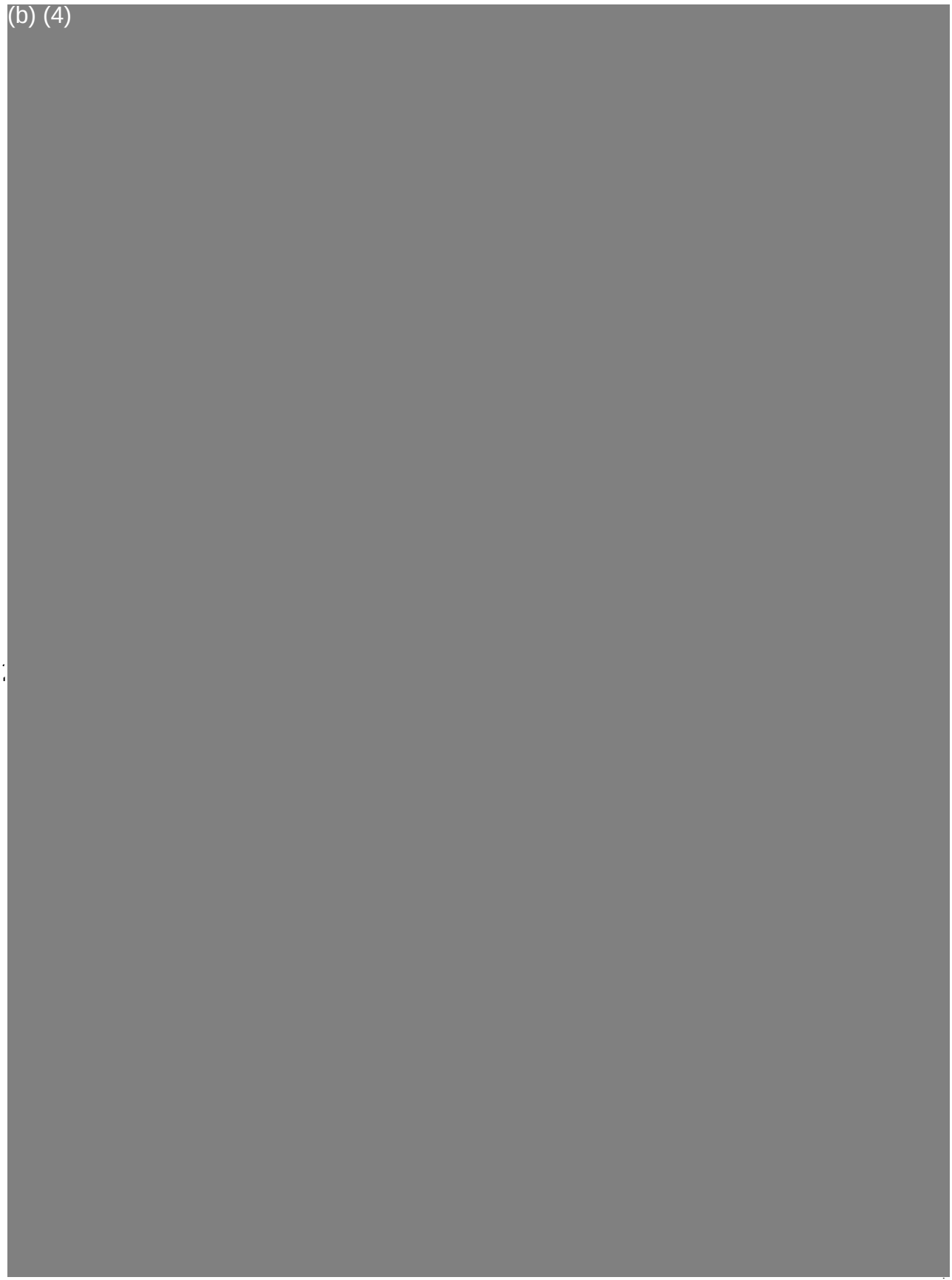
Submitted by Regulatory Insight, Inc.
for Erchonia Medical, Inc.

Reviewed by Richard P. Felten, DSORD, GSDB

Richard P Felten

(b) (4)

(b) (4)



(b) (4)

I recommend that the above issues be transmitted to Mr. Kevin Walls, Regulatory Insight, Inc and he be notified that the application was being placed on HOLD. The deficiencies will be communicated to him by electronic mail and an effort will be made to contact him by telephone.

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

March 14, 2012

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: Addendum to 510(k) #K120257 for the Erchonia® MLS, Zerona

Dear Sir or Madam,

This document is being submitted as an addendum to 510(k) #K120257 for the Erchonia® MLS, Zerona. The purpose of this addendum is to change the indications for use to the non-invasive dermatological aesthetic treatment for body contouring and as a non-invasive dermatological aesthetic treatment for the reduction of circumference of the arm.

The change of the indications for use is predicated on email communications with Mr. Neil Ogden, Chief, General Surgery Devices Branch, and Mr. Richard Felten, Lead Reviewer, in which it was determined that the addition of the more general indication for use for body contouring may possibly be added due to clinical data that was presented in K082609 regarding the results with hips, waists and thighs, along with the data presented in this 510(k) regarding the results with arms.

Please refer to the following changes to K120257 provided below.

Please replace the CDRH Premarket Review Submission Cover Sheet, Form FDA 3514, submitted in the original 510(k) application with the one that is contained in **Appendix A** of this addendum.

On Page 1 of the original 510(k) application, please replace the Trade Name with Erchonia® MLS, Zerona

On Page 2 of the original 510(k) application, please replace the Indications for Use statement with the following:

The MLS, Zerona™ is indicated the non-invasive dermatological aesthetic treatment for body contouring and as a non-invasive dermatological aesthetic treatment for the reduction of circumference of the arm.

The new Indications for Use Statement is contained in **Appendix B** of this addendum.

On Page 4 of the original 510(k) application, please replace the Substantial Equivalence table with the following:

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

Comparison of the New and Predicate Devices

Device	Erchonia® MLS, Zerona™	Erchonia MLS Laser
510(k)	N/A	K082609
Indications for Use	The MLS, Zerona™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring and as a non-invasive dermatological aesthetic treatment for the reduction of circumference of the arm.	The Erchonia® ML Scanner (MLS) is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs
Power	1 mw	1 mw
Wavelength	Red 630 nm – 640 nm (near infrared)	Red 630 nm – 640 nm (near infrared)
Waveform	Pulsed	Pulsed
Energy Source	Five diodes, each collected then line dispersed and rotated	Five diodes, each collected then line dispersed and rotated
Power Supply	AC	AC
Energy Delivery	Machine mounted probe	Machine mounted probe
Treatment Time	0 – 9.9 minutes	0 – 9.9 minutes
Target Size	Line pattern, mechanically rotated to form circles and scanned over treatment area.	Line pattern, 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.

Please refer to the new Operation & Maintenance Manual contained in **Appendix C**.

We hope the information contained in the original 510(k) premarket notification, along with the information enclosed in this addendum is sufficient for finding the MLS, Zerona™ substantially equivalent. Please let me know whether you have any questions or concerns or you require any additional information.

Respectfully yours,

Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.

Indications for Use

510(k) Number (if known): _____

Device Name: Erchonia® MLS, Zerona™

Indications for Use: The MLS, Zerona™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring and as a non-invasive dermatological aesthetic treatment for the reduction of circumference of the arm.

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)

Acknowledgements & Accreditations

We at Erchonia ® Corporation would like to thank you for purchasing the Erchonia® MLS, Zerona™ device.

Erchonia ® Corporation is an ISO certified company and is audited from time to time by outside governing agencies, including the FDA, to be sure to stay in compliance with the highest quality standards. Our company operates according to and our devices are manufactured according with:

- FDA Good Manufacturing Practices
- ISO 9001 :2000 - Quality
- ISO 13485:2003 – Medical
- ISO 60825-1 - Laser Safety
- FDA Laser Class 2
- FDA Device Class II
- IEC Laser Class 2
- IEC Device Class 1
- MDD 93/42/EEC
- EN/IEC 60601-1-2 EMC
- EN/IEC EN60601-1-1 Safety
- Model Number: ARC
- Software Version ARM-E Rev A (1-9-12)
  - **ARM-E-TS Rev A**
  - **ARM-E-PLC Rev A**

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

Doc. No.	Issue Date	CR #	Revision	Rev Date
MLS-O&M MLS Zerona	1/11/2012	510(k) Release	0	1/11/2012

Legend:
The following symbols are used throughout this manual to show areas of concern. For your safety, and for the care of the device, please read and take note of these warnings and cautions.

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

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

Refers to the part of the medical device which comes into physical contact with the patient in order for the device to carry out its intended function.

US National Consideration:
When using in the US, the equipment is intended to be powered by a 120V source. If powered by a 240V source in the US, then the power source must be a center-tapped, 240V single phase circuit.

Erchonia® Corporation
2021 Commerce Dr. McKinney, TX 75069
Phone +1 888-242-0571 • Fax +1 214.544.2228
www.Erchonia.com
Patent(s): US – 6,013,096, Patent Pending

CAUTION: FEDERAL LAW RESTRICTS THE USE OF THIS DEVICE BY ORDER OF PHYSICIAN

MLS, Zerona Components

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

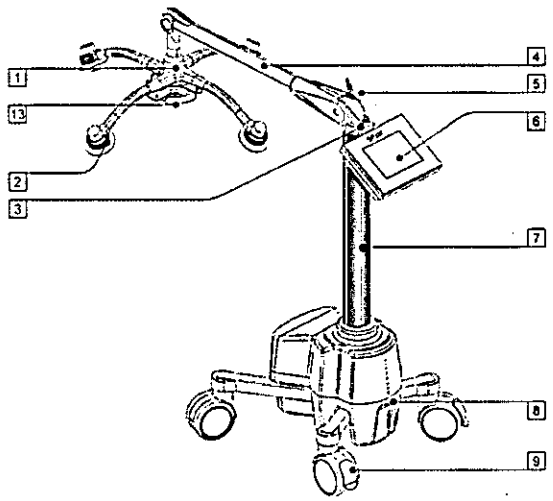


Fig. 1

1. Laser Head Assembly
2. Laser Output Head
3. Power Safety Lockout Key
4. Laser Arm
5. Arm Lock
6. Touch screen Control Surface
7. Main Upright of Base
8. Power Inlet
9. Rear Wheel Lock
10. Electrical Connector – (Page 4)
11. Locking Nut – (Page 4)
12. Power Cord – not shown
13. Handle

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].

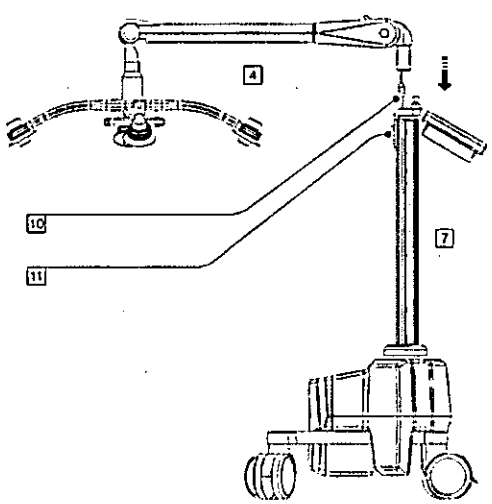
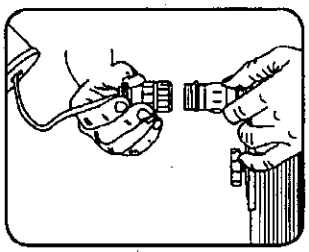
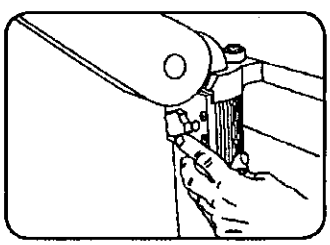
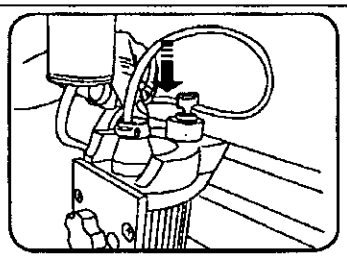
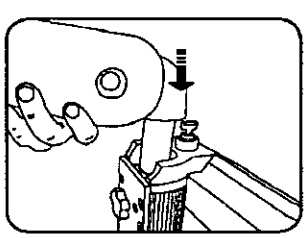
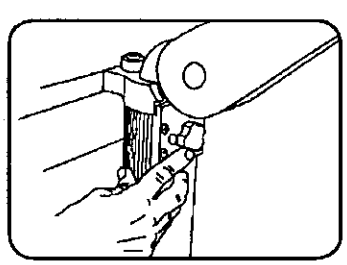


Fig. 2

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. This is important so the two halves do not separate over time.**	 Fig. 3
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 treaded 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.

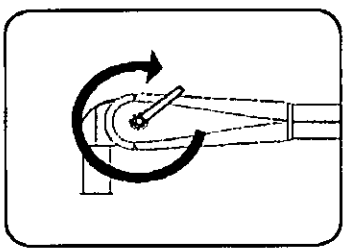


Fig. 8

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.

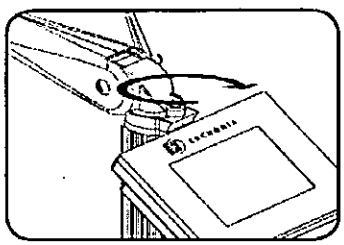


Fig. 9

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.

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.

When moving the head assembly into the desired position, make sure to use the handle on the side of the head assembly (fig 1, #13) 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.

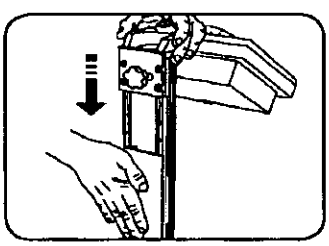


Fig. 10

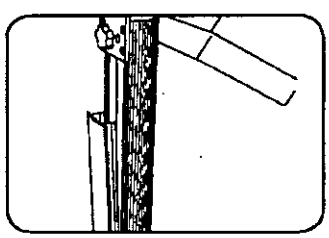


Fig. 11

Introduction to Contents

The Erchonia® MLS, Zerona™ laser package is comprised of (1) MLS, Zerona, (1) pair of patient protective eyewear, (1) Power Cord, (2) Keys, and this user guide. The components of this package are detailed below.

Erchonia® MLS, Zerona ™

The Erchonia® MLS, Zerona™ is made up of five independent 635 nanometer diodes. Laser devices are typically constructed to emit a "spot" of light. The Erchonia® MLS, Zerona™ laser utilizes internal mechanics that collects the light emitted from the diode and processes through a proprietary patented lens which redirects the beam with a line refractor. The lines generated by each head are rotated via a patented rotation device that operates independent of each other to ensure thorough coverage. The target area is approximately 8" x 10" inches or 80 square inches, approximately 516 square centimeters.

Power

The power switch is the key switch on top of the Touch screen, ref Item 3, FIG 1. The unit will not operate unless key is in the ON position. Turning the key to the OFF position satisfies the FDA requirement for mechanical lock out, ensuring the safety of non-authorized users. The power switch has a fail-safe system which ensures the 110/240 voltage from a wall socket can never come in contact with the user. The system uses a 2 amp fuse, which will only require replacement if there is an issue. To replace, locate fuse holder in back of base unit, pull fuse holder out of enclosure, replace fuses and reinsert. Use only rated T2A 250V. The device includes a transformer which converts AC power to match the power output i.e. 110V or 240V. Only a plug prong adaptor is required (available at any retail electronics store). Once the adaptor is affixed to the plug end, put into wall socket. Input: 100-240V-0.5-1.5A 50-60 Hz.

NOTE: Make sure the power cord is plugged into device 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. Fuses to be rated a T2A 250V with an input to cover 100 – 240V~ 1.5-.5A, 50-60 Hz.

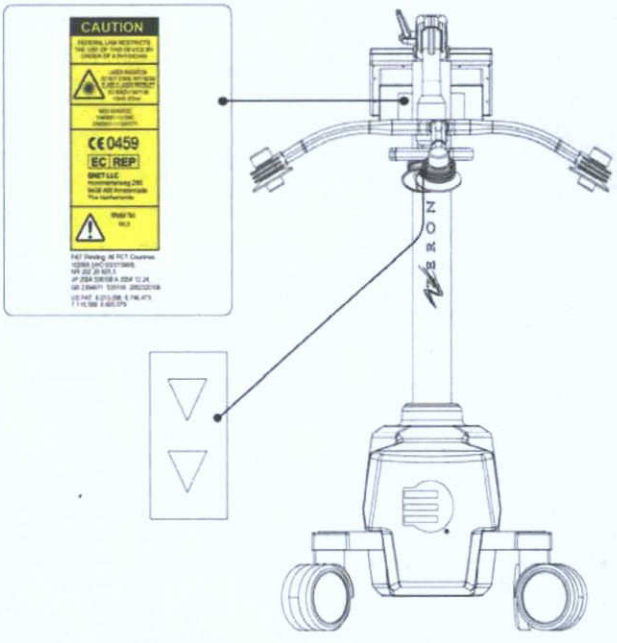
Protective Eyewear

The Erchonia® MLS, Zerona™ is classified as a Class 2 laser. This designation represents a current standard for use in order to ensure the safety of the patient.

 The MLS, Zerona™ device is classified as a Class 2 Laser. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 device is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging. To ensure there is no possible instance of residual effect, we have included a pair of specialty patient glasses for use by the patient during treatment

Labeling

The 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 2 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.



Manufacturer and Distributor Information

Manufacturer's Information

Erchonia Corporation
2021 Commerce Dr.
McKinney, TX. USA 75069
+1.214.544.2227

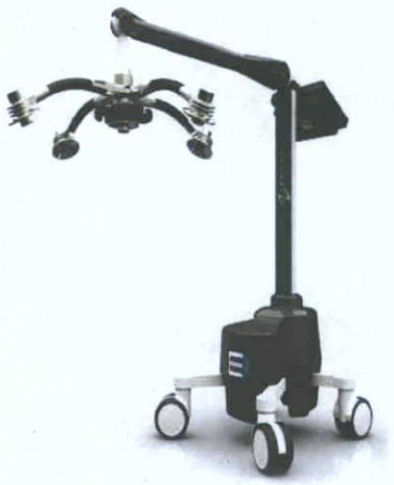
Distributor Information

Erchonia Corporation
2021 Commerce Dr.
McKinney, TX. USA 75069
+1.214.544.2227

The Erchonia® MLS, Zerona™ Device

The Erchonia® MLS, Zerona™ device is a self-contained device created for use of non-invasive dermatological aesthetic treatment for body contouring. It is easy to use, compact, all in one, mains powered unit.

The Erchonia® MLS, Zerona™ device has been classified by the FDA as a Class 2 Laser product and a Class 2 in accordance to IEC 60825-1 (EU). These are the current standards for use that ensures the safety of the user.



Technical Information

Technical documentation required by international end-users, in case of necessary reparations, will be provided by our EU agent. These documents will be supplied once the manufacturer, working with the EU agent, makes the determination that the requested documents do not constitute a disclosure of priority or patent protected information and are a part of the filed and documented technical file.

Transportation and Storage

The unit must be stored and/or transported in conditions not to exceed -30 to +70°C (-22 to +158°F) @ 0-100% Relative Humidity Non-Condensing.

Intended Use

The MLS, Zerona™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring and as a non-invasive dermatological aesthetic treatment for the reduction of circumference of the arm.

Visual Inspection

This completes the listing and the description of the parts of the Erchonia® MLS, Zerona™ device. Once you are familiar with each part and you are sure that each part is in good working order, read the next section.

Protocol -- Non-invasive Dermatological Aesthetic Protocol for the Upper Arms

1. Each patient receives six total procedures administered across a two-week time frame; three procedures per week; each one at least two days, but no more than three days, apart.
2. Each procedure administration will take a total of 40 minutes; 20 minutes per arm.
3. The procedure administration protocol for each session is as follows:
    a. The patient lies comfortably on his or her stomach on the treatment table, extending his or her right arm to rest at a 90 degree angle to his or her body flat on the treatment table, palm down.
    b. The patient is correctly fitted with the laser safety glasses.
    c. The fixed center diode of the device is positioned at a distance of 6.00 inches above the skin and directed on the patient's mid upper arm.
    d. The other four rotating diodes are positioned 120 degrees apart and tilted 30 degrees off the centerline (mid upper arm) of the center scanner.
    e. The device is activated for 20 minutes. The 5 rotating diodes emit a laser beam of approximately 17 mW with a wavelength of 635 nm red light. Each diode 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.
    f. This process is repeated for the patient's left arm.
    g. The patient removes the laser safety glasses and the session is over.

Protocol -- Non-invasive Dermatological Aesthetic Protocol for the Front of the Body

1. The patient lies comfortably flat on his or her back on the table such that the front area of the patient's body encompassing the region spanning from the patient's stomach (abdomen) down through the hips and frontal aspect of both thighs, is facing upwards.

2. The center diode of the Erchonia® MLS, Zerona™ is positioned at a distance of 6.00 inches above the patient, centered along the body's midline (the "line" that vertically "dissects" the body into two equal halves).
3. The Erchonia® MLS, Zerona™ is activated for 20 minutes. Each scanner emits to the patient a laser beam of approximately 17mW with a wavelength of 635 nm, and creates a spiraling circle pattern that is totally random and independent from the others. These patterns overlap each other to guarantee total coverage within the target area of approximately 516 square centimeters.

Protocol -- Non-invasive Dermatological Aesthetic Protocol for the Back of the Body

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

Clinical Trial Summary

A DOUBLE-BLIND, PLACEBO-CONTROLLED RANDOMIZED EVALUATION OF THE EFFECT OF THE ERCHONIA® ML SCANNER (MLS) ON BODY CONTOURING OF THE WAIST, HIPS AND THIGHS.
Erchonia Medical. Inc.

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

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

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

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

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

Table 1: Table of Subject Demographics

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

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

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

Table 2: Mean Baseline measurements

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

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

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

STUDY RESULTS

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

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

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

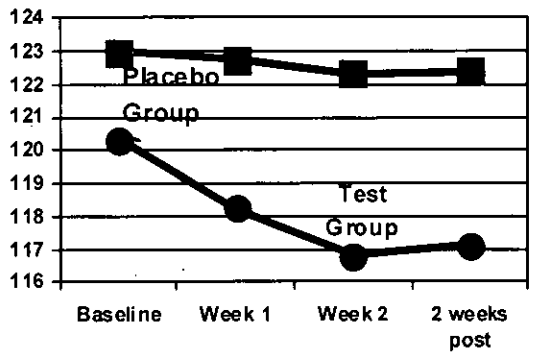
The magnitude of the mean change in total circumference measurement was a decrease of 3.521 inches for subjects who received the study procedures with the actual Erchonia® MLS and a decrease of 0.684 inches for subjects who received the study procedures with a 'fake' (placebo) laser device. A t-test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

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

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

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

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



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

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

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

Table 4: Mean individual body area circumference measurements.

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

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

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

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

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

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

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

AN EVALUATION OF THE EFFECTIVENESS OF THE ERCHONIA® ML SCANNER (MLS) AS A NON-INVASIVE DERMATOLOGICAL AESTHETIC TREATMENT FOR THE REDUCTION OF CIRCUMFERENCE OF THE UPPER ARMS
Erchonia Corporation

BACKGROUND: The purpose of this clinical study was to demonstrate the effectiveness of the Erchonia® MLS, Zerona™ for non-invasive body contouring of the upper arms by applying the MLS, Zerona™ to the upper arms 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 two (62) subjects completed this study. Of the 62 participating subjects, 31 were randomized to the active procedure group and 31 were randomized to the placebo group.

Subjects were those aged 18 to 65 years who were deemed suitable for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that had failed

to respond to diet and exercise; specifically for the indication of body contouring of the bilateral upper arms, as per the American Academy of Cosmetic Surgery's 2006 Guidelines for Liposuction Surgery developed by a joint Ad Hoc Committee of the American Society of Liposuction Surgery (ASLSS) and the American Academy of Cosmetic Surgery (AACS), and/or for the procedure of brachioplasty (upper arm lift).

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

Table 1: Table of Subject Demographics

Gender	**Female**		**Male**	
n=62	*number*	%	*number*	%
	60	97%	2	3%
Ethnicity	**Caucasian**		**Hispanic**	
n=62	*number*	%	*number*	%
	37	60%	21	34%
	African American		**Caucasian/African American**	
	number	%	*number*	%
	2	3%	2	3%

STUDY MEASURES: Circumference measurements at three points on the upper arms, and body mass index (BMI) were recorded at baseline, study mid-point (week 1), study endpoint (week 2), and study follow-up two weeks later. Subject satisfaction with the procedure outcome was recorded at study endpoint.

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

Table 2: Mean Baseline measurements

	Test Group n=31	**Placebo Group n=31**
Body Mass Index (BMI)	29.57	30.57
Right Upper Arm Circumference (cms.)	95.67	94.66
Left Upper Arm Circumference (cms.)	95.81	94.92

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

STUDY PROCEDURE: Subjects received six procedure administrations with the Erchonia® MLS, Zerona™ to the right and left upper arms, across a consecutive two-week period: three procedures per week, each procedure two to three days apart.

STUDY RESULTS

(i) **Total Circumference Measurements**: The study primary outcome measure was based on individual circumference measurements taken at 3 points along each of the subject's upper arms combined to attain a single circumference measurement for each of the right arm and the left arm, separately.

It was pre-determined that a subject would be considered a study success if he or she attained a 1.25 cm or greater reduction in combined circumference measurement for each of the right and left upper arms, separately, from baseline to study endpoint (after completion of the two-week procedure phase).

58% of subjects who received the study procedures with the actual Erchonia® MLS, Zerona™ attained a decrease in combined circumference measurement of 1.25 cms or greater for each of the right and left upper arms, separately, compared with 3% 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 55% to be statistically significant at $p<0.000005$.

The mean change in total circumference for subjects who received the study procedures with the actual Erchonia® MLS, Zerona™ was a decrease of 1.85 cms for the right upper arm, a decrease of 1.84 cms for the left upper arm and decrease of 3.70 cms for both upper arms combined. The mean change in total circumference for subjects who received the study procedures with the 'fake' (placebo) laser device was a decrease of 0.08 cms for the right upper arm, a decrease of 0.23 cms for the left upper arm and decrease of 0.31 cms for both upper arms combined.

Paired samples t-tests found the changes in upper arm circumference measurements for subjects in the test group to be statistically significant, as shown in Table 3 below. The changes in upper arm circumference measurements for subjects in the placebo group were not found to be statistically significant, as shown in Table 4 below.

Table 3: Paired samples t-tests for test group subjects

Test Group	μa-μb	t	df	p(two-tailed)	significance
Right Arm	1.855	+9.61	30	<0.0001	p<0.0001
Left Arm	1.842	+8.98	30	<0.0001	p<0.0001
Right & Left Arms	3.70	+10.65	30	<0.0001	p<0.0001

Table 4: Paired samples t-tests for placebo group subjects

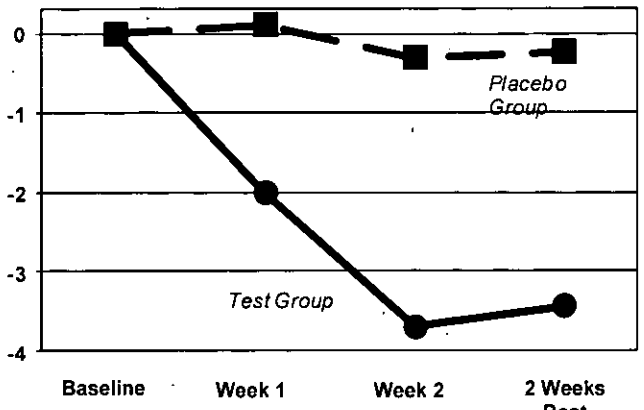
Placebo Group	μa-μb	t	df	p(two-tailed)	p	significance
Right Arm	0.0806	+0.83	30	0.413	p>0.05	Not significant
Left Arm	0.23	+1.95	30	0.061	p>0.05	Not significant
Right & Left Arms	0.31	+1.67	30	0.105	p>0.05	Not significant

Table 5 and Chart 1 below show the mean change in total upper arm circumference measurements (right and left arms combined) across the four study measurement time points.

Table 5: Mean total circumference measurements (cms) across evaluation points

	Test Group	Placebo Group
Baseline	191.48	189.58
Midpoint (week 1)	189.47	189.69
Endpoint (week 2)	187.78	189.27
Follow-up (week 4)	188.04	189.34

Chart 1: Mean change in total upper arm circumference measurements (cms) at each study evaluation point relative to baseline



For test group subjects, total circumference measurements decreased progressively from baseline across the procedure administration phase, indicating a progressive and cumulative treatment effect of the laser. However, for placebo group subjects, total circumference measurements were unchanged across the procedure administration phase relative to baseline.

Total circumference measurements stabilized for test group subjects across the subsequent 2-week follow-up assessment period during which time no laser procedures were administered, indicating duration of the treatment effect up to at least 2 weeks following the end of laser procedure administration.

(ii) Change in body mass index (BMI): BMI measurements did not change significantly across and between any of the evaluation time points for either test or placebo subject groups. However, upper arm circumference measurements did change significantly across and between evaluation points for test group subjects but not for placebo group subjects. This combined finding further supports the effectiveness of the Erchonia® MLS, Zerona™ device as it demonstrates that the change in body shape (reduction in cms for the upper arms) attained for test group subjects in this study at this test site resulted from the Erchonia® MLS, Zerona™ device applications and not from change in body mass index as a result of incidental weight loss.

(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 upper arms attained using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied.

65% of test group subjects reported being 'Satisfied' (Very or Somewhat Satisfied) with the outcome of the study procedures compared with 22% 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

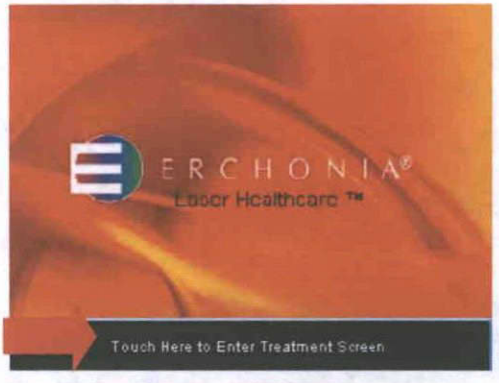
subject.

CONCLUSION: The Erchonia® MLS, Zerona™ is an effective tool for body contouring, significantly reducing circumference measurements when applied to the bilateral upper arms over a 2-week period.

Mechanical Instructions for Use: How to Use the Device

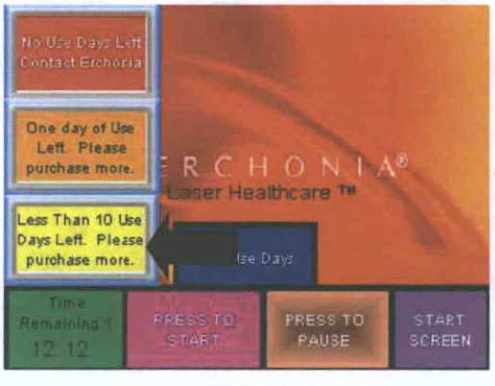
Operating the Device

Press "Touch Here to Enter Treatment Screen" button, this will take you to the Erchonia Preset Protocol (Mode) Selection screen.



Press "PRESS TO START" button to begin the non-invasive arm reduction 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.

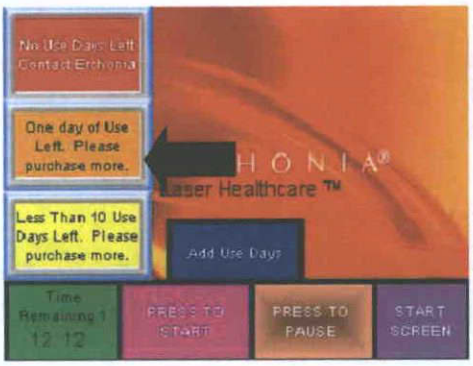
This device requires an update every 30 days from software installation. You are required to contact your distributor for an update code



NOTE: Notification will start to display on the protocol screen to inform you that you have 10 calendar days until the device will lockout any further treatments.

You must contact the distributor for a device update code and will only unlock once the code is imputed into the device.

Once the UPDATE DUE screen appears, it will remain until an update code is entered or the 10 days expire.



NOTE: Once the 10 days expire, the machine will stop operating and a notification will display on the touchscreen to advise you to CONTACT ERCHONIA FOR DEVICE UPDATE.

Warnings

1) The long-term effects of prolonged use of non-thermal laser exposure are not known.
2) The device should not be used over, or near, cancerous lesions, as conclusive tests have not been done.
3) The device should not be used when you are in the bath or shower because electrical shock may occur.
4) To avoid any possible danger to the eyes, do not shine the laser light directly into your eyes.
5) Keep the device out of the reach of children at all times.
6) Changes to the use of the laser controls or to the performance of treatments other than those specified in this manual may cause hazardous radiation exposure.

Cautions

1) Safety of non-thermal laser for use during pregnancy has not been shown.
2) Caution should be used over areas of skin that lack normal sensation (feeling).
3) The device should be used only with the parts recommended for use by the manufacturer.
4) Avoid any liquid getting into the device.
5) Avoid contact with flammable products, or with air with oxygen or nitrous oxide.
6) To ensure proper use and to mitigate the possibility of interference, avoid placing in close proximity to other electromagnetic devices.

NOTE: If due to misuse, failure to follow cautions or unforeseen circumstances the device is damaged, contact the manufacturer.

Maintenance & Cleaning

The Erchonia® MLS, Zerona™ device, if used according to the instructions in this manual will work well for years. For proper care, it is best to:

1. Do regular visual checks for signs of damage to the device other than normal wear and tear. If you are concerned about damage, please contact the manufacturer to see if action needs to be taken.
2. If you see a change in how the device works while in the ON position, please contact the manufacturer to see if action needs to be taken.
3. The inside parts of the device should not need any maintenance; however, if you think there is a problem because the device is not working well or is working differently than before, the device must be sent to the manufacturer.
4. Since the MLS, Zerona™ is placed on the floor and designed to be in conjunction with a table or chair for ease of the patient. The platform in which the patient's arm rests is to be cleaned using disinfectant wipes.
5. If during treatment any part of the device touches the skin, follow the cleaning process defined in step #4, to correct.
6. Fuses can be replaced by the end-user. The fuse holder is part of the power inlet module, see item #7, Device Description. To replace, pull open fuse drawer, remove spent fuse, insert new fuse rated at T2A 250V 100-240V~.5 – 1.5A, 50 – 60 Hz.

Disposal

The Erchonia® MLS, Zerona™ is a self-contained unit that gives out light energy and as such creates no byproducts that require control. However, as a courtesy Erchonia offers disposal services. To take advantage of the offer, when the device cannot be used properly and/or cannot be repaired, send to manufacturer for disposal.

Warranty Information

Detailed description of the Terms and Condition for warranty of the Erchonia® MLS, Zerona™ device.

Limited Warranty

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

Terms and Conditions

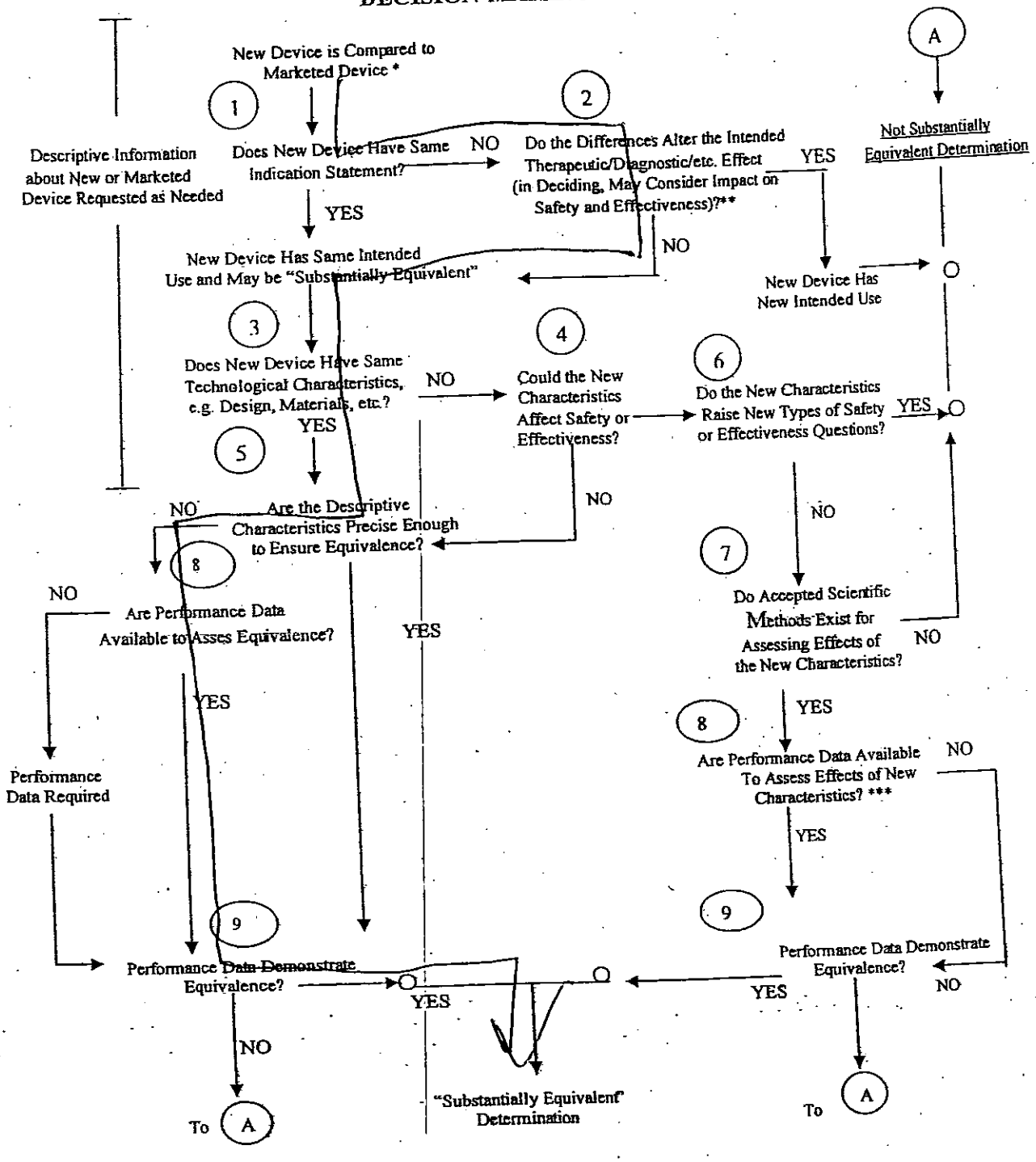
- Shipping for warranty repair and / or maintenance within the first 90 days will be paid for by the manufacturer.
- Shipping for warranty repair and / or maintenance after 90 days will be paid for by the consumer.
- Warranties of Erchonia Corporation products are not transferable unless sold by a company-approved distributor, reseller and/or leasing company.
- The warranty DOES NOT cover repair to damage caused by:

Accident, misuse or abuse
Lack of responsible care
Use of an unapproved power cord
Alteration to or disassembly of the device
Loss of parts
Exposure to the elements
Ingress of liquid (liquid entering the device)

Point of Contact

If for any reason, you are not satisfied with this product or have warranty concerns or questions about how to use the device, please call +1 888-242-0571 for immediate help.

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



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

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

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

K120257/S3
SU/DSRD

Regulatory Insight, Inc.

Worldwide Medical Device Submissions and Quality Systems

May 8, 2012

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

K120 MAY 09 2012

RE: Response to FDA's Request for Additional Information for K120257 - Erchonia® MLS, Zerona

Dear Mr. Felten,

The following is Erchonia Medical's response to FDA's request for additional information for 510(k) #K120257 for the Erchonia® MLS, Zerona, dated May 4, 2012, and communicated to Elvira Walls by telephone.

(b) (4)

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

(b) (4)

We hope the information provided in this response is sufficient for finding the Erchonia® MLS, Zerona substantially equivalent. Please let me know if you require any additional information or have any other questions or concerns.

Respectfully yours,

Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.

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

May 8, 2012

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

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Respectfully yours,

Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.

Indications for Use

510(k) Number (if known): _____

Device Name: Erchonia® MLS, Zerona™

Indications for Use: The Erchonia® MLS, Zerona™ is indicated for non-invasive dermatological aesthetic treatment for the reduction of the circumference of the upper arms.

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)

Acknowledgements & Accreditations

We at Erchonia ® Corporation would like to thank you for purchasing the Erchonia® MLS, Zerona™ device.

Erchonia ® Corporation is an ISO certified company and is audited from time to time by outside governing agencies, including the FDA, to be sure to stay in compliance with the highest quality standards. Our company operates according to and our devices are manufactured according with:

- FDA Good Manufacturing Practices
- ISO 9001 :2000 - Quality
- ISO 13485:2003 – Medical
- ISO 60825-1 - Laser Safety
- FDA Laser Class 2
- FDA Device Class II
- IEC Laser Class 2
- IEC Device Class 1
- MDD 93/42/EEC
- EN/IEC 60601-1-2 EMC
- EN/IEC EN60601-1-1 Safety
- Model Number: ARC
- Software Version ARM-E Rev A (1-9-12)
  - **ARM-E-TS Rev A**
  - **ARM-E-PLC Rev A**

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

Doc. No.	Issue Date	CR #	Revision	Rev Date
ARC-O&M	8/29/2011	Initial Release	1	1/11/2012

Legend:
The following symbols are used throughout this manual to show areas of concern. For your safety, and for the care of the device, please read and take note of these warnings and cautions.

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

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

Refers to the part of the medical device which comes into physical contact with the patient in order for the device to carry out its intended function.

US National Consideration:
When using in the US, the equipment is intended to be powered by a 120V source. If powered by a 240V source in the US, then the power source must be a center-tapped, 240V single phase circuit.

Erchonia® Corporation
2021 Commerce Dr. McKinney, TX 75069
Phone +1 888-242-0571 • Fax +1 214.544.2228
www.Erchonia.com
Patent(s): US – 6,013,096, Patent Pending

Table of Contents

Section 1

CAUTION: FEDERAL LAW RESTRICTS THE USE OF THIS DEVICE BY ORDER OF PHYSICIAN

Introduction to Contents

Identifies and describes each item included in the Erchonia ® laser package

The Erchonia ® MLS, ZERONA™ device package is made up of the following items:

- The Erchonia® MLS, ZERONA™ device.
- A power cord
- Operation & Maintenance manual
- Laser Safety Glasses
- 2 keys

In addition to the equipment items, we have included this Operation & Maintenance manual that contains:

- Written instructions for use and care
- Compliance information and label identification

Each Erchonia® device has been through a complete Quality Assurance check to be sure that you, the user, get the best quality product. Through the shipping process, it is possible that some loss or damage will occur. Please take the time to check that you have received each

item, and that each item looks to be in good working order.

The Erchonia® MLS, ZERONA Device

The Erchonia® MLS, ZERONA™ device is a self-contained device created for use of the reduction of circumference of the upper arms. It is easy to use, compact, all in one, mains powered unit.

The Erchonia® MLS, ZERONA™ device has been classified by the FDA as a Class 2 Laser product and a Class 2 in accordance to IEC 60825-1 (EU). These are the current standards for use that ensures the safety of the user.

Technical Information

Technical documentation required by international end-users, in case of necessary reparations, will be provided by our EU agent. These documents will be supplied once the manufacturer, working with the EU agent, makes the determination that the requested documents do not constitute a disclosure of priority or patent protected information and are a part of the filed and documented technical file.

Transportation and Storage

The unit must be stored and/or transported in conditions not to exceed -30 to +70ºC (-22 to +158ºF) @ 0-100% Relative Humidity Non-Condensing.

Description of the Erchonia® MLS, ZERONA device

Detailed description of the Erchonia® MLS, ZERONA™ device including labels and operating (how to use) instructions.

The Erchonia® MLS, ZERONA™ device contains five diodes, each a 635nm with a tolerance of ±5 nanometer. The diodes are specially created and patented electric diodes that emit greater than 5mW output and do not exceed FDA Laser Class 2.

The Erchonia® MLS, ZERONA™ device is made according to the FDA Good Manufacturing Practices, according to IEC / CE standards and in compliance to ISO standards. The Erchonia® MLS, ZERONA™ device is a Class II Medical device.

Each of these governing agencies asks for certain labeling. All required labels are fixed to the device according to the relevant codes. Each label is shown and described in Figure 2.

Intended Use

The MLS, ZERONA™ is intended for use of the reduction of circumference of the upper arms.

Device Identification

This section shows and describes the different parts of the Erchonia® MLS, ZERONA™ device. These are shown to help get familiar with the device and all of its parts to make sure the device operated properly. Fig 1 Shows the MLS, ZERONA device in three positions.

Fig. 1

1. Base Adjustment Lever (2)
2. Angle Adjustment Lever (2)
3. Touch Screen
4. Key Switch
5. Laser Output Head
6. Arm Rest Pad
7. Power Inlet Module/Fuse Holder

1) ***Base Adjustment Lever*** **–** On both sides of the base, there are two levers that when released (pulling away from device) allow the end used to adjust the height of the device. Once the desired height is obtained the levers must be locked (pressing towards the device) to support the weight of the patient's arm and laser heads. To adjust tension, rotate lever in a counter clockwise direction to tighten and clockwise direction to loosen.

Ensure to control the upper portion of the device when lowering by placing your hand under the arm rest to support the weight and slowly lower to desired height before locking levers in place. To adjust tension, rotate lever in a counter clockwise direction to tighten and clockwise direction to loosen. Over rotating may cause damage to the device

2) ***Angle Adjustment Lever*** – On both sides below the arm rest, there are two levers that when rotated counter clockwise will allow the end user to adjust the angle of the laser heads and arm rest.

Ensure to control the upper portion of the device when tilting by holding the arm rest raising/lowering slowly to desired angle before tightening levers. Rotate levers clockwise until tension is snug. Over rotating may cause damage to the device

3) ***Touch Screen*** **–** The touch screen functions as a display screen and an input panel, providing information to the end user and a means to operate the device by touching the appropriate icon.

4) ***Key Switch*** **–** The key switch is the ON/OFF mechanism, shown as "O" = off and "I" = on. After insertion turn it to the right to turn on. Because the device has 2 computers when you first turn it on it will take a few moments to initialize up before use. The unit will not operate unless key is in the ON position. Turning the key to the OFF position satisfies the FDA requirement for mechanical lock out, ensuring the safety of non-authorized users.

5) ***Laser Output Head*** – Each one of the five laser output heads emits a 635nm red laser light. Each laser contains electronic diodes, with patented optics. These diodes when activated generate laser energy thereby emitting red beam(s). This specially designed and patented laser diode was created to ensure the laser beam is focused and directed for the most optimal use.


The MLS, ZERONA device is classified as a Class 2 Laser. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 device is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging. To ensure there is no possible instance of residual effect, we have included a pair of specialty patient glasses for use by the patient during treatment.

6) ***Arm Rest Pad*** – The padded platform, in which the patient lays the arm on to be treated.


This is the only portion of the device that comes into physical contact with the patient. This pad can be removed for ease of cleaning. For cleaning, use a disinfectant wipe.

7) ***Power Inlet Module/Fuse Holder*** – the power cord, which plugs into mains, is detachable. This is the place 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. Fuses to be rated a T2A 250V with an input to cover 100 – 240V~ 1.5-.5A, 50-60 Hz. Ref: Maintenance section for replacement instructions.

Labeling

This 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.

The diagram above 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 label covers International criteria, each of the laser diodes (5) have a label affixed that show the direction of the laser beam output.

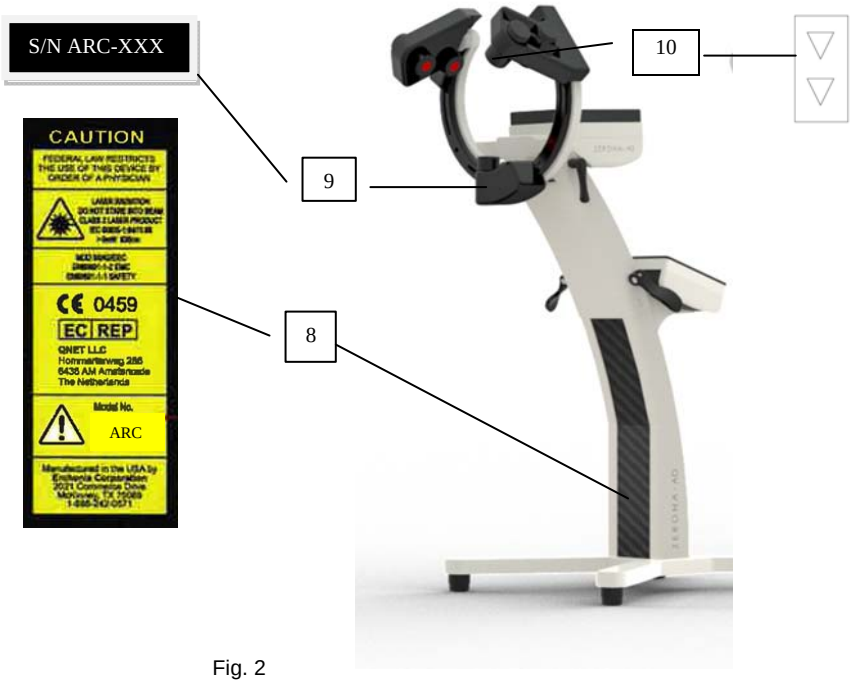


Fig. 2

8) Compliance Label – Contains all the governing agencies required information regarding the device, including but not limited to the US FDA device classification, EU classification, output information and power inlet symbols. Also includes the manufacturer name and address.

9) Serial Number **–** The unique identifier for the device. All information regarding this unit is associated with the serial number.

10)Laser Output – Each of the laser diodes (5) have a label affixed that show the direction of the laser beam output.

Visual Inspection

This completes the listing and the description of the parts of the Erchonia® MLS, ZERONA™ device. Once you are familiar with each part and you are sure that each part is in good working order, read the next section.

Protocol -- Non-invasive Dermatological Aesthetic Protocol for the Reduction of Circumference of the Upper Arms

1. Each patient receives six total procedures administered across a two-week time frame; three procedures per week; each one at least two days, but no more than three days, apart.
2. Each procedure administration will take a total of 40 minutes; 20 minutes per arm.
3. The procedure administration protocol for each session is as follows:
    a. The patient lies comfortably on his or her stomach on the treatment table, extending his or her right arm to rest at a 90 degree angle to his or her body flat on the treatment table, palm down.
    b. The patient is correctly fitted with the laser safety glasses.
    c. The fixed center diode of the device is positioned at a distance of 6.00 inches above the skin and directed on the patient's mid upper arm.
    d. The other four rotating diodes are positioned 120 degrees apart and tilted 30 degrees off the centerline (mid upper arm) of the center scanner.
    e. The device is activated for 20 minutes. The 5 rotating diodes emit a laser beam of approximately 17 mW with a wavelength of 635 nm red light. Each diode 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.
    f. This process is repeated for the patient's left arm.
    g. The patient removes the laser safety glasses and the session is over.

Mechanical Instructions for Use: How to Use the Device

To turn the device ON, place the key in the key lock and turn to the ON position. **NOTE:** The device 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 manufactures logo.

Press “>>Touch Here to Enter Treatment Screen<<” button, this will take you to the pre-set protocol screen. Press “PRESS TO START” button to begin the non-invasive arm reduction 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.

The device is preprogrammed to treat for a total of twenty minutes. Therefore in twenty minutes you will need to position the device on the second arm, manipulate the laser heads, and then press “PRESS TO START” button to continue with the remainder of the application. When done return the key to the OFF position.

Manufacturer Information

The manufacturer’s name, address and telephone number, as shown below.

Manufacturer Information

Erchonia ® Corporation
2021 Commerce Drive
McKinney, Texas 75069 USA
+1 888-242-0571
www.Erchonia.com

Distributor Information

Erchonia ® Corporation
2021 Commerce Drive
McKinney, Texas 75069 USA
+1 888-242-0571
www.Erchonia.com

Section 3

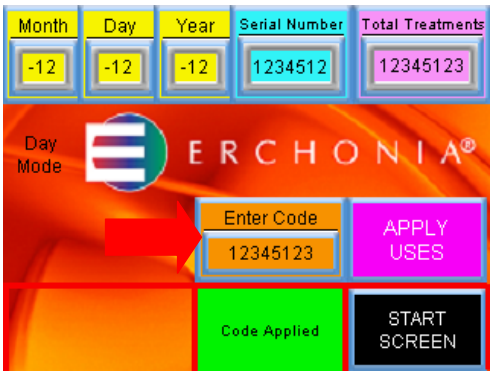
Activate Treatment Protocol

### Operating the Device Press “Touch Here to Enter Treatment Screen” button, this will take you to the Erchonia Preset Protocol (Mode) Selection screen.	
Press “PRESS TO START” button to begin the non-invasive arm reduction 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.	

Device Update

This device requires an update every 30 days from software installation. You are required to contact your distributor for an update code **NOTE: Notification will start to display on the protocol screen to inform you that you have 10 calendar days until the device will lockout any further treatments.** **You must contact the distributor for a device update code and will only unlock once the code is imputed into the device.**	
Once the UPDATE DUE screen appears, it will remain until an update code is entered or the 10 days expire. **NOTE: Once the 10 days expire, the machine will stop operating and a notification will display on the touchscreen to advise you to CONTACT ERCHONIA FOR DEVICE UPDATE.**	
To enter the update code, tap the circled E of the Erchonia logo on the Introductory Splash Screen. The “Add Use Days” button will appear also displaying the device Serial Number.	

Tap the “Add Use Days” button. This will take you to the “Day Mode” screen. To enter the update code, tap the “Enter Code” box, an entry screen will appear.

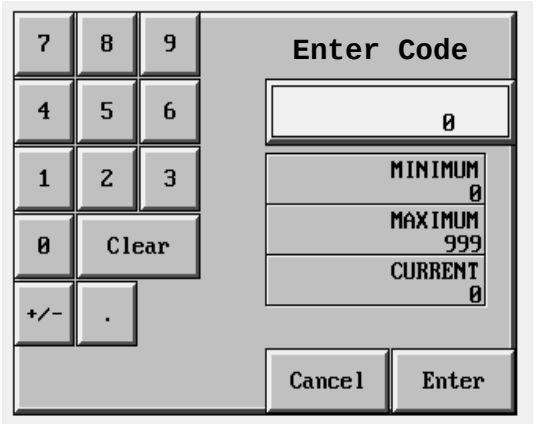


Enter the code received from the Distributor by selecting one number at a time, reading left to right. When the number in total appears in the field under ENTER CODE, tap enter.

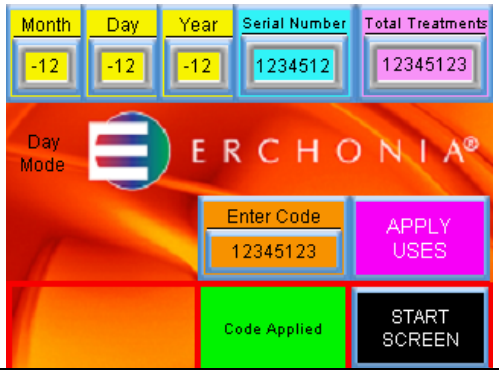
Code entered will display in the “Enter Code” icon

Tap the “APPLY USES” icon

A green flashing icon reading ‘Code Applied” will appear under the “Update Code” box.



NOTE: If Code is entered incorrectly, a flashing red icon will appear under the “Update Code” box displaying “Incorrect Code”. Repeat code entry process.



Application and Administration

The Erchonia MLS, Zerona device is intended for the reduction of circumference of the upper arms. Below is the summary of the clinical trial and the results of same.

Clinical Trial Summary

AN EVALUATION OF THE EFFECTIVENESS OF THE ERCHONIA® ML SCANNER (MLS) AS A NON-INVASIVE DERMATOLOGICAL AESTHETIC TREATMENT FOR THE REDUCTION OF CIRCUMFERENCE OF THE UPPER ARMS
Erchonia Corporation

BACKGROUND: The purpose of this clinical study was to demonstrate the effectiveness of the Erchonia® ML Scanner (MLS) for non-invasive body contouring of the upper arms by applying the MLS to the upper arms 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 two (62) subjects completed this study. Of the 62 participating subjects, 31 were randomized to the active procedure group and 31 were randomized to the placebo group.

Subjects were those aged 18 to 65 years who were deemed suitable for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that had failed to respond to diet and exercise; specifically for the indication of body contouring of the bilateral upper arms, as per the American Academy of Cosmetic Surgery's 2006 Guidelines for Liposuction Surgery developed by a joint Ad Hoc Committee of the American Society of Liposuction Surgery (ASLSS) and the American Academy of Cosmetic Surgery (AACS), and/or for the procedure of brachioplasty (upper arm lift).

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

Table 1: Table of Subject Demographics

Gender	**Female**		**Male**	
n=62	*number*	*%*	*number*	*%*
	60	97%	2	3%
Ethnicity	**Caucasian**		**Hispanic**	
n=62	*number*	*%*	*number*	*%*
	37	60%	21	34%
	African American		**Caucasian/African American**	
	number	*%*	*number*	*%*
	2	3%	2	3%

STUDY MEASURES: Circumference measurements at three points on the upper arms, and body mass index (BMI) were recorded at baseline, study mid-point (week 1), study endpoint

(week 2), and study follow-up two weeks later. Subject satisfaction with the procedure outcome was recorded at study endpoint.

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

Table 2: Mean Baseline measurements

	Test Group n=31	**Placebo Group n=31**
Body Mass Index (BMI)	29.57	30.57
Right Upper Arm Circumference (cms.)	95.67	94.66
Left Upper Arm Circumference (cms.)	95.81	94.92

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

STUDY PROCEDURE: Subjects received six procedure administrations with the Erchonia® MLS to the right and left upper arms, across a consecutive two-week period: three procedures per week, each procedure two to three days apart.

STUDY RESULTS

(i) Total Circumference Measurements: The study primary outcome measure was based on individual circumference measurements taken at 3 points along each of the subject's upper arms combined to attain a single circumference measurement for each of the right arm and the left arm, separately.

It was pre-determined that a subject would be considered a study success if he or she attained a 1.25 cm or greater reduction in combined circumference measurement for each of the right and left upper arms, separately, from baseline to study endpoint (after completion of the two-week procedure phase).

58% of subjects who received the study procedures with the actual Erchonia® MLS attained a decrease in combined circumference measurement of 1.25 cms or greater for each of the right and left upper arms, separately, compared with 3% 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 55% to be statistically significant at $p<0.000005$.

The mean change in total circumference for subjects who received the study procedures with the actual Erchonia® MLS was a decrease of 1.85 cms for the right upper arm, a decrease of 1.84 cms for the left upper arm and decrease of 3.70 cms for both upper arms combined. The mean change in total circumference for subjects who received the study procedures with the

'fake' (placebo) laser device was a decrease of 0.08 cms for the right upper arm, a decrease of 0.23 cms for the left upper arm and decrease of 0.31 cms for both upper arms combined.

Paired samples t-tests found the changes in upper arm circumference measurements for subjects in the test group to be statistically significant, as shown in Table 3 below. The changes in upper arm circumference measurements for subjects in the placebo group were not found to be statistically significant, as shown in Table 4 below.

Table 3: Paired samples t-tests for test group subjects

Test Group	μa-μb	t	df	p(two-tailed)	significance
Right Arm	1.855	+9.61	30	<0.0001	p<0.0001
Left Arm	1.842	+8.98	30	<0.0001	p<0.0001
Right & Left Arms	3.70	+10.65	30	<0.0001	p<0.0001

Table 4: Paired samples t-tests for placebo group subjects

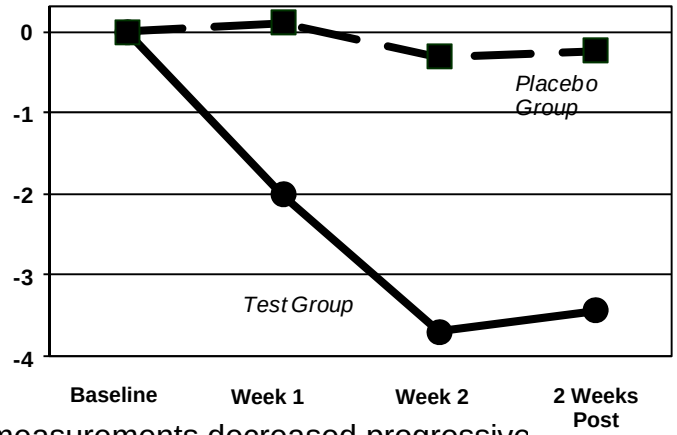
Placebo Group	μa-μb	t	df	p(two-tailed)	p	significance
Right Arm	0.0806	+0.83	30	0.413	p>0.05	Not significant
Left Arm	0.23	+1.95	30	0.061	p>0.05	Not significant
Right & Left Arms	0.31	+1.67	30	0.105	p>0.05	Not significant

Table 5 and Chart 1 below show the mean change in total upper arm circumference measurements (right and left arms combined) across the four study measurement time points.

Table 5: Mean total circumference measurements (cms) across evaluation points

	Test Group	Placebo Group
Baseline	191.48	189.58
Midpoint (week 1)	189.47	189.69
Endpoint (week 2)	187.78	189.27
Follow-up (week 4)	188.04	189.34

Chart 1: Mean change in total upper arm circumference measurements (cms) at each study evaluation point relative to baseline



For test group subjects, total circumference measurements decreased progressively from baseline across the procedure administration phase, indicating a progressive and cumulative treatment effect of the laser. However, for placebo group subjects, total circumference measurements were unchanged across the procedure administration phase relative to baseline.

Total circumference measurements stabilized for test group subjects across the subsequent 2-week follow-up assessment period during which time no laser procedures were administered, indicating duration of the treatment effect up to at least 2 weeks following the end of laser procedure administration.

(ii) Change in body mass index (BMI): BMI measurements did not change significantly across and between any of the evaluation time points for either test or placebo subject groups. However, upper arm circumference measurements did change significantly across and between evaluation points for test group subjects but not for placebo group subjects. This combined finding further supports the effectiveness of the Erchonia® MLS device as it demonstrates that the change in body shape (reduction in cms for the upper arms) attained for test group subjects in this study at this test site resulted from the Erchonia® MLS device applications and not from change in body mass index as a result of incidental weight loss.

(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 upper arms attained using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied.

65% of test group subjects reported being 'Satisfied' (Very or Somewhat Satisfied) with the outcome of the study procedures compared with 22% 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® MLS is an effective tool for body contouring, significantly reducing circumference measurements when applied to the bilateral upper arms over a 2-week period.

Warnings/Cautions

Any device, if not used properly, can harm the user and / or damage the unit. Each governing agency concerned with the health and welfare of humanity has listed possible hazards and made suggestions to protect the user and reduce the risk of using damaged products. By following the WARNINGS and CAUTIONS listed below, you will reduce the risk of harm to yourself or patient and damage to the MLS, ZERONA™ device.

Warnings

1) The long-term effects of prolonged use of non-thermal laser exposure are not known.
2) The device should not be used over, or near, cancerous lesions, as conclusive tests have not been done.

3) The device should not be used when you are in the bath or shower because electrical shock may occur.
4) To avoid any possible danger to the eyes, do not shine the laser light directly into your eyes.
5) Keep the device out of the reach of children at all times.
6) Changes to the use of the laser controls or to the performance of treatments other than those specified in this manual may cause hazardous radiation exposure.

Cautions

1) Safety of non-thermal laser for use during pregnancy has not been shown.
2) Caution should be used over areas of skin that lack normal sensation (feeling).
3) The device should be used only with the parts recommended for use by the manufacturer.
4) Avoid any liquid getting into the device.
5) Avoid contact with flammable products, or with air with oxygen or nitrous oxide.
6) To ensure proper use and to mitigate the possibility of interference, avoid placing in close proximity to other electromagnetic devices.

NOTE: If due to misuse, failure to follow cautions or unforeseen circumstances the device is damaged, contact the manufacturer.

Maintenance & Cleaning

The Erchonia® MLS, ZERONA™ device, if used according to the instructions in this manual will work well for years. For proper care, it is best to:

1. Do regular visual checks for signs of damage to the device other than normal wear and tear. If you are concerned about damage, please contact the manufacturer to see if action needs to be taken.

2. If you see a change in how the device works while in the ON position, please contact the manufacturer to see if action needs to be taken.

3. The inside parts of the device should not need any maintenance; however, if you think there is a problem because the device is not working well or is working differently than before, the device must be sent to the manufacturer.

4. Since the MLS, ZERONA™ is placed on the floor and designed to be in conjunction with a table or chair for ease of the patient. The platform in which the patient's arm rests is to be cleaned using disinfectant wipes.

5. If during treatment any part of the device touches the skin, follow the cleaning process defined in step #4, to correct.

6. Fuses can be replaced by the end-user. The fuse holder is part of the power inlet module, see item #7, Device Description. To replace, pull open fuse drawer, remove spent fuse, insert new fuse rated at T2A 250V 100-240V~.5 – 1.5A, 50 – 60 Hz.

Disposal

The Erchonia® MLS, ZERONA™ is a self-contained unit that gives out light energy and as such creates no byproducts that require control. However, as a courtesy Erchonia offers disposal services. To take advantage of the offer, when the device cannot be used properly and/or cannot be repaired, send to manufacturer for disposal.

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Section 4

Warranty Information

Detailed description of the Terms and Condition for warranty of the Erchonia® MLS, ZERONA™ device.

Limited Warranty

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

Terms and Conditions

- Shipping for warranty repair and / or maintenance within the first 90 days will be paid for by the manufacturer.
- Shipping for warranty repair and / or maintenance after 90 days will be paid for by the consumer.
- 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 repair to damage caused by:

Accident, misuse or abuse
Lack of responsible care
Use of an unapproved power cord
Alteration to or disassembly of the device
Loss of parts
Exposure to the elements
Ingress of liquid (liquid entering the device)

Point of Contact

If for any reason, you are not satisfied with this product or have warranty concerns or questions about how to use the device, please call +1 888-242-0571 for immediate help.

ERCHONIA® ML Scanner (MLS)

Follow-Up to:
An evaluation of the effectiveness of the Erchonia® ML Scanner (MLS) as a non-invasive dermatological aesthetic treatment for the reduction of circumference of the upper arms

Version 1.1; January 4, 2011

Follow-up Results Report

ERCHONIA CORPORATION

February 16, 2012

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(b)(4) Test Data

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

March 23, 2012

ERCHONIA MEDICAL, INC.
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT
GREENWOOD VILLAGE, COLORADO 80127
ATTN: KEVIN WALLS

510k Number: K120257

Product: MLS, ZERONA-AD

The additional information you have submitted has been received.

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

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

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

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

Sincerely,

510(k) Staff

57

Grayson, Giovanna *

From: Microsoft Outlook
To: 'kevin@reginsight.com'
Sent: Friday, March 23, 2012 8:50 AM
Subject: Relayed: Ack Letter

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

'kevin@reginsight.com'

Subject: Ack Letter

Sent by Microsoft Exchange Server 2007

58

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Friday, March 23, 2012 8:50 AM
To: 'kevin@reginsight.com'
Subject: Ack Letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 23, 2012
WALLS
KEVIN
ERCHONIA MEDICAL, INC.
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT
GREENWOOD VILLAGE, COLORADO 80127
ATTN: KEVIN WALLS

510k Number: K120257

Product: MLS, ZERONA-AD

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Sincerely,

510(k) Staff

K120257/S1

Regulatory Insight, Inc.

Worldwide Medical Device Submissions and Quality Systems

March 21, 2012

FDA CDRH

MAR 22 2012

Mr. Richard Felten
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: Response to FDA's Request for Additional Information for K120257 - Erchonia® MLS, Zerona

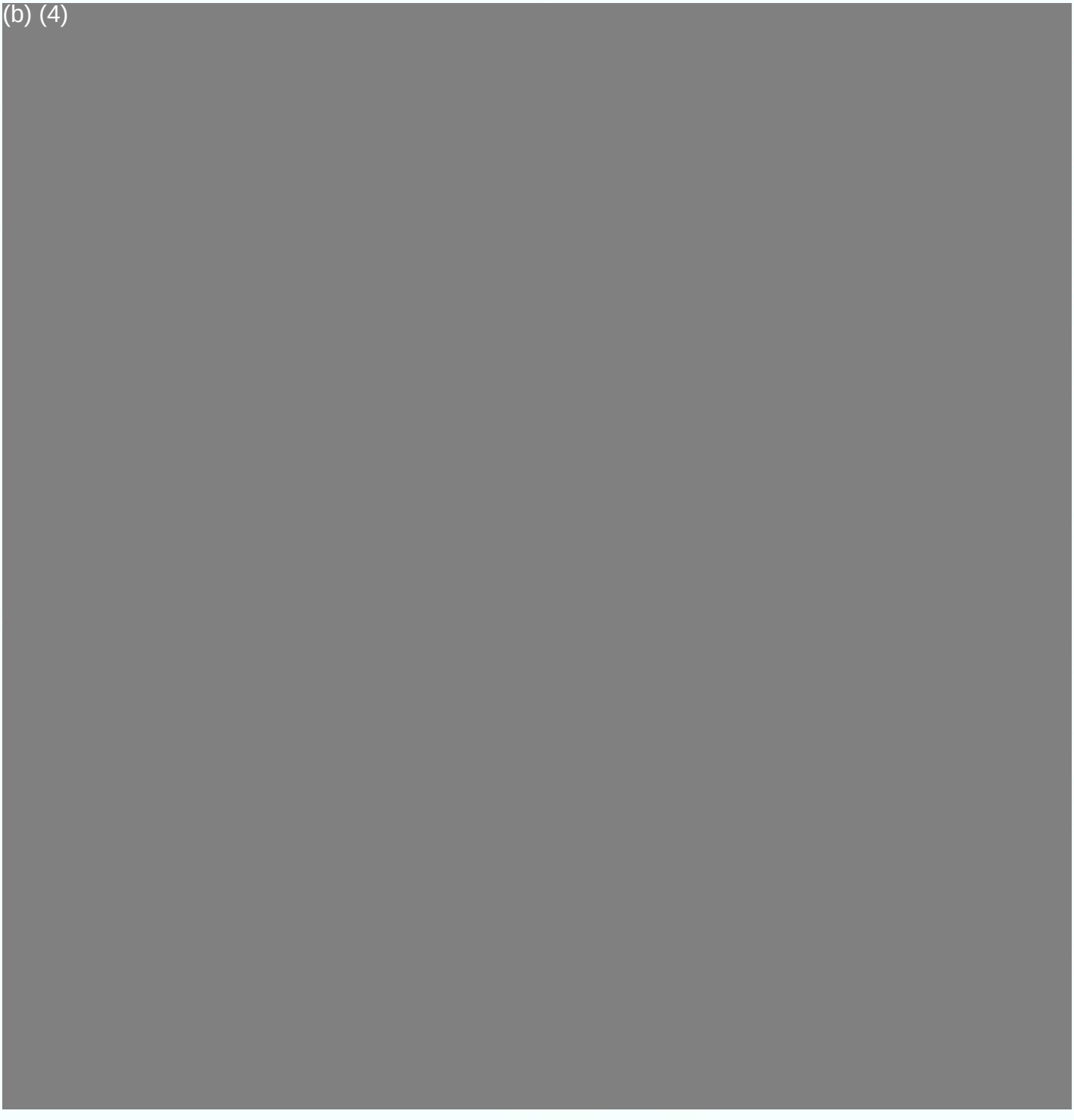
Dear Mr. Felten,

The following is Erchonia Medical's response to FDA's request for additional information for 510(k) #K120257 for the Erchonia® MLS, Zerona, dated March 16, 2012, and sent to me by email.

(b) (4)

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

(b) (4)



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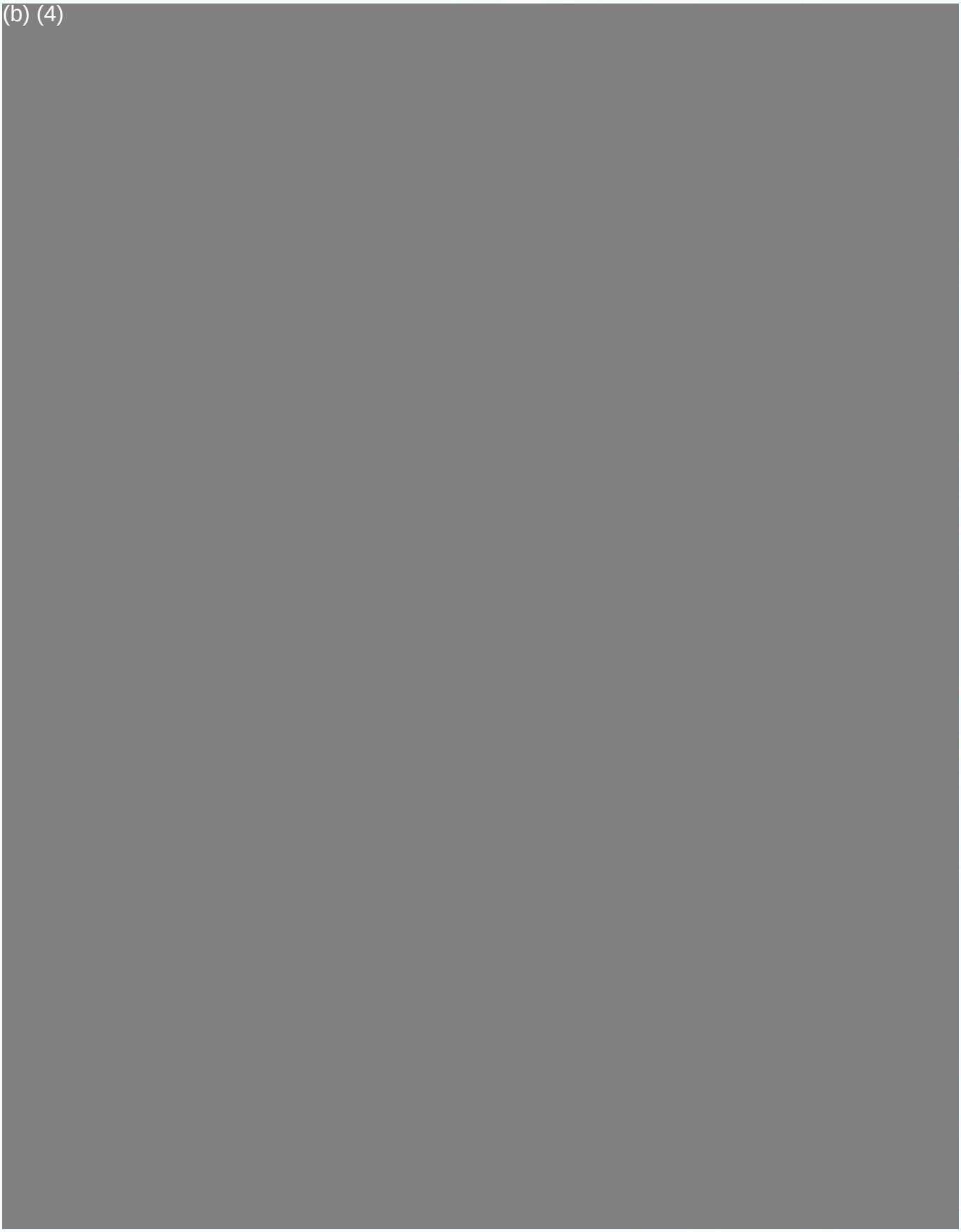

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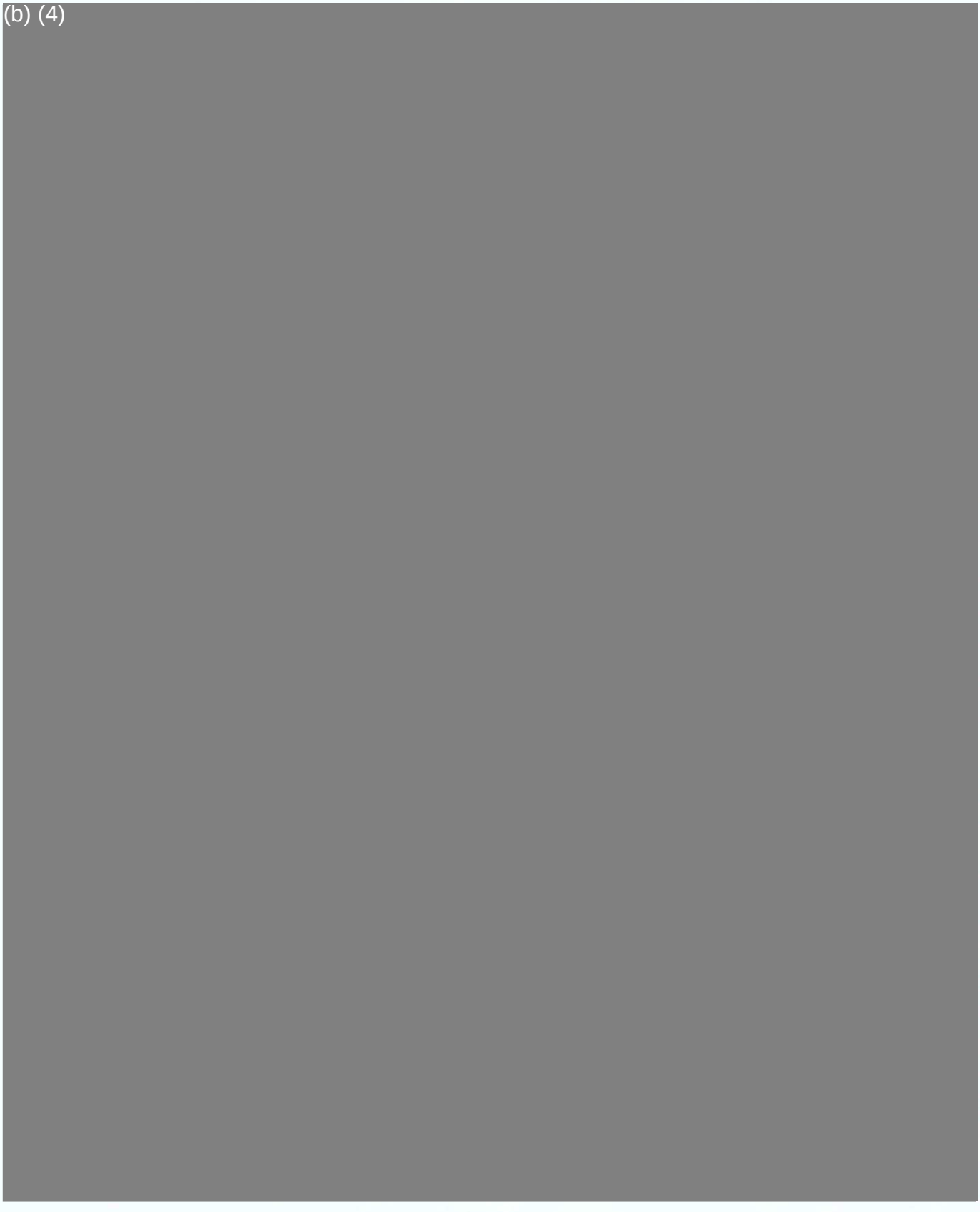

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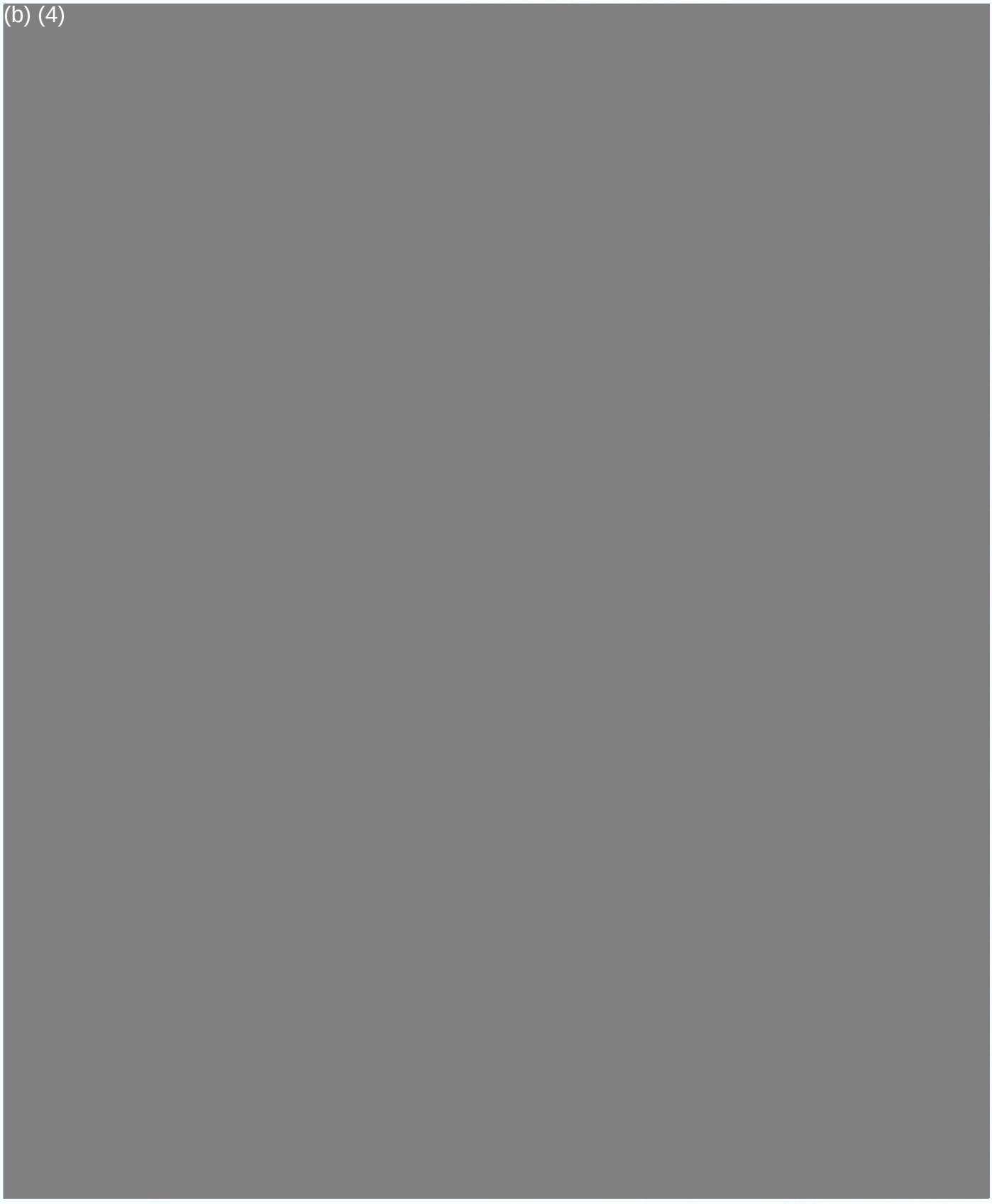


(b) (4)

We hope the information provided in this response is sufficient for finding the Erchonia® MLS, Zerona substantially equivalent. Please let me know if you require any additional information or have any other questions or concerns.

Respectfully yours,

Kevin Walls, RAC
Principal Consultant
Regulatory Insight, Inc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
03/14/2012	(b) (4)	K120257

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

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

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

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

PSC Publishing Services (301) 443-6740 EF

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

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

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

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

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

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

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

- ☐ Response to FDA correspondence:

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

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

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

- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	OLI	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K082609	1	ML Scanner	1	Erchonia
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	MLS, Zerona™	1	
2		2	
3		3	
4		4	
5		5	

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

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

Data Included in Submission

- ☐ Laboratory Testing
- ☐ Animal Trials
- ☒ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

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

Indications *(from labeling)*

The Erchonia® The MLS ZERONA™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring and as a non-invasive dermatological aesthetic treatment for the reduction of circumference of the upper arm.

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

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Erchonia Medical, Inc.		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: Steven Shanks	Contact Title: President	Contact E-mail Address: SShanks@erchonia.com	

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

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

SECTION I — UTILIZATION OF STANDARDS

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

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

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

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

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

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

Indications for Use

510(k) Number (if known): K120257

Device Name: Erchonia® MLS, Zerona™

Indications for Use: The MLS, Zerona™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring and as a non-invasive dermatological aesthetic treatment for the reduction of circumference of the upper arm.

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)

Acknowledgements & Accreditations

We at Erchonia ® Corporation would like to thank you for purchasing the Erchonia® MLS, Zerona™ device.

Erchonia ® Corporation is an ISO certified company and is audited from time to time by outside governing agencies, including the FDA, to be sure to stay in compliance with the highest quality standards. Our company operates according to and our devices are manufactured according with:

- FDA Good Manufacturing Practices
- ISO 9001 :2000 - Quality
- ISO 13485:2003 – Medical
- ISO 60825-1 - Laser Safety
- FDA Laser Class 2
- FDA Device Class II
- IEC Laser Class 2
- IEC Device Class 1
- MDD 93/42/EEC
- EN/IEC 60601-1-2 EMC
- EN/IEC EN60601-1-1 Safety
- Model Number: ARC
- Software Version ARM-E Rev A (1-9-12)
  - **ARM-E-TS Rev A**
  - **ARM-E-PLC Rev A**

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

Doc. No.	Issue Date	CR #	Revision	Rev Date
MLS-O&M MLS Zerona	1/11/2012	510(k) Release	0	1/11/2012

Legend:
The following symbols are used throughout this manual to show areas of concern. For your safety, and for the care of the device, please read and take note of these warnings and cautions.

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

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

Refers to the part of the medical device which comes into physical contact with the patient in order for the device to carry out its intended function.

US National Consideration:
When using in the US, the equipment is intended to be powered by a 120V source. If powered by a 240V source in the US, then the power source must be a center-tapped, 240V single phase circuit.

Erchonia® Corporation
2021 Commerce Dr. McKinney, TX 75069
Phone +1 888-242-0571 • Fax +1 214.544.2228
www.Erchonia.com
Patent(s): US – 6,013,096, Patent Pending

CAUTION: FEDERAL LAW RESTRICTS THE USE OF THIS DEVICE BY ORDER OF PHYSICIAN

MLS, Zerona Components

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

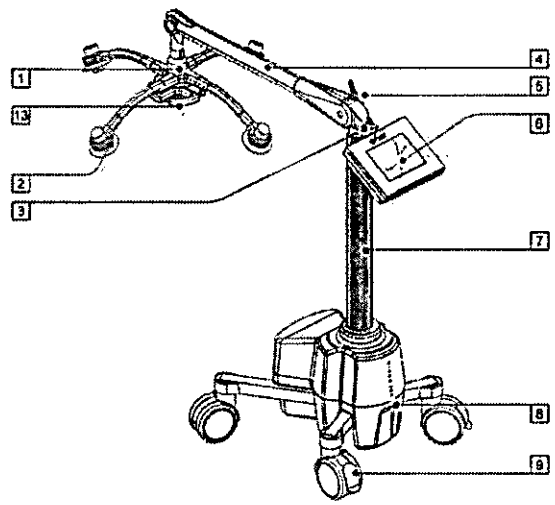


Fig. 1

1. Laser Head Assembly
2. Laser Output Head
3. Power Safety Lockout Key
4. Laser Arm
5. Arm Lock
6. Touch screen Control Surface
7. Main Upright of Base
8. Power Inlet
9. Rear Wheel Lock
10. Electrical Connector – (Page 4)
11. Locking Nut – (Page 4)
12. Power Cord – not shown
13. Handle

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].

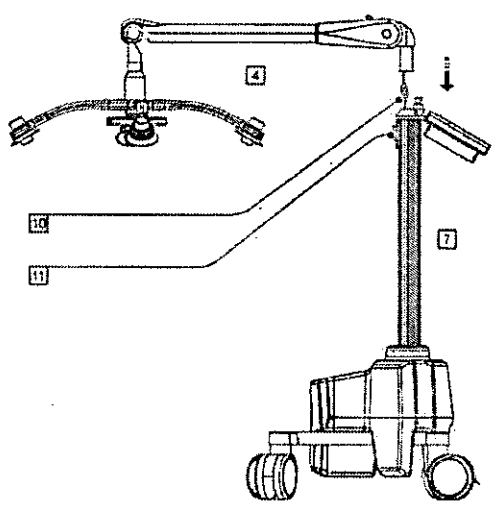


Fig. 2

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

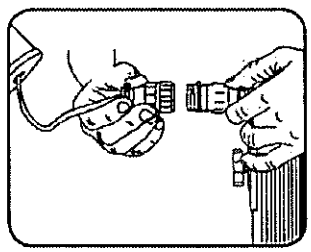


Fig. 3

Step 2:

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

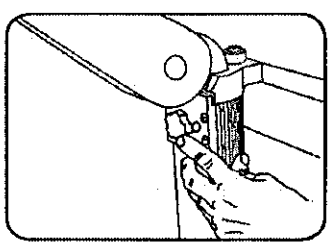


Fig. 4

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

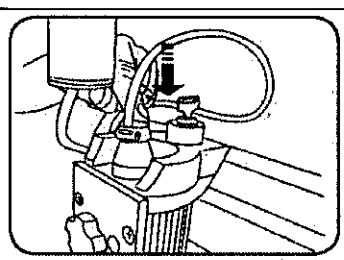


Fig. 5

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.

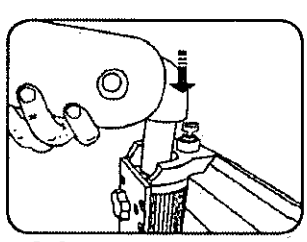


Fig. 6

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 treaded 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.

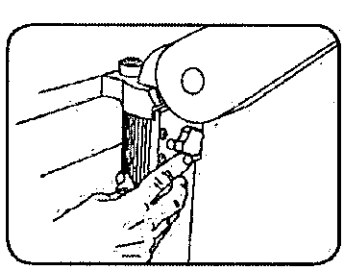


Fig. 7

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.

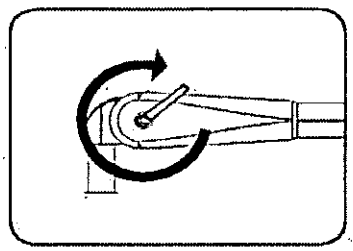


Fig. 8

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.

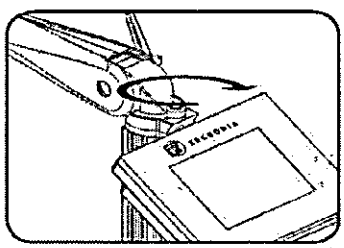


Fig. 9

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.

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.

When moving the head assembly into the desired position, make sure to use the handle on the side of the head assembly (fig 1, #13) 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.

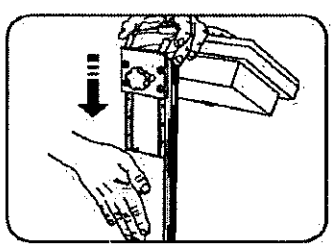


Fig. 10

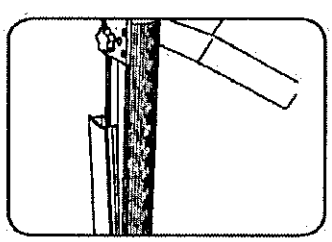


Fig. 11

Introduction to Contents

The Erchonia® MLS, Zerona™ laser package is comprised of (1) MLS, Zerona, (1) pair of patient protective eyewear, (1) Power Cord, (2) Keys, and this user guide. The components of this package are detailed below.

Erchonia® MLS, Zerona ™

The Erchonia® MLS, Zerona™ is made up of five independent 635 nanometer diodes. Laser devices are typically constructed to emit a "spot" of light. The Erchonia® MLS, Zerona™ laser utilizes internal mechanics that collects the light emitted from the diode and processes through a proprietary patented lens which redirects the beam with a line refractor. The lines generated by each head are rotated via a patented rotation device that operates independent of each other to ensure thorough coverage. The target area is approximately 8" x 10" inches or 80 square inches, approximately 516 square centimeters.

Power

The power switch is the key switch on top of the Touch screen, ref Item 3, FIG 1. The unit will not operate unless key is in the ON position. Turning the key to the OFF position satisfies the FDA requirement for mechanical lock out, ensuring the safety of non-authorized users. The power switch has a fail-safe system which ensures the 110/240 voltage from a wall socket can never come in contact with the user. The system uses a 2 amp fuse, which will only require replacement if there is an issue. To replace, locate fuse holder in back of base unit, pull fuse holder out of enclosure, replace fuses and reinsert. Use only rated T2A 250V. The device includes a transformer which converts AC power to match the power output i.e. 110V or 240V. Only a plug prong adaptor is required (available at any retail electronics store). Once the adaptor is affixed to the plug end, put into wall socket. Input: 100-240V-0.5-1.5A 50-60 Hz.

NOTE: Make sure the power cord is plugged into device 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. Fuses to be rated a T2A 250V with an input to cover 100 – 240V~ 1.5-.5A, 50-60 Hz.

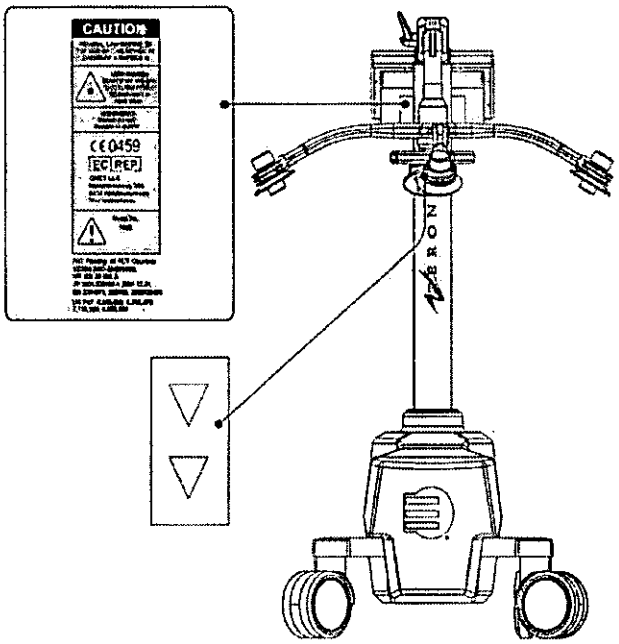
Protective Eyewear

The Erchonia® MLS, Zerona™ is classified as a Class 2 laser. This designation represents a current standard for use in order to ensure the safety of the patient.

The MLS, Zerona™ device is classified as a Class 2 Laser. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 device is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging. To ensure there is no possible instance of residual effect, we have included a pair of specialty patient glasses for use by the patient during treatment

Labeling

The 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 2 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.



Manufacturer and Distributor Information

Manufacturer's Information
Erchonia Corporation
2021 Commerce Dr.
McKinney, TX. USA 75069
+1.214.544.2227

Distributor Information
Erchonia Corporation
2021 Commerce Dr.
McKinney, TX. USA 75069
+1.214.544.2227

The Erchonia® MLS, Zerona™ Device

The Erchonia® MLS, Zerona™ device is a self-contained device created for use of non-invasive dermatological aesthetic treatment for body contouring. It is easy to use, compact, all in one, mains powered unit.

The Erchonia® MLS, Zerona™ device has been classified by the FDA as a Class 2 Laser product and a Class 2 in accordance to IEC 60825-1 (EU). These are the current standards for use that ensures the safety of the user.

Technical Information

Technical documentation required by international end-users, in case of necessary reparations, will be provided by our EU agent. These documents will be supplied once the manufacturer, working with the EU agent, makes the determination that the requested documents do not constitute a disclosure of priority or patent protected information and are a part of the filed and documented technical file.

Transportation and Storage

The unit must be stored and/or transported in conditions not to exceed -30 to +70ºC (-22 to +158ºF) @ 0-100% Relative Humidity Non-Condensing.

Intended Use

The MLS, Zerona™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring and as a non-invasive dermatological aesthetic treatment for the reduction of circumference of the upper arm.

Visual Inspection

This completes the listing and the description of the parts of the Erchonia® MLS, Zerona™ device. Once you are familiar with each part and you are sure that each part is in good working order, read the next section.

Protocol -- Non-invasive Dermatological Aesthetic Protocol for the Upper Arms

1. Each patient receives six total procedures administered across a two-week time frame; three procedures per week; each one at least two days, but no more than three days, apart.
2. Each procedure administration will take a total of 40 minutes; 20 minutes per arm.
3. The procedure administration protocol for each session is as follows:
    a. The patient lies comfortably on his or her stomach on the treatment table, extending his or her right arm to rest at a 90 degree angle to his or her body flat on the treatment table, palm down.
    b. The patient is correctly fitted with the laser safety glasses.
    c. The fixed center diode of the device is positioned at a distance of 6.00 inches above the skin and directed on the patient's mid upper arm.
    d. The other four rotating diodes are positioned 120 degrees apart and tilted 30 degrees off the centerline (mid upper arm) of the center scanner.
    e. The device is activated for 20 minutes. The 5 rotating diodes emit a laser beam of approximately 17 mW with a wavelength of 635 nm red light. Each diode 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.
    f. This process is repeated for the patient's left arm.
    g. The patient removes the laser safety glasses and the session is over.

Protocol -- Non-invasive Dermatological Aesthetic Protocol for the Front of the Body

1. The patient lies comfortably flat on his or her back on the table such that the front area of the patient's body encompassing the region spanning from the patient's stomach (abdomen) down through the hips and frontal aspect of both thighs, is facing upwards.

2. The center diode of the Erchonia® MLS, Zerona™ is positioned at a distance of 6.00 inches above the patient, centered along the body's midline (the "line" that vertically "dissects" the body into two equal halves).
3. The Erchonia® MLS, Zerona™ is activated for 20 minutes. Each scanner emits to the patient a laser beam of approximately 17mW with a wavelength of 635 nm, and creates a spiraling circle pattern that is totally random and independent from the others. These patterns overlap each other to guarantee total coverage within the target area of approximately 516 square centimeters.

Protocol -- Non-invasive Dermatological Aesthetic Protocol for the Back of the Body

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

Clinical Trial Summary

A DOUBLE-BLIND, PLACEBO-CONTROLLED RANDOMIZED EVALUATION OF THE EFFECT OF THE ERCHONIA® ML SCANNER (MLS) ON BODY CONTOURING OF THE WAIST, HIPS AND THIGHS.
Erchonia Medical. Inc.

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

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

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

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

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

Table 1: Table of Subject Demographics

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

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

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

Table 2: Mean Baseline measurements

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

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

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

STUDY RESULTS

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

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

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

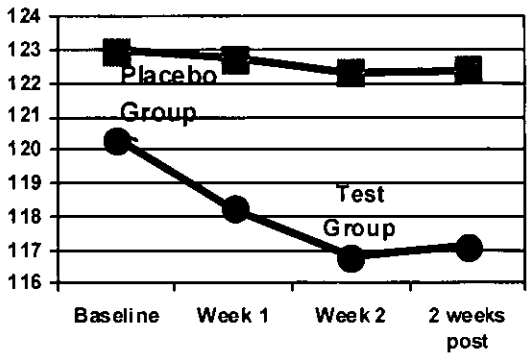
The magnitude of the mean change in total circumference measurement was a decrease of 3.521 inches for subjects who received the study procedures with the actual Erchonia® MLS and a decrease of 0.684 inches for subjects who received the study procedures with a 'fake' (placebo) laser device. A t-test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

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

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

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

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



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

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

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

Table 4: Mean individual body area circumference measurements.

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

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

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

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

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

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

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

AN EVALUATION OF THE EFFECTIVENESS OF THE ERCHONIA® ML SCANNER (MLS) AS A NON-INVASIVE DERMATOLOGICAL AESTHETIC TREATMENT FOR THE REDUCTION OF CIRCUMFERENCE OF THE UPPER ARMS
Erchonia Corporation

BACKGROUND: The purpose of this clinical study was to demonstrate the effectiveness of the Erchonia® MLS, Zerona™ for non-invasive body contouring of the upper arms by applying the MLS, Zerona™ to the upper arms 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 two (62) subjects completed this study. Of the 62 participating subjects, 31 were randomized to the active procedure group and 31 were randomized to the placebo group.

Subjects were those aged 18 to 65 years who were deemed suitable for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that had failed

to respond to diet and exercise; specifically for the indication of body contouring of the bilateral upper arms, as per the American Academy of Cosmetic Surgery's 2006 Guidelines for Liposuction Surgery developed by a joint Ad Hoc Committee of the American Society of Liposuction Surgery (ASLSS) and the American Academy of Cosmetic Surgery (AACS), and/or for the procedure of brachioplasty (upper arm lift).

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

Table 1: Table of Subject Demographics

Gender	**Female**		**Male**	
n=62	*number*	*%*	*number*	*%*
	60	97%	2	3%
Ethnicity	**Caucasian**		**Hispanic**	
n=62	*number*	*%*	*number*	*%*
	37	60%	21	34%
	African American		**Caucasian/African American**	
	number	*%*	*number*	*%*
	2	3%	2	3%

STUDY MEASURES: Circumference measurements at three points on the upper arms, and body mass index (BMI) were recorded at baseline, study mid-point (week 1), study endpoint (week 2), and study follow-up two weeks later. Subject satisfaction with the procedure outcome was recorded at study endpoint.

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

Table 2: Mean Baseline measurements

	Test Group n=31	**Placebo Group n=31**
Body Mass Index (BMI)	29.57	30.57
Right Upper Arm Circumference (cms.)	95.67	94.66
Left Upper Arm Circumference (cms.)	95.81	94.92

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

STUDY PROCEDURE: Subjects received six procedure administrations with the Erchonia® MLS, Zerona™ to the right and left upper arms, across a consecutive two-week period: three procedures per week, each procedure two to three days apart.

STUDY RESULTS

(i) Total Circumference Measurements: The study primary outcome measure was based on individual circumference measurements taken at 3 points along each of the subject's upper arms combined to attain a single circumference measurement for each of the right arm and the left arm, separately.

It was pre-determined that a subject would be considered a study success if he or she attained a 1.25 cm or greater reduction in combined circumference measurement for each of the right and left upper arms, separately, from baseline to study endpoint (after completion of the two-week procedure phase).

58% of subjects who received the study procedures with the actual Erchonia® MLS, Zerona™ attained a decrease in combined circumference measurement of 1.25 cms or greater for each of the right and left upper arms, separately, compared with 3% 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 55% to be statistically significant at $p<0.000005$.

The mean change in total circumference for subjects who received the study procedures with the actual Erchonia® MLS, Zerona™ was a decrease of 1.85 cms for the right upper arm, a decrease of 1.84 cms for the left upper arm and decrease of 3.70 cms for both upper arms combined. The mean change in total circumference for subjects who received the study procedures with the 'fake' (placebo) laser device was a decrease of 0.08 cms for the right upper arm, a decrease of 0.23 cms for the left upper arm and decrease of 0.31 cms for both upper arms combined.

Paired samples t-tests found the changes in upper arm circumference measurements for subjects in the test group to be statistically significant, as shown in Table 3 below. The changes in upper arm circumference measurements for subjects in the placebo group were not found to be statistically significant, as shown in Table 4 below.

Table 3: Paired samples t-tests for test group subjects

Test Group	μa-μb	t	df	p(two-tailed)	significance
Right Arm	1.855	+9.61	30	<0.0001	p<0.0001
Left Arm	1.842	+8.98	30	<0.0001	p<0.0001
Right & Left Arms	3.70	+10.65	30	<0.0001	p<0.0001

Table 4: Paired samples t-tests for placebo group subjects

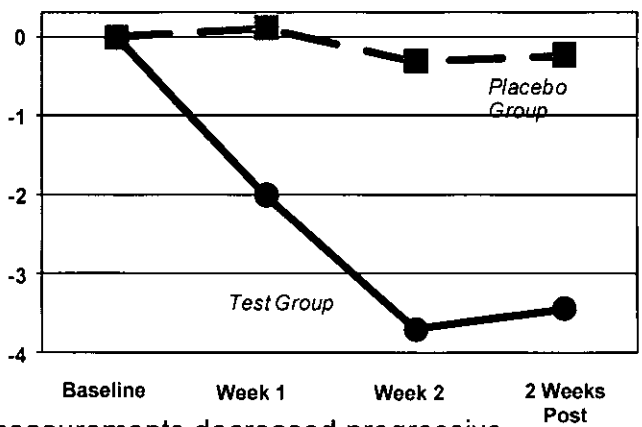
Placebo Group	μa-μb	t	df	p(two-tailed)	p	significance
Right Arm	0.0806	+0.83	30	0.413	p>0.05	Not significant
Left Arm	0.23	+1.95	30	0.061	p>0.05	Not significant
Right & Left Arms	0.31	+1.67	30	0.105	p>0.05	Not significant

Table 5 and Chart 1 below show the mean change in total upper arm circumference measurements (right and left arms combined) across the four study measurement time points.

Table 5: Mean total circumference measurements (cms) across evaluation points

	Test Group	Placebo Group
Baseline	191.48	189.58
Midpoint (week 1)	189.47	189.69
Endpoint (week 2)	187.78	189.27
Follow-up (week 4)	188.04	189.34

Chart 1: Mean change in total upper arm circumference measurements (cms) at each study evaluation point relative to baseline



For test group subjects, total circumference measurements decreased progressively from baseline across the procedure administration phase, indicating a progressive and cumulative treatment effect of the laser. However, for placebo group subjects, total circumference measurements were unchanged across the procedure administration phase relative to baseline.

Total circumference measurements stabilized for test group subjects across the subsequent 2-week follow-up assessment period during which time no laser procedures were administered, indicating duration of the treatment effect up to at least 2 weeks following the end of laser procedure administration.

(ii) Change in body mass index (BMI): BMI measurements did not change significantly across and between any of the evaluation time points for either test or placebo subject groups. However, upper arm circumference measurements did change significantly across and between evaluation points for test group subjects but not for placebo group subjects. This combined finding further supports the effectiveness of the Erchonia® MLS, Zerona™ device as it demonstrates that the change in body shape (reduction in cms for the upper arms) attained for test group subjects in this study at this test site resulted from the Erchonia® MLS, Zerona™ device applications and not from change in body mass index as a result of incidental weight loss.

(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 upper arms attained using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied.

65% of test group subjects reported being 'Satisfied' (Very or Somewhat Satisfied) with the outcome of the study procedures compared with 22% 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

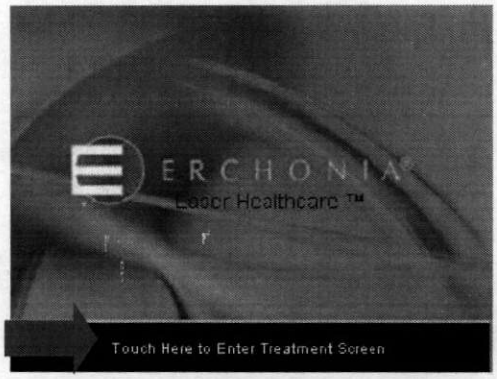
subject.

CONCLUSION: The Erchonia® MLS, Zerona™ is an effective tool for body contouring, significantly reducing circumference measurements when applied to the bilateral upper arms over a 2-week period.

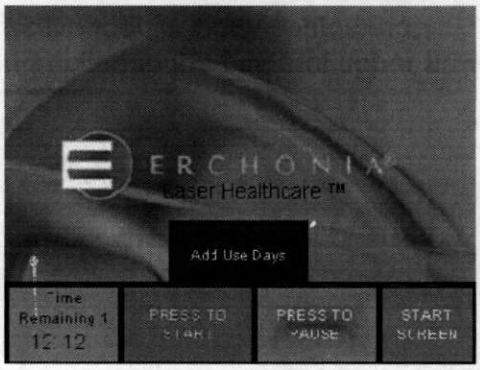
Mechanical Instructions for Use: How to Use the Device

Operating the Device

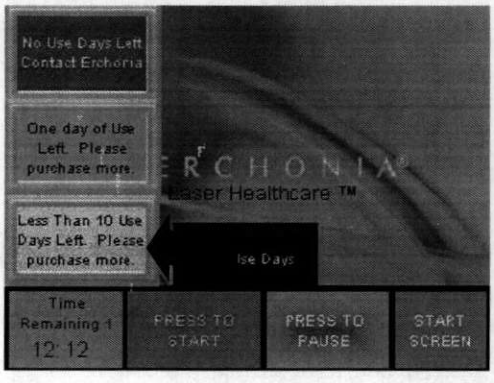
Press "Touch Here to Enter Treatment Screen" button, this will take you to the Erchonia Preset Protocol (Mode) Selection screen.



Press "PRESS TO START" button to begin the non-invasive arm reduction 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.



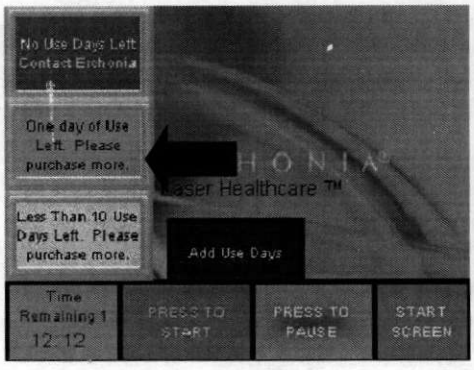
This device requires an update every 30 days from software installation. You are required to contact your distributor for an update code



NOTE: Notification will start to display on the protocol screen to inform you that you have 10 calendar days until the device will lockout any further treatments.

You must contact the distributor for a device update code and will only unlock once the code is imputed into the device.

Once the UPDATE DUE screen appears, it will remain until an update code is entered or the 10 days expire.



NOTE: Once the 10 days expire, the machine will stop operating and a notification will display on the touchscreen to advise you to CONTACT ERCHONIA FOR DEVICE UPDATE.

Warnings

1) The long-term effects of prolonged use of non-thermal laser exposure are not known.
2) The device should not be used over, or near, cancerous lesions, as conclusive tests have not been done.
3) The device should not be used when you are in the bath or shower because electrical shock may occur.
4) To avoid any possible danger to the eyes, do not shine the laser light directly into your eyes.
5) Keep the device out of the reach of children at all times.
6) Changes to the use of the laser controls or to the performance of treatments other than those specified in this manual may cause hazardous radiation exposure.

Cautions

1) Safety of non-thermal laser for use during pregnancy has not been shown.
2) Caution should be used over areas of skin that lack normal sensation (feeling).
3) The device should be used only with the parts recommended for use by the manufacturer.
4) Avoid any liquid getting into the device.
5) Avoid contact with flammable products, or with air with oxygen or nitrous oxide.
6) To ensure proper use and to mitigate the possibility of interference, avoid placing in close proximity to other electromagnetic devices.

NOTE: If due to misuse, failure to follow cautions or unforeseen circumstances the device is damaged, contact the manufacturer.

Maintenance & Cleaning

The Erchonia® MLS, Zerona™ device, if used according to the instructions in this manual will work well for years. For proper care, it is best to:

1. Do regular visual checks for signs of damage to the device other than normal wear and tear. If you are concerned about damage, please contact the manufacturer to see if action needs to be taken.

2. If you see a change in how the device works while in the ON position, please contact the manufacturer to see if action needs to be taken.

3. The inside parts of the device should not need any maintenance; however, if you think there is a problem because the device is not working well or is working differently than before, the device must be sent to the manufacturer.

4. Since the MLS, Zerona™ is placed on the floor and designed to be in conjunction with a table or chair for ease of the patient. The platform in which the patient's arm rests is to be cleaned using disinfectant wipes.

5. If during treatment any part of the device touches the skin, follow the cleaning process defined in step #4, to correct.

6. Fuses can be replaced by the end-user. The fuse holder is part of the power inlet module, see item #7, Device Description. To replace, pull open fuse drawer, remove spent fuse, insert new fuse rated at T2A 250V 100-240V~.5 – 1.5A, 50 – 60 Hz.

Disposal

The Erchonia® MLS, Zerona™ is a self-contained unit that gives out light energy and as such creates no byproducts that require control. However, as a courtesy Erchonia offers disposal services. To take advantage of the offer, when the device cannot be used properly and/or cannot be repaired, send to manufacturer for disposal.

Warranty Information

Detailed description of the Terms and Condition for warranty of the Erchonia® MLS, Zerona™ device.

Limited Warranty

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

Terms and Conditions

- Shipping for warranty repair and / or maintenance within the first 90 days will be paid for by the manufacturer.
- Shipping for warranty repair and / or maintenance after 90 days will be paid for by the consumer.
- 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 repair to damage caused by:

Accident, misuse or abuse
Lack of responsible care
Use of an unapproved power cord
Alteration to or disassembly of the device
Loss of parts
Exposure to the elements
Ingress of liquid (liquid entering the device)

Point of Contact

If for any reason, you are not satisfied with this product or have warranty concerns or questions about how to use the device, please call +1 888-242-0571 for immediate help.

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

May 03, 2012

ERCHONIA MEDICAL, INC.
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT
GREENWOOD VILLAGE, COLORADO 80127
ATTN: KEVIN WALLS

510k Number: K120257

Product: MLS, ZERONA-AD

The additional information you have submitted has been received.

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

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

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

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

Sincerely,

510(k) Staff

Grayson, Giovanna *

From: Microsoft Outlook
To: 'kevin@reginsight.com'
Sent: Thursday, May 03, 2012 12:09 PM
Subject: Relayed: ACK LETTER

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

'kevin@reginsight.com'

Subject: ACK LETTER

Sent by Microsoft Exchange Server 2007

26

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Thursday, May 03, 2012 12:09 PM
To: 'kevin@reginsight.com'
Subject: ACK LETTER
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

May 03, 2012
WALLS
KEVIN
ERCHONIA MEDICAL, INC.
C/O REGULATORY INSIGHT, INC.
5401 S. COTTONWOOD CT
GREENWOOD VILLAGE, COLORADO 80127
ATTN: KEVIN WALLS

510k Number: K120257

Product: MLS, ZERONA-AD

The additional information you have submitted has been received.

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

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Sincerely,

510(k) Staff

27

Regulatory Insight, Inc.

K120257 | 32

May 1, 2008

Mr. Richard Felten
Food and Drug Administration
Center for Devices and Radiological Health
HFZ-401
9200 Corporate Blvd., HFZ 480
Rockville, MD 20850

RE: Response to Request for Additional Information for Erchonia® MLS Laser 510(k)# K120257

Dear Mr. Felten,

The information enclosed is respectfully being submitted in response to FDA's request for additional information, dated April 26, 2012 and sent to us by email, regarding 510(k) # K120257 for the Erchonia® MLS Laser. An electronic copy of the response has also been e-mailed to Mr. Richard Felten.

Sincerely,

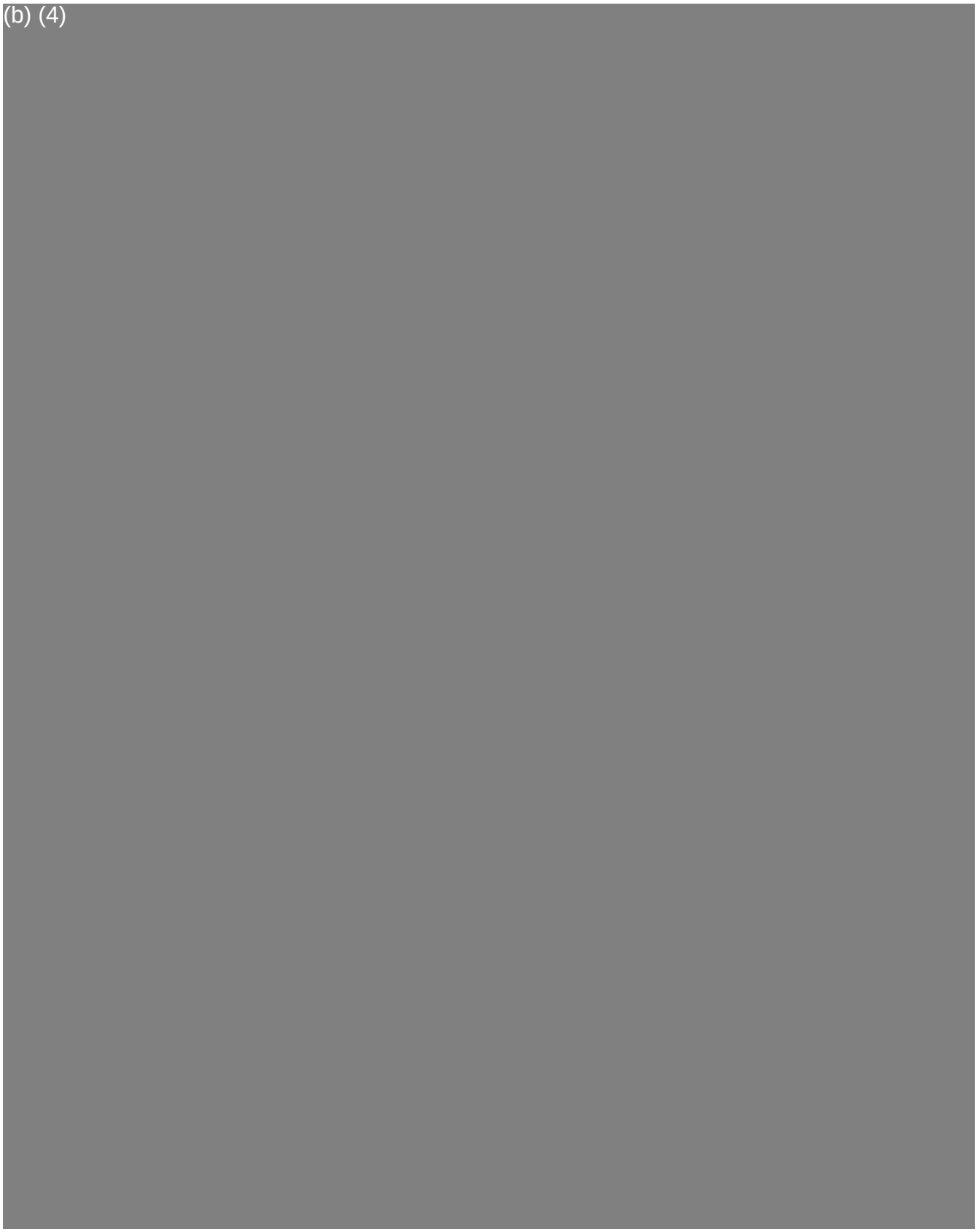
Elvira Walls
Clinical Consultant
Regulatory Insight, Inc.

1C35

5401 S. Cottonwood Court ♦ Greenwood Village, Colorado 80121 ♦ U.S.A.
Phone: (303) 972-5129 ♦ Fax: (720) 963-5413
E-mail: info@reginsight.com ♦ Web: www.reginsight.com

(b) (4)

(b) (4)

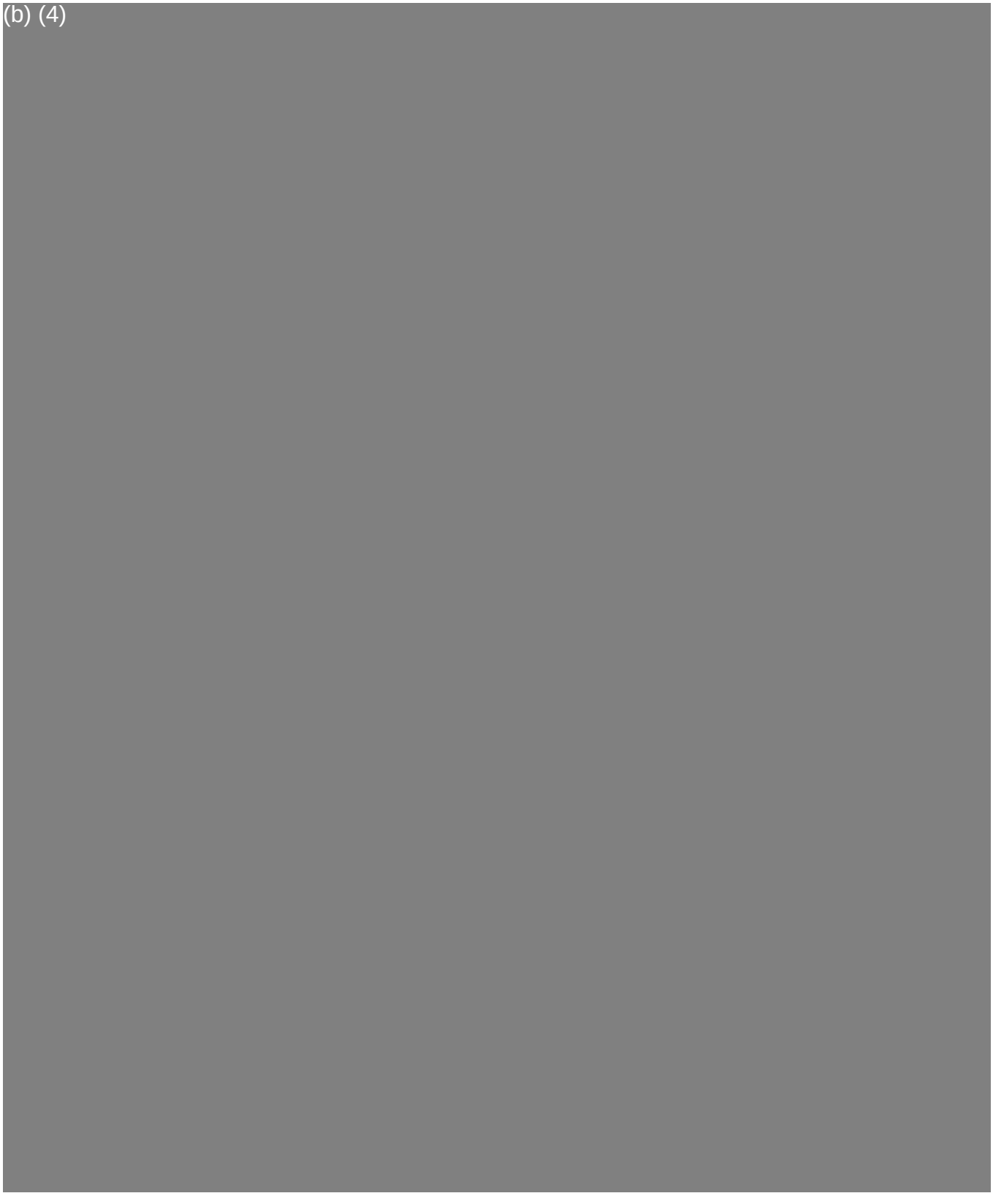


(b) (4)

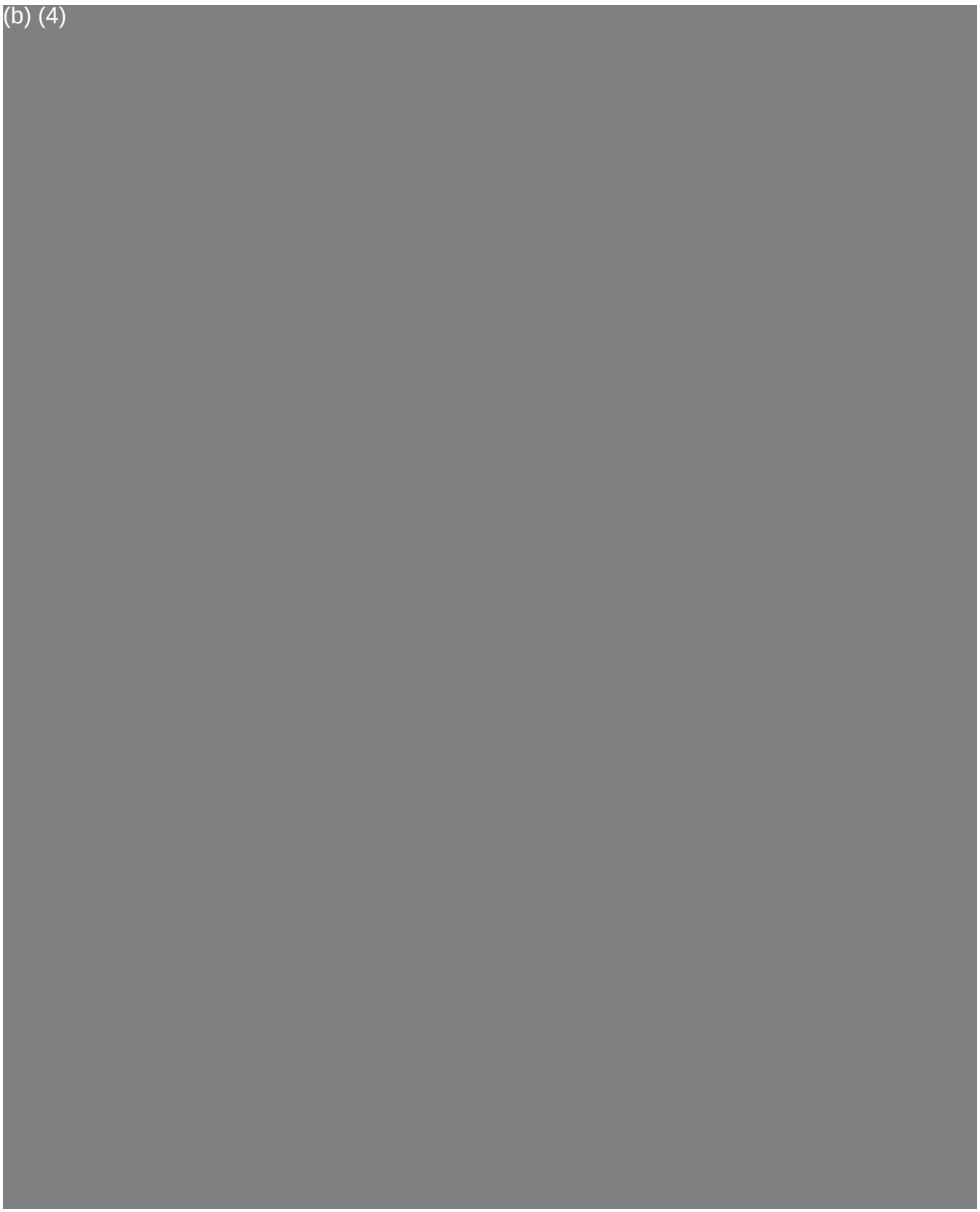
[redacted]

(b) (4)

(b) (4)



(b) (4)



(b) (4)

(b) (4)

ERCHONIA® ML Scanner (MLS)

Follow-Up to:
An evaluation of the effectiveness of the Erchonia® ML Scanner (MLS) as a non-invasive dermatological aesthetic treatment for the reduction of circumference of the upper arms

Version 1.1; January 4, 2011

Follow-up Results Report

ERCHONIA CORPORATION

February 16, 2012

TABLE OF CONTENTS

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
01/24/2012	(b) (4)	

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

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

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

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

PSC Publishing Services (301) 443-6740 EF

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

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

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

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

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

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

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

- ☐ Response to FDA correspondence:

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

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

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

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	OLI	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K082609	ML Scanner	Erchonia
2			
3			
4			
5			
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	MLS, Zerona-AD	
2		
3		
4		
5		

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

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

Data Included in Submission

- ☐ Laboratory Testing
- ☐ Animal Trials
- ☒ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
OLI	878.5400	☐ Class I ☒ Class II

Classification Panel

General & Plastic Surgery

☐ Class III ☐ Unclassified

Indications *(from labeling)*

The Erchonia® MLS, Zerona-AD is indicated for a non-invasive dermatological aesthetic treatment for the reduction of circumference of the arm.

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

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Erchonia Medical, Inc.		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: Steven Shanks	Contact Title: President	Contact E-mail Address: SShanks@erchonia.com

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

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

SECTION I — UTILIZATION OF STANDARDS

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

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

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

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

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

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

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

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, Amendmen

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], www.fda.gov/cdrh/stdsprog.html

[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 www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE	

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ 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:

Center for Devices and Radiological Health
1350 Piccard Drive
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.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2, (Second Edition, 2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnet

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 5-28		
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.	☑	☐
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE	

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
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DESCRIPTION		
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* 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.

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Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

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

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#12-220	
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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ 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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
01/24/2012	(b) (4)	K120257

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

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

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

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

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

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

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

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

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

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

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

- ☐ Response to FDA correspondence:

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

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

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

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1 OLI	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K082609	ML Scanner	Erchonia
2			
3			
4			
5			
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	MLS, Zerona™	
2		
3		
4		
5		

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

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

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☒ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

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

Indications *(from labeling)*

The Erchonia® The MLS ZERONA™ is indicated for the non-invasive dermatological aesthetic treatment for body contouring.

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

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Erchonia Medical, Inc.		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: Steven Shanks	Contact Title: President	Contact E-mail Address: SShanks@erchonia.com	

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

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

SECTION I — UTILIZATION OF STANDARDS

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

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

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

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

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CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
05/08/2012	(b) (4)	K120257

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

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

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

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

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

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

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

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

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

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

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

- ☐ Response to FDA correspondence:

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

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

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

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	OLI	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K082609	1	ML Scanner	1	Erchonia
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	MLS, Zerona™	1	
2		2	
3		3	
4		4	
5		5	

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

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

Data Included in Submission

- ☐ Laboratory Testing
- ☐ Animal Trials
- ☒ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
OLI	878.5400	☐ Class I ☒ Class II

Classification Panel

General & Plastic Surgery

☐ Class III ☐ Unclassified

Indications *(from labeling)*

The Erchonia® ML Scanner (MLS) is indicated for non-invasive dermatological aesthetic treatment for the reduction of the circumference of the upper arms.

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

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

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Erchonia Medical, Inc.	2032513
Division Name *(if applicable)*	**Phone Number *(including area code)***
	214-544-2227
Street Address	**FAX Number *(including area code)***
2021 Commerce Dr.	214-544-2228

City	State / Province	ZIP Code	Country
McKinney	Texas	75069	USA

Contact Name	Contact Title	Contact E-mail Address
Steven Shanks	President	SShanks@erchonia.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	**Phone Number *(including area code)***
Street Address	**FAX Number *(including area code)***

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	**Phone Number *(including area code)***
Street Address	**FAX Number *(including area code)***

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No. 60601-1	Standards Organization IEC	Standards Title Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.	Version	Date 10/31/2005
2	Standards No. 60601-1-2	Standards Organization AAMI / ANSI / IEC	Standards Title Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests	Version	Date 09/09/2008
3	Standards No. 60825-1	Standards Organization IEC	Standards Title Safety of laser products - Part 1: Equipment classification and requirements CORRIGENDUM 1	Version	Date 03/18/2011
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

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

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