ERCHONIA® OBESITY LASER

A double-blind, placebo-controlled, randomized evaluation of the effect of the Erchonia® Obesity Laser on the reduction of the circumference of the hips, waist and upper abdomen for individuals with Body Mass Index (BMI) of 30 to 40 kg/m²

ERCHONIA CORPORATION

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PURPOSE OF STUDY

The purpose of this clinical study is to determine the effectiveness of the Erchonia® Obesity Laser, manufactured by ERCHONIA CORPORATION (the Company), for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals with a Body Mass Index (BMI) between 30 kg/m² and 40 kg/m² intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and upper abdomen by applying green diode (532 nm) energy around the waist, hips and thighs for 30 minutes, twelve (12) times across four (4) weeks.

EXPECTED RESULTS

Following completion of the four-week study procedure administration phase with the Erchonia® Obesity Laser, it is anticipated that significantly more subjects in the test group than in the placebo group will show a minimum reduction of 3.0 inches in combined hips-waist-upper abdomen circumference measurement (in ins).

INDICATION FOR USE

The results of this clinical study will be used to support the following indication for use statement: "The Erchonia® Obesity Laser is indicated for use for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals with Body Mass Index (BMI) between 30 kg/m² and 40 kg/m² intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and upper abdomen."

LABELING

Once cleared for market in the U.S., the Erchonia® Obesity Laser will be labeled as prescription devices, per 21 CFR § 801.109.

SUPPORTING MATERIALS

This study protocol is based on the following clinical study protocols whose results were used to successfully support subsequent FDA 510(k) regulatory submissions that resulted in the following circumference reduction related clearances being attained for Erchonia low level laser devices:

- **K123237** (532 nm green light diodes)
  Erchonia® Zerona™ 2.0 Laser: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

- **K121695 & K082609** (635 nm red light diodes)
  Erchonia® ML Scanner (MLS) & Erchonia® Zerona: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

- **K121690 & K120257** (635 nm red light diodes)
  Erchonia® MLS, Zerona, Zerona-AD: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of the upper arms.

The intended application/indication in this study is comparable to the above FDA-cleared indications, with the difference being that the Sponsor wishes to evaluate the effectiveness of a laser employing 10 green diodes (532 nm) energy output on reduction of hips/waist/upper abdomen circumference for individuals with a BMI in the range of 30 to 40 kg/m^2.

DEVICE INFORMATION: ERCHONIA® OBESITY LASER

DEVICE DESCRIPTION AND DETAILS

The Erchonia® Obesity Laser is intended to be evaluated in this study for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals with a Body Mass Index (BMI) between 30 kg/m² and 40 kg/m² intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and upper abdomen.

The Erchonia® Obesity Laser to be used in this study is made up of 10 independent 17 mW, 532 nm green laser diodes, each diode positioned 120 degrees apart from the next with each titled at a 30 degree angle.

The Erchonia® Obesity Laser is a variable frequency device. The variable frequency feature of the Erchonia® Obesity Laser is a pulsed wave, defined as containing a selected series of breaks, variances that are preprogrammed.

The Erchonia® Obesity Laser utilizes internal mechanics that collects the light emitted from 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® Obesity Laser has the following specifications:

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

Pictures of the Erchonia® Obesity Laser to be used in this clinical study are shown in Figure 1 on the following page.

Figure 1: The Erchonia® Obesity Laser

REGULATORY BACKGROUND

The Erchonia® Obesity Laser emits 532 nm green diode laser energy as does the Erchonia® Zerona™ 2.0 Laser that recently received clearance by the FDA for the following circumference-reduction indication for use, similar in application and intent to the clearance being sought through the results of this clinical study:

- **K123237:** (532 nm green light diodes)
  Erchonia® Zerona™ 2.0 Laser: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

In addition, two Erchonia low level lasers emitting 635nm red diode energy have received clearance by the FDA for circumference-reduction applications, also similar in application and intent to the clearance being sought through the results of this clinical study, as follows:

- **K121695 & K082609** (635 nm red light diodes)
  Erchonia® ML Scanner (MLS) & Erchonia® Zerona: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

- **K121690 & K120257** (635 nm red light diodes)
  Erchonia® MLS, Zerona, Zerona-AD: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of the upper arms.

The intended device application and indication for use being sought through this clinical study is comparable to the above FDA-cleared indications, employing 532 nm green laser diodes as in K123237 to evaluate the effectiveness of the application of ten (10) 532 nm green diodes energy output in lieu of six (6) 532 nm green diodes on the reduction of hips/waist/upper abdomen circumference for individuals with a BMI in the range of 30 to 40 kg/m². The intended total treatment administration time of 30 minutes remains unchanged.

DETERMINATION OF DEVICE SAFETY

RISK AND PREVENTION OF EYE INJURY

The Erchonia® Obesity Laser is classified by the FDA/IEC as a Class 2 laser device. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 laser is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging.

To ensure there is no possible instance of residual effect, a pair of specialty glasses (shown in Figures 2 and 3 below) is provided for use during procedure applications with the Erchonia® Obesity Laser device for both the Administration Investigator and the subject.

These safety glasses are KenTek Corporation KenTek C22-KMT-6101 light blue safety glasses. These safety glasses have the following specifications:

- ✓ OD 0.47 @ 532 nm
- ✓ VLT 63%
- ✓ 635D LB2
- ✓ KTK CE 2056

Figure 2: KenTek Corporation KenTek C22-KMT-6101 Light Blue Safety Glasses

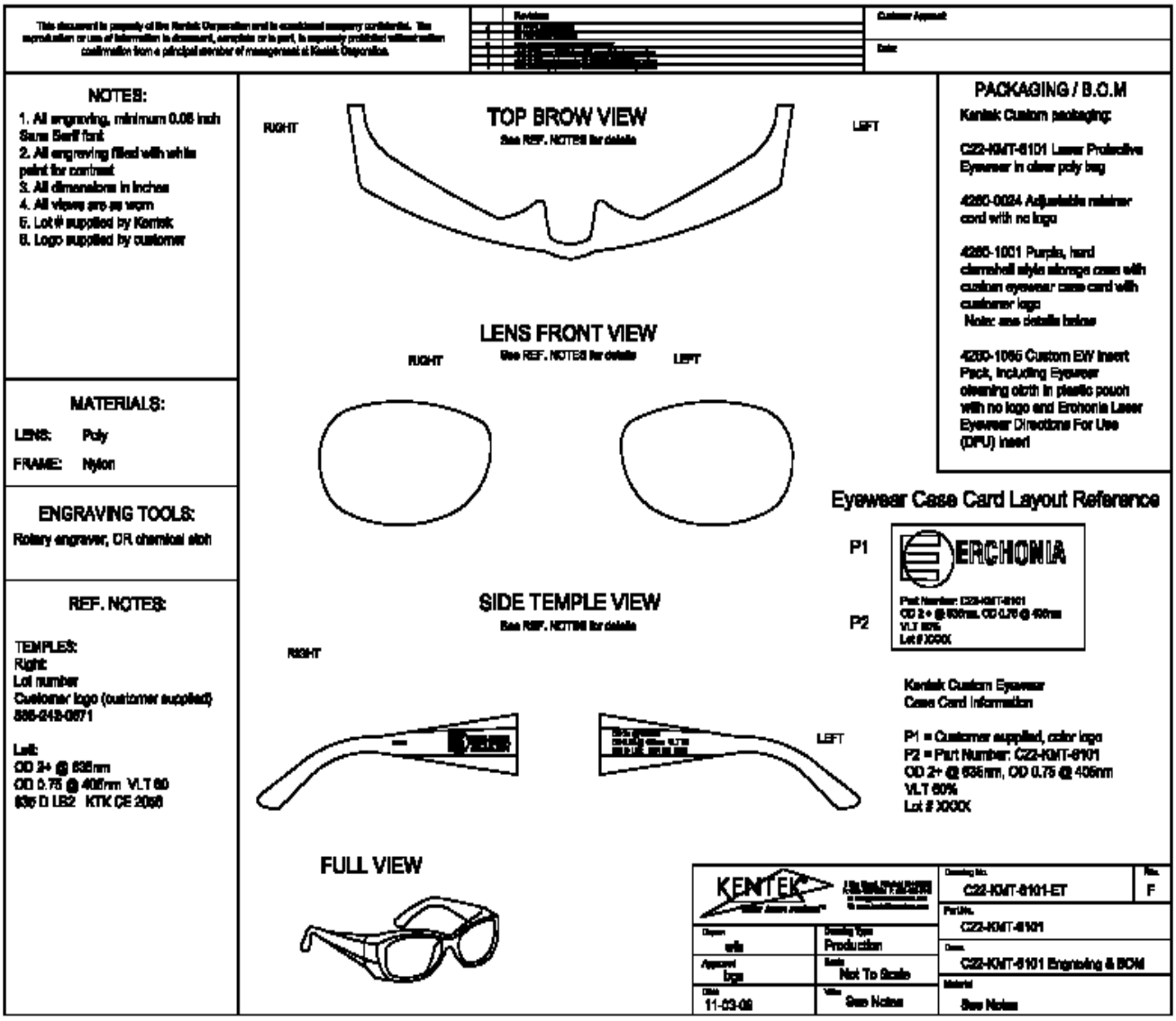


Figure 3: KenTek Corporation KenTek C22-KMT-6101 Safety Glasses Specifications

FOOD AND DRUG ADMINISTRATION (FDA) DETERMINATION OF NON-SIGNIFICANT RISK (NSR) STATUS

(i) Regulatory Clearances**:** The Food and Drug Administration (FDA) has determined the family of Erchonia® low level laser devices, including those employing 532 nm green diodes, to be non-significant risk (NSR) through numerous **510(k) clearances**, as follows.

1. K123237: (532 nm green light diodes)
Erchonia® Zerona™ 2.0 Laser: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

2. K121695 & K082609 (635 nm red light diodes)
Erchonia® ML Scanner (MLS) & Erchonia® Zerona: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

3. K121690 & K120257 (635 nm red light diodes)
Erchonia® MLS, Zerona, Zerona-AD: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of the upper arms.

4. K101430
MLS-AC Derma Scanner™: is indicated while using the red diodes for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin, and while using the blue diode, to treat moderate inflammatory Acne Vulgaris.

5. K082609
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.

6. K072206
Erchonia® EML Laser: is indicated for the temporary reduction in post-surgery pain at 24 hours after surgery following bilateral breast augmentation surgery.

7. K062792
Erchonia IOTO_240: is a galvanic generator that is indicated for use in tap water iontophoresis to treat palmer hyperhidrosis and plantar hyperhidrosis.

8. K050672
Erchonia® EVRL Laser: The Erchonia EVRL Laser is generally indicated:

a. while using the red diode, for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin, and
b. while using the blue diode, to treat dermatological conditions, and specifically indicated to treat moderate inflammatory Acne Vulgaris.

9. K041139
Erchonia® EML Laser: is indicated as an adjunct to liposuction procedures of the thighs, hips and stomach for reduction of pain associated with the recovery process.

10. K100509
Erchonia® THL1 Laser: is indicated for use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

(ii) Pre-IDE Reviews**:** FDA has previously reviewed numerous clinical study protocols employing various Erchonia® Corporation low level laser devices, including all of the clinical studies conducted in support of the above 510(k) clearances and employing 532 nm green diodes. For all of the FDA's pre-IDE reviews of Erchonia low level laser clinical study protocols, there was concurrence from FDA that the clinical study protocols and application of the Erchonia laser devices therein were considered non-significant risk (NSR).

INSTITUTIONAL REVIEW BOARD (IRB) DETERMINATION OF NON-SIGNIFICANT RISK (NSR) STATUS

Erchonia® Corporation low level laser devices have been determined to be non-significant risk (NSR) when applied in various clinical studies through several IRBs, including those involving application of 532 nm green diode energy and application for circumference reduction indications, as follows:

- Western Institutional Review Board (WIRB®) has previously determined Erchonia low level laser devices to be non-significant risk (NSR) when applied in the following clinical studies:

1. **WIRB PRO NUM: 20110331:** Erchonia® 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

2. **WIRB PRO NUM: 20120911:** Erchonia® MLS: 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 five-day treatment protocol clinical study protocol

3. **WIRB PRO NUM: 20110758**: Erchonia® MLS: A pilot evaluation of the effect of the Erchonia® ML Scanner (MLS) laser device on enhancing body weight loss, fat loss and circumference reduction of the waist, hips and thighs clinical study protocol

4. **WIRB PRO NUM: 20121548:** Erchonia® MLS: A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) laser on reducing pain associated with degenerative arthritis (osteoarthritis) of the midfoot clinical study protocol

5. **WIRB PRO NUM: 20121330:** Erchonia LUNULA™**:** An Evaluation of the Effect of the Erchonia LUNULA™ on Treating Toenail Onychomycosis Clinical Study Protocol; Version 6.0 August 7, 2012

6. **WIRB PRO NUM: 20110461:** Erchonia FX-405™**:** An Evaluation of the Effect of the Erchonia FX-405™ on Treating Toenail Onychomycosis Clinical Study Protocol; Version 3.0 March 19, 2011

7. **WIRB PRO NUM: 20120787:** Erchonia® MLS: A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) on low back pain clinical study protocol

8. **WIRB PRO NUM: 20120489:** Erchonia® MLS: A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) on lipid panel levels clinical study protocol

9. **WIRB PRO NUM: 20111793:** Erchonia® MLS: A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) laser on chronic heel pain clinical study protocol

- Independent Review Consulting, Inc.'s/Ethical and Independent Review Services has previously determined Erchonia low level laser devices to be non-significant risk (NSR) when applied in the following clinical studies:

1. **IRC# 07150, NSR# DER-006:** Erchonia® MLS**:** A double blind, placebo-controlled randomied evaluation of the effect of the Erchonia® ML Scanner (MLS) on body contouring of the waist, hips and thighs clinical study protocol.

2. **IRC# 09120, NSR# DER-015:** Erchonia® MLS**:** A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) on reducing the appearance of cellulite clinical study protocol.

3. **IRC# 08167, NSR# DER-009:** Erchonia® MLS**:** A double blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) on capsular contracture clinical study protocol.

4. **IRC# 09059, NSR# DER-010:** Erchonia® MLS**:** A double blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) in combination with silicone sheets on cellulite pilot study protocol.

- Chesapeake Research Review, Inc. determined the Erchonia® ML Scanner (MLS) laser device to be a non-significant risk (NSR) device when applied in the following study:

1. **Pro. # 00006393:** Erchonia® MLS**:** A pilot evaluation of the effect of the Erchonia® ML Scanner (MLS) as applied to the abdomen on reducing visceral abdominal fat in patients with HIV-associated lipodystrophy.

OTHER POTENTIAL RISKS

Other potential risks and their mitigation include:

(i) Electric shock: operator risk only: mitigated through electrical safety testing.
(ii) Electromagnetic interference: mitigated through EMC/EMI testing.
(iii) User error: mitigated through instructions for use documentation.

STUDY INDICATION, RATIONALE AND JUSTIFICATION; THEORY OF MECHANISM OF OPERATION; & SUPPORTING BIOLOGICAL AND CLINICAL DATA

STUDY INDICATION AND RATIONALE

Cosmetic procedures, including those specifically targeting weight loss and body contouring form a large, constantly-growing market. According to the American Society of Plastic Surgeons (ASPS) 2011 report, the market for cosmetic procedures has continued to show significant growth over the past two years, with 13.8 million cosmetic plastic surgery procedures (both surgical and minimally-invasive procedures combined) performed in the United States in 2011, up 5 percent (5%) since 2010. Cosmetic surgical procedures, specifically, increased 2 percent (2%), with nearly 1.6 million cosmetic surgical procedures having been performed in 2011. In particular, liposuction procedures increased 1% in 2011 over 2010, with 205,000 liposuction procedures performed in 2011 throughout the United States.

However, while surgical cosmetic procedures did increase significantly from 2010 to 2011, it is reported that the overall growth in cosmetic procedures is being primarily driven by a substantial rise in minimally-invasive procedures. Cosmetic minimally-invasive procedures increased 6 percent (6%), with nearly 12.2 million cosmetic minimally-invasive procedures having been performed in 2011. This highlights both the growing consumer demand for cosmetic procedures in general, and even more strongly for cosmetic procedures that are non- or minimally-invasive and do not involve surgical procedures and the associated risks, potential complications and lengthy and painful recovery processes that accompany these surgical cosmetic procedures.

These statistics; therefore, highlight the fact that increasing consumer demand for cosmetic procedures is being driven by an even greater increasing consumer demand for alternative, non- or minimally-invasive means of attaining these cosmetic improvement goals, with the associated advantages of efficiency, ease, no- to minimal-risk involvement and no or quick recovery times compared with the risks and downsides associated with comparable surgical cosmetic procedures such as general anesthesia risks, post-surgical complications, infection and scarring, and lengthy and painful recovery processes.

STUDY JUSTIFICATION

The current standard surgical cosmetic procedure for reduction of body circumference is liposuction. However, surgical liposuction carries significant risks and potential complications including:

- ✓ Infection
- ✓ Bruising and Swelling around the treatment area
- ✓ Numbness and Pain: loss of sensitivity and/or numbness, and pain, in the treatment area
- ✓ Bleeding; possibility of blood clots forming at the treatment site
- ✓ Scarring: where the sutures were placed; possible keloids formation
- ✓ Nerve Damage
- ✓ Lengthy, involved and painful recovery process with down time from general everyday activities including work and exercise.

Low level laser light therapy, such as that provided through application of the Erchonia® Obesity Laser as proposed in this clinical study protocol, offers a simple, non-invasive, safe, effective and side-effect free alternative to achieving body circumference reduction.

Justification for this assertion of anticipated safety and effectiveness of the Erchonia® Obesity Laser for application to reducing subdermal fat is found through three FDA clearances for Erchonia® Low Level Laser devices for fat reduction indications, with the most recently-cleared Erchonia laser device emitting 532 nm green light; and the other two laser devices emitting 635 nm red light.

For all three 510(k) clearances, the assigned Product Code is OLI, defined as follows:

- ✓ *Device:* Fat reducing low level laser
- ✓ *Regulation Description:* Low level laser system for aesthetic use
- ✓ *Definition:* Non-invasive reduction in fat layer for body contouring
- ✓ *Technical Method:* Use of low level laser energy to create pores in adipocyte cells to release lipoproteins
- ✓ *Target Area*: Adipocyte cells within the fat layer of the body, this could include waist, thighs, abdomen, hips, etc...

Under 21 CFR 878,5400, the FDA identifies this generic type of device as: "A Low Level Laser System for Aesthetic Use is a device using low level laser energy for the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use."

The above-referenced 510(k) clearances for application of Erchonia red diode and green diode lasers for fat reduction indications are the following:

- **K123237** (532 nm green light diodes)

Erchonia® Zerona™ 2.0 Laser: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

- **K121695 & K082609** (635 nm red light diodes)

Erchonia® ML Scanner (MLS) & Erchonia® Zerona: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

- **K121690 & K120257** (635 nm red light diodes)

Erchonia® MLS, Zerona, Zerona-AD: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of the upper arms.

Therefore, both 532 nm green diode and 635 nm red diode Erchonia low level lasers have been determined safe and effective by the FDA for application for fat reduction/body circumference reduction indications for multiple body areas, such that evaluation of application of the Erchonia green diode (532 nm) laser device to reducing body circumference in more overweight individuals is a natural extension of its proven and accepted application for body circumference reduction purposes.

THEORY OF MECHANISM OF OPERATION OF THE APPLICATION OF ERCHONIA® LASERS FOR CIRCUMFERENCE REDUCTION INDICATIONS

It follows from the information presented above in the 'Study Indication, Rationale and Justification' sections above that the theory of mechanism of operation of the application of Erchonia® low level lasers for circumference reduction has been well-established, proven and accepted.

Both Erchonia Corporation 532 nm green light ad 635 nm red light laser devices have been cleared by the FDA for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs, and of the upper arms (K121695 & K082609; K121690 & K120257; and K123237).

Each of these clearances has been classified under Product Code 'OLI'. Under 21 CFR 878,5400, FDA identifies this generic type of device as: "A Low Level Laser System for Aesthetic Use is a device using low level laser energy for the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells for non-invasive aesthetic use."

This determination is supported by the results of a study performed by Dr. Neira using Erchonia red and green diode lasers, wherein it was found using electron microscopy that a transitory pore in the adipocyte cell membrane formed following six minutes of irradiation with Erchonia's dual-diode electric laser at 10 Mw (using both the 532 nm green diode and the 635 nm red diode). The formation of the transitory pore allowed for fat to pass from the intracellular space into the extra-cellular space. Dr. Neira's research was subsequently reaffirmed by Dr. Susan Lim using a Standard and Cryo Scanning Electron Micrographs, in which she demonstrated the formation of the transitory pore as well as the movement of fat droplets across the membrane.

Therefore, the biochemical effect of Erchonia® low level laser light therapy devices (both 532 nm green and 635 nm red diodes) stimulates the mitochondria of the adipocyte cells which in turn increases the production of ATP. The newly synthesized ATP triggers the up-regulation of cyclic adenosine monophosphate (cAMP). cAMP has been shown to stimulate cytoplasmic lipase, triggering the conversion of triglycerides into fatty acids and glycerol that can easily pass through the cell membrane. The transitory pore is evidence that the laser is allowing for the movement of fatty acids, glycerol, and triglycerides to pass across the membrane and into extra-cellular space. Through vasodilation of nearby blood vessels and arteries, oxidization of the triglycerides and fatty acids occurs within the extra-cellular space.

SUPPORTING BIOLOGICAL DATA

The following abstract support the theory of adipose tissue liquefaction for the purpose of body contouring

1) Fat Liquefaction: Effect of Low-Level Laser Energy on Adipose Tissue.
Plastic & Reconstructive Surgery. 110(3):912-922, September 1, 2002.
Neira, Rodrigo M.D.; Arroyave, Jose B.S.C.E., T.E.M., S.E.M.; Ramirez, Hugo M.V.; Ortiz, Clara Lucia M.D.; Solarte, Efrain Dr. rer. nat.; Sequeda, Federico Ph.D.; Gutierrez, Maria Isabel M.D., M.Sc., Ph.D.

Low level laser energy has been increasingly used in the treatment of a broad range of conditions and has improved wound healing, reduced edema, and relieved pain of various etiologies. This study examined whether 635 nm low level lasers had an effect on adipose tissue in vivo and the procedural implementation of lipoplasty/liposuction techniques. The experiment investigated the effect of 635 nm, 10 mW diode laser radiation with exclusive energy dispersing optics. Total energy values of 1.2 J/cm2, 2.4 J/cm2, and 3.6 J/cm2 were applied on human adipose tissue taken from lipectomy samples of 12 healthy women. The tissue samples were irradiated for 0, 2, 4, and 6 minutes with and without tumescent solution and were studied using the protocols of transmission electron microscopy and scanning electron microscopy. Non-irradiated tissue samples were taken for reference. More than 180 images were recorded and professionally evaluated. All microscopic results showed that without laser exposure the normal adipose tissue appeared as a grape-shaped node. After 4 minutes of laser exposure, 80 percent of the fat was released from the adipose cells; at 6 minutes of laser exposure, 99 percent of the fat was released from the adipocyte. The released fat was collected in the interstitial space. Transmission electron microscopic images of the adipose tissue taken at x 60,000 showed a transitory pore and complete deflation of the adipocytes. The low level laser energy affected the adipose cell by causing a transitory pore in the cell membrane to open, which permitted the fat content to go from inside to outside the cell. The cells in the interstitial space and the capillaries remained intact. Low level laser-assisted lipoplasty has a significant impact on the procedural implementation of lipoplasty techniques.

SUPPORTING CLINICAL DATA: ERCHONIA CORPORATION CLINICAL TRIAL RESULTS

The following is summaries of the results of the clinical trials performed and submitted in support of the FDA clearances for the body contouring/fat reduction indications as reported above (K121695 & K082609; K121690 & K120257; and K123237).

1) **An Evaluation of the effectiveness of the Erchonia® Scanner device (GLS) as a non-invasive dermatological aesthetic treatment for the reduction of circumference of the waist, hips and thighs; *Version 2.0, March 24, 2011*** *(cleared and marketed as the Erchonia® Zerona™ 2.0 Laser)*

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

DEVICE DESCRIPTION
The Erchonia® Scanner device (GLS) used in this study employed 532 nm green laser diodes.

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

STUDY SUBJECT POPULATION
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.

Study subject age ranged from 20 to 63 years and averaged 38 years (n=49). Forty-six (46) subjects (84%) were female and 9 subjects were male (16%). Fifty-six (56) subjects (92%) were Caucasian, 3 subjects (5%) were Middle Eastern, and 2 subjects (3%) were African American.

Subjects were males and females aged 18 to 65 years with a Body Mass Index (BMI) of less than 30 kg/m² and who were deemed suitable for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that do not respond to diet and exercise; specifically for the indication of body contouring in the areas of the waist, hips and bilateral thighs. (As per the American Academy of Cosmetic Surgery's 2006 Guidelines for Liposuction Surgery developed by *A joint Ad Hoc Committee of the American Society of Lipo-Suction Surgery (ASLSS) and the American Academy of Cosmetic Surgery(AACS)).*

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

STUDY MEASURES
Circumference measurements (inches) of the waist, hips, right thigh and left thigh were recorded at baseline, study mid-point (week 1), study endpoint (week 2), and study follow-up two weeks later. Subject satisfaction with procedure outcome was recorded at study endpoint.

STATISTICAL ANALYSIS

Primary Efficacy Outcome Analysis

The study primary outcome measure was defined as the change in total combined inches in circumference measurements (waist, hips and bilateral thighs) from baseline (pre-procedure) to following completion of the two-week procedure administration phase (study endpoint: end of week 2).

Individual Subject Success Criteria

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 combined inches in circumference measurements across this primary evaluation period.

Overall Study Success Criteria

It was pre-determined that the study would be considered an overall success if the proportion of individual subject successes in the test (active procedure) group was at least 35% greater than the proportion of individual subject successes in the placebo (sham procedure) group.

68.57% of subjects who received the study procedures with the actual (active) Erchonia® GLS attained a decrease in combined circumference measurements of 3.0 inches or greater compared with 18.75% of subjects who received the study procedures with a 'fake' (placebo) laser device. A Fischer's Exact Test for two independent proportions found this difference of 49.82% between subject procedure groups to be statistically significant at $p<0.0001$.

Change Scores

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

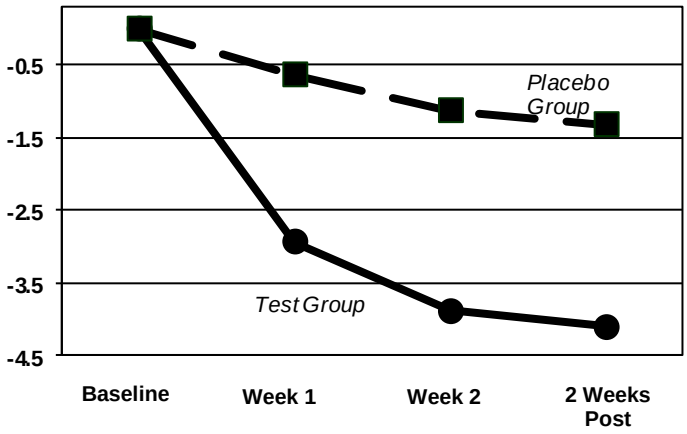
Table 13 and Chart 1 below show the mean change in combined circumference measurements (waist, hips, and right and left thigh circumference measurements combined) across the four study measurement time points for the intent-to-treat (ITT) study subject population.

ITT analysis was conducted for all randomized subjects who had a measurement recorded at baseline. All 67 randomized subjects had circumference measurements recorded at baseline, at week 1 and at week 2 measurement points. Thirteen (13) of the 67 subjects did not have circumference measurements recorded at the 2 weeks post-procedure measurement point: 8 subjects who had been randomized to the test group and 5 subjects who had been randomized to the placebo group. For these 13 subjects, the last observation carried forward (LOCF) procedure was employed, such that the subject's week 2 circumference measurement was carried forward as the week 2 post-procedure measurement.

Table 1: Mean total circumference measurements (ins.) across evaluation points

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

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



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

Individual Body Area Circumference Measurements

Table 2 below shows the mean circumference measurements for each individual body area of the waist, hips and right and left thighs, by study procedure group, at each of the four evaluation points, for the ITT population

Table 2: Individual body area circumference measurements across study duration by procedure group for the ITT population

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

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

Study Outcome Satisfaction Ratings
At completion of the study procedure administration phase, the subject was asked to rate how satisfied he or she was with any overall change in the appearance of the waist-hips-bilateral thighs area attained using the following five-point scale: Very Satisfied; Somewhat Satisfied; Neither Satisfied nor Dissatisfied; Not Very Satisfied; Not at All Satisfied. Sixty-five percent (65%) of test group subjects reported being 'Satisfied' ('Very Satisfied' or 'Somewhat Satisfied') with the outcome of the study procedures compared with 19% of placebo subjects.

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.

2) 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

PURPOSE OF STUDY
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.

DEVICE DESCRIPTION
The Erchonia® MLS laser device used in this study employed 635nm red laser diodes.

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

STUDY SUBJECT POPULATION
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.

Sixty (60) subjects (97%) were female and 2 subjects were male (3%). Thirty seven (37) subjects (60%) were Caucasian, 21 subjects (34%) were Hispanic, 2 subjects (3%) were African American, and 2 subjects (3%) were Caucasian and African American.

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).

PROCEDURE ADMINISTRATION
Subjects received six total procedure administrations with the Erchonia® MLS (active or sham) to the right and left upper arms across a consecutive two-week period: three procedures per week, each procedure at two to three days apart, at the investigator's test site.

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.

STATISTICAL ANALYSIS

Primary Efficacy Outcome Analysis

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 $p<0.000005$.

Change Scores

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 1 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 2 below.

Table 1: 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 2: Paired samples t-tests for placebo group subjects

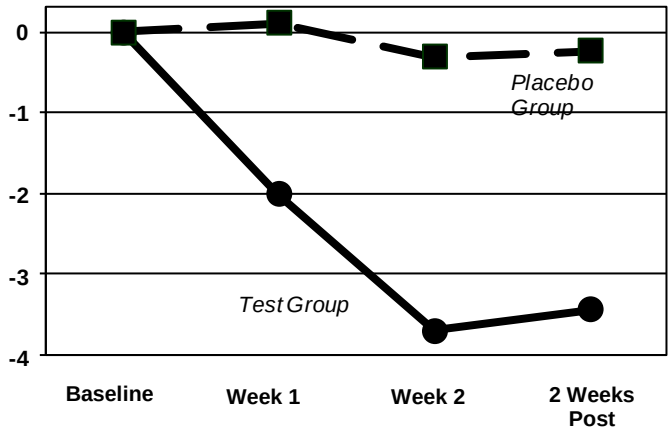
Placebo Group	μa-μb	**t**	**df**	**p(two-tailed)**	**p**	**significance**
Right Arm	0.0806	+0.83	30	0.413	p>0.05	Not significant
Left Arm	0.23	+1.95	30	0.061	p>0.05	Not significant
Right & Left Arms	0.31	+1.67	30	0.105	p>0.05	Not significant

Table 3 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 3: 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.

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.

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. Sixty-five per cent (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.

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.

3) 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 clinical study protocol: *Version 5, September 18, 2007.*

PURPOSE OF STUDY

The purpose of this clinical study was to determine the effectiveness of the Erchonia® ML Scanner (MLS) manufactured by ERCHONIA CORPORATION (the Company) as a non-invasive alternate therapy to liposuction for the purpose of body contouring of the waist, hips and thighs.

DEVICE DESCRIPTION

The Erchonia® MLS laser device used in this study employed 635 nm red laser diodes.

STUDY DESIGN

This clinical study was a placebo-controlled, randomized, double-blind parallel group three-center design.

STUDY SUBJECT POPULATION

There were 67 enrolled subjects: 35 randomized to the active treatment group and 32 randomized to the placebo group. Sixty four (64) subjects were female and 3 subjects were male. Sixty six (66) subjects were Caucasian, and one was Caucasian and African American.

All subjects were deemed suitable for liposuction or for use of liposuction techniques for the removal of localized deposits of adipose tissues that do not respond to diet and exercise; specifically for the indication of body contouring in the areas of the waist, hips and bilateral thighs. (As per the American Academy of Cosmetic Surgery's 2006 Guidelines for Liposuction Surgery developed by A joint Ad Hoc Committee of the American Society of Liposuction Surgery (ASLSS) and the American Academy of Cosmetic Surgery (AACS)).

PROCEDURE ADMINISTRATION

Each subject received six total procedure administrations with the Erchonia® MLS (active or sham) across a consecutive two-week period: three procedures per week, each procedure at least two days but no more than three days apart, at the investigator's test site.

STATISTICAL ANALYSIS

Primary Efficacy Outcome Analysis

The primary efficacy outcome measure was defined as the change in total combined inches in circumference measurements (waist, hips and bilateral thighs) from study baseline (pre-procedure) to study endpoint (following completion of the two-week procedure administration phase with the Erchonia® MLS laser device).

Individual subject success criteria

The individual subject success criteria was defined as at least a 3.0 inch reduction in combined circumference measurements for the waist, hips and bilateral thighs from baseline to endpoint.

Overall study success criteria.

Overall study success criteria was defined as at least a 35% difference between treatment groups, comparing the proportion of individual successes in each group.

Evaluation Time Point
The evaluation time point at which study success was analyzed was following completion of the sixth and final study procedure administration, two weeks after treatment phase onset.

Primary Outcome Measure Analyses

Proportion of successes
Table 1 below shows the number and percentage of test and placebo group subjects who met the study **individual subject success criteria**

Table 1: Individual Success Criteria met by treatment group

	Test subjects	**Placebo subjects**
n	35	32
n meeting success criteria	22	2
% meeting success criteria	**62.86%**	**6.25%**

There is a **difference of 56.61% between procedure groups**, such that 56.61% more test group than placebo group subjects showed a total decrease in combined circumference measurements from pre-procedure to study end point of 3 inches or greater, exceeding the pre-established target of a 35% difference between treatment groups by almost 22%.

A **Fischer's Exact Test for two independent proportions** was conducted to compare the proportion of successes between treatment groups. The results are as follows:

2 X 2 Table	**Success Met**	**Success Not Met**	
Test Group	22	13	35
Placebo Group	2	30	32
	24	43	67

- p(one-tailed) < 0.00001
- p(two-tailed) < 0.00001

The difference was found to be **statistically significant at p<0.00001**, meaning that the two treatment groups gave significantly different results, such that the greater treatment effect observed for subjects in the test group relative to subjects in the placebo group is statistically significant and can be attributed to the efficacy of the application of the Erchonia® MLS over a placebo device.

Change scores

Table 2 below shows the mean and standard deviation of the magnitude of the change in combined circumference measurements from pre-procedure to study end point for test versus placebo subjects.

Table 2: Mean and standard deviation of the change in circumference by treatment group

	Test subjects (n=35)	**Placebo subjects (n=32)**
Mean	-3.521	-0.684
SD	1.854	1.233

A **t-test for independent samples** was conducted to compare the two independent group means for the continuous variable of mean change in combined circumference (total number of inches) from study baseline to end point. The difference was found to be **statistically significant at p<0.0001:** μa-μb=-2.8378*;* t=-7.30; df=65; p(two-tailed)<0.0001, such that the mean decrease in number of total inches for test group subjects was significantly greater than for placebo group subjects.

In confirmation, a **One-Way ANOVA for 2 Independent Samples** was conducted to compare the same two independent group means for means changed in combined inches lost. The results were significant at p<0.0001 (F=53.36).

Secondary Efficacy Outcome Analysis

Change in inches in combined waist-hips-thighs circumference across all measurement points
Circumference measurements were recorded at baseline, end of procedure administration week 1, end of procedure administration week 2 (study end point) and 2 weeks post-procedure.

Table 3 below shows the mean and standard deviation total circumference measurements by treatment group at each of the four time points.

Table 3: Total circumference measurements across study duration by treatment group

	Test Group			Placebo Group		
	n	**Mean**	**St. Dev.**	**n**	**Mean**	**St. Dev.**
Baseline	35	120.31	7.96	32	122.99	10.54
Week 1	35	118.25	8.31	32	122.73	10.49
Week 2	35	116.79	8.11	32	122.31	10.82
2 weeks post	35	117.09	7.96	32	122.37	10.43

A series of One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples was performed to assess for differences in total circumference measurements across the four time points for each treatment group.

- *Test Subjects*

For subjects assigned to the test device group, a significant change (decrease) in total circumference measurement was detected (F=40.8371, p<0.0001). A subsequent Tukey HSD test revealed that significant decreases in total circumference measurements (significant at the p<0.01 level) occurred between:

- ✓ Baseline and week 1
- ✓ Baseline and week 2
- ✓ Baseline and 2 weeks post
- ✓ Week 1 and week 2
- ✓ Week 1 and 2 weeks post

… while the change in total circumference measurements between week 2 and 2 weeks post procedure was not statistically significant (p>0.05).

Therefore, for test subjects…

- Compared with baseline, total circumference measurements were statistically significantly lower at all three subsequent evaluation points: week 1, week 2 and 2 weeks post-procedure, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.
- While a statistically significant decrease in total circumference measurement occurred following the first week of 3 laser procedures, this measure showed a second statistically significant decrease following the second week of 3 laser procedures, indicating a progressive and cumulative treatment effect of the laser.
- The lack of a statistically significant change in total circumference measurement between week 2 and the follow-up measurement point of 2 weeks post-procedure indicates duration of the treatment effect up to at least 2 weeks following the end of laser procedure administration.

➢ *Placebo Subjects*

For subjects assigned to the placebo device group, the changes in total circumference measurement between and across measurement points were **not statistically significant** for any interval (F=2.4118, p=0.0717; p>0.05).

Change in inches in combined waist-hips-thighs circumference between measurement points: A comparison between test and placebo procedure groups

Table 4 below shows the mean and standard deviation of the change in total circumference measurements by treatment group between each of the four time points.

Table 4: Mean and standard deviation of the change in total circumference measurements between evaluation periods by treatment group

	Test Group			Placebo Group		
	n	**Mean**	**St. Dev.**	**n**	**Mean**	**St. Dev.**
Baseline – week 1	35	-2.06	1.94	32	-0.27	1.89
Baseline - week 2	35	-3.52	1.85	32	-0.68	1.23
Baseline – 2 weeks post	35	-3.21	1.87	32	-0.62	1.21
Week 1 – week 2	35	-1.46	1.70	32	-0.42	2.20
Week 1 – 2 weeks post	35	-1.15	2.86	32	-0.36	1.95
Week 2 – week 4	35	0.31	2.10	32	0.06	1.05

A series of **t-tests for independent samples** was conducted to evaluate the significance of the difference in change in total circumference measurements between evaluation points between treatment groups. The change differences were statistically significantly different between treatment groups between the following evaluation periods:

- ✓ Baseline to week 1: p<0.0005
- ✓ Baseline to week 2: p<0.0001
- ✓ Baseline to 2 weeks post procedure: p<0.0001
- ✓ Week 1 to week 2: p<0.05

Therefore, the changes in total circumference measurements between baseline and all subsequent measurement points, and between weeks 1 and 2 evaluation points, were statistically significantly greater for subjects in the test group than for subjects in the placebo group. These findings support the efficacy of the true Erchonia laser device over the placebo device in this study.

Change in inches in individual area circumference measurements across measurement points

Table 5 below shows the mean and standard deviation circumference measurements for each of the individual treatment areas, by treatment group, at each of the four time points.

Table 5: Individual treatment area circumference measurements across study duration by treatment group

	Test Group			Placebo Group		
Waist	**n**	**Mean**	**St. Dev.**	**n**	**Mean**	**St. Dev.**
Baseline	35	33.94	3.63	32	34.85	3.83
Week 1	35	33.38	3.39	32	34.85	3.76
Week 2	35	32.96	3.51	32	34.60	3.93
2 weeks post	35	32.86	3.65	32	34.53	3.81
Hip	**n**	**Mean**	**St. Dev.**	**n**	**Mean**	**St. Dev.**
Baseline	35	38.99	2.87	32	39.88	3.77
Week 1	35	38.26	3.71	32	39.80	3.57
Week 2	35	37.94	3.60	32	39.67	3.73
2 weeks post	35	38.29	2.83	32	39.66	3.66
Right thigh	**n**	**Mean**	**St. Dev.**	**n**	**Mean**	**St. Dev.**
Baseline	35	23.80	1.52	32	24.12	2.04
Week 1	35	23.31	1.41	32	24.10	2.09
Week 2	35	22.95	1.40	32	24.07	2.10
2 weeks post	35	23.02	1.49	32	24.16	2.05
Left thigh	**n**	**Mean**	**St. Dev.**	**n**	**Mean**	**St. Dev.**
Baseline	35	23.59	1.40	32	24.14	1.95
Week 1	35	23.30	1.34	32	23.98	2.02
Week 2	35	22.94	1.27	32	23.97	2.11
2 weeks post	35	22.92	1.28	32	24.02	1.96

A series of **One-Way Analysis of Variance (ANOVA) for 4 Correlated Samples** was performed to assess for differences in individual area circumference measurements across the four time points for each treatment group.

Waist Circumference

- *Test Subjects*

For subjects assigned to the test device group, a significant change (decrease) in circumference measurements for the waist was detected ($F=26.2357$, $p<0.0001$). A subsequent Tukey HSD test revealed that statistically significant decreases in circumference measurements for the waist occurred between:

- ✓ Baseline and week 1 ($p<0.01$)
- ✓ Baseline and week 2 ($p<0.01$)
- ✓ Baseline and 2 weeks post procedure ($p<0.01$)
- ✓ Week 1 and week 2 ($p<0.05$)
- ✓ Week 1 and 2 weeks post procedure ($p<0.01$)

… while the change in total circumference measurements between week 2 and 2 weeks post procedure was not statistically significant ($p>0.05$).

Therefore, for test subjects…

- Compared with baseline, circumference measurements for the **waist** were statistically significantly lower at all three subsequent evaluation points: week 1, week 2 and 2 weeks post-procedure, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.
- While a statistically significant decrease in circumference measurements for the waist occurred following the first week of 3 laser procedures, this measure showed a second statistically significant decrease following the second week of 3 laser procedures, indicating a progressive and cumulative treatment effect of the laser.
- The lack of a statistically significant change in waist circumference measurement between week 2 and the follow-up measurement point of 2 weeks post-procedure indicates duration of the treatment effect up to at least 2 weeks following the end of laser procedure administration.

- *Placebo Subjects*

For subjects assigned to the placebo device group, the changes in waist circumference measurement across measurement points were **not statistically significant** for any interval ($F=2.1692$, $p=0.097$ $p>0.05$).

Hip Circumference

- *Test Subjects*

For subjects assigned to the test device group, a significant change (decrease) in circumference measurements for the hip was detected ($F=6.0118$, $p<0.001$). A subsequent Tukey HSD test revealed that statistically significant decreases in circumference measurements for the hip occurred between:

- ✓ Baseline and week 1 ($p<0.05$)
- ✓ Baseline and week 2 ($p<0.05$)
- ✓ Baseline and 2 weeks post procedure ($p<0.05$)

Therefore, for test subjects, compared with baseline, circumference measurements for the **hip** were statistically significantly lower at all three subsequent evaluation points: week 1, week 2 and 2 weeks post-procedure, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.

- *Placebo Subjects*

For subjects assigned to the placebo device group, the changes in hip circumference measurement across measurement points were **not statistically significant** for any interval (F=1.6784, p=0.177 p>0.05).

Right Thigh Circumference

- *Test Subjects*

For subjects assigned to the test device group, a significant change (decrease) in circumference measurements for the right thigh was detected (F=22.0542, p<0.0001). A subsequent Tukey HSD test revealed that statistically significant decreases in circumference measurements for the right thigh occurred between:

- ✓ Baseline and week 1 (p<0.01)
- ✓ Baseline and week 2 (p<0.01)
- ✓ Baseline and 2 weeks post procedure (p<0.01)
- ✓ Week 1 and week 2 (p<0.05)

… while the change in total circumference measurements between week 2 and 2 weeks post procedure was not statistically significant (p>0.05).

Therefore, for test subjects…

- Compared with baseline, circumference measurements for the **right thigh** were statistically significantly lower at all three subsequent evaluation points: week 1, week 2 and 2 weeks post-procedure, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.
- While a statistically significant decrease in circumference measurements for the right thigh occurred following the first week of 3 laser procedures, this measure showed a second statistically significant decrease following the second week of 3 laser procedures, indicating a progressive and cumulative treatment effect of the laser.
- The lack of a statistically significant change in right thigh circumference measurement between week 2 and the follow-up measurement point of 2 weeks post-procedure indicates duration of the treatment effect up to at least 2 weeks following the end of laser procedure administration.

- *Placebo Subjects*

For subjects assigned to the placebo device group, the changes in right thigh circumference measurement across measurement points were **not statistically significant** for any interval (F=0.4048, p=0.7499 p>0.05).

Left Thigh Circumference

- *Test Subjects*

For subjects assigned to the test device group, a significant change (decrease) in circumference measurements for the left thigh was detected ($F=25.6971$, $p<0.0001$). A subsequent Tukey HSD test revealed that statistically significant decreases in circumference measurements for the left thigh occurred between:

- ✓ Baseline and week 1 ($p<0.01$)
- ✓ Baseline and week 2 ($p<0.01$)
- ✓ Baseline and 2 weeks post procedure ($p<0.01$)
- ✓ Week 1 and week 2 ($p<0.01$)
- ✓ Week 1 and 2 weeks post procedure ($p<0.01$)

… while the change in total circumference measurements between week 2 and 2 weeks post procedure was not statistically significant ($p>0.05$).

Therefore, for test subjects…

- Compared with baseline, circumference measurements for the **left thigh** were statistically significantly lower at all three subsequent evaluation points: week 1, week 2 and 2 weeks post-procedure, demonstrating effectiveness of the laser procedures that was maintained over time, including a 2-week period where there were no laser procedure administrations.
- While a statistically significant decrease in circumference measurements for the left thigh occurred following the first week of 3 laser procedures, this measure showed a second statistically significant decrease following the second week of 3 laser procedures, indicating a progressive and cumulative treatment effect of the laser.
- The lack of a statistically significant change in left thigh circumference measurement between week 2 and the follow-up measurement point of 2 weeks post-procedure indicates duration of the treatment effect up to at least 2 weeks following the end of laser procedure administration.

- *Placebo Subjects*

Based on the ITT population, for subjects assigned to the placebo device group, the changes in left thigh circumference measurement across measurement points were **not statistically significant** for any interval ($F=2.0517$, $p=0.1120$ $p>0.05$).

In conclusion, the results of the ANOVA analyses of the changes in individual area circumference measurements across the 4 evaluation time points for both test group and placebo group subjects for the per protocol population are consistent with and fully supportive of the respective ANOVA analysis results that indicate effectiveness of the Erchonia laser when considering each treatment area individually and absence of effectiveness of application of the placebo laser device.

In addition, neither weight measurements nor Body Mass Index (BMI) measurements changed significantly across and between any of the measurement points for either test or placebo subject groups. However, circumference measurements did change significantly across and between measurement points for test group subjects but not for placebo group subjects for both the ITT and per protocol population analyses. This combined finding further supports the effectiveness of the Erchonia laser device as it demonstrates that the change in body shape

(reduction in inches at the waist, hip and thighs) attained for test group subjects in this study resulted from the Erchonia® MLS device applications and not from incidental weight loss or change in BMI.

Study outcome satisfaction ratings: A comparison between test and placebo procedure groups
At the 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 following the procedure administration with the Erchonia® MLS using the following five-point scale:

- ✓ Very Satisfied
- ✓ Somewhat Satisfied
- ✓ Neither Satisfied nor Dissatisfied
- ✓ Not Very Satisfied
- ✓ Not at All Satisfied

Thirty (30) of the 35 test subjects (86%) and 31 of the 32 placebo subjects (97%) responded to this question.

Table 6 below shows the number/percent of subjects who reported each level of satisfaction/ dissatisfaction by treatment group.

Table 6: Number/percent of subjects by study outcome satisfaction level by treatment group.

	Test group (n=30)		**Placebo group (n=31)**	
	n	**%**	**n**	**%**
Very satisfied	8	27%	1	3%
Somewhat satisfied	13	43%	7	23%
Neither satisfied nor dissatisfied	8	27%	12	38%
Not very satisfied	1	3%	7	23%
Not at all satisfied	0	0%	4	13%

A **Fischer's Exact Test for two independent proportions** was conducted to compare the proportion of 'satisfied' versus 'dissatisfied' subjects between treatment groups. The results are presented below:

2 X 2 Table	**Satisfied**	**Dissatisfied**	
Test Group	21	1	22
Placebo Group	8	11	19
	29	12	

The difference was found to be **statistically significant at p(2-tailed)=0.0003: p<0.0005**, meaning that the two treatment groups gave significantly different ratings, such that the **higher study outcome satisfaction ratings reported by subjects in the test group than by subjects in the placebo group is statistically significant and can be attributed to the efficacy of the application of the Erchonia® MLS over a placebo device.**

No adverse events were observed or reported throughout the study.

STUDY DESIGN

This clinical study is a double-blind, placebo-controlled randomized dual-site evaluation of the effect of the Erchonia® Obesity Laser employing ten 532 nm green diodes for non-invasive circumference reduction of the hips, waist and upper abdomen in individuals with Body Mass Index between 30 kg/m² and 40 kg/m².

PROCEDURE GROUPS

Each subject will be randomized to either the test procedure group or to the placebo procedure group, as follows:

Test procedure group: Subjects randomized to the test procedure group will receive the study procedures with the active (true) Erchonia® Obesity Laser.

Placebo procedure group: Subjects randomized to the placebo procedure group will receive the study procedures with a 'fake' (placebo) Erchonia® Obesity Laser.

DOUBLE BLIND DESIGN

This clinical study will be a double-blind design, such that neither the subject nor the investigator involved in recording study assessments will be aware of whether a subject has been assigned to the test procedure group or to the control (placebo) procedure group until after the study is complete.

Maintenance of study double-blind throughout the entire course of the study will be achieved through the following means:

1) Each subject will be randomly assigned to Procedure Group A or to Procedure Group B. Subjects assigned to Procedure Group A will be treated with the Erchonia® Obesity Laser A and subjects assigned to Procedure Group B will be treated with Erchonia® Obesity Laser B. Only one designated individual (employee) at the study Sponsor's work site will know which label ('A' or 'B') corresponds to the actual (test) Erchonia® Obesity Laser device and which label corresponds to the 'fake' device until the final study data analysis is complete. The Sponsor representative will ensure that this information is stored and maintained confidentially at the Sponsor's work site. This knowledge will not be shared with the investigators, the subjects, or the study Monitor until the final data analysis is complete.

2) The fake (placebo) Erchonia® Obesity Laser is designed to have the same physical appearance as the actual Erchonia® Obesity Laser, including the appearance of any **visible** light output, such that both the test and sham devices emit light when activated that is indistinguishable to both the subject and to the investigator. As the laser light also does not put out any notable degree of heat or noise, these are not distinguishing factors for subjects between the two groups, either.

3) There will be two independent investigators interacting with subjects:

   (i) *Administration Investigator*: The Administration Investigator will be responsible for administrating the study procedures; and
   (ii) *Assessment Investigator*: The Assessment Investigator will be responsible for recording the study outcome measures.

Only the Administration Investigator will be aware of whether a subject is assigned to Procedure Group A or to Procedure Group B, although he or she will not be made aware of whether A or B corresponds to the true or fake laser. Neither the Assessment Investigator nor the subject will even be aware of the subject's A/B Group assignment. In this way, the Assessment Investigator will not be able to form an association between A/B Procedure Group and active/sham device over the course of the study if a treatment effect is observed.

4) During the laser procedures, both the subject and the Administration Investigator will wear the safety glasses that filter out the laser light spectrum for further blinding security.

RANDOMIZATION

Subject allocation to procedure group will be via variable block randomization with varying block sizes of two, four and six used at random to minimize the likelihood of predicting the next procedure group assignment. In addition, randomization will be stratified by test site.

Randomization will be attained using computer generation sequence methodology, insuring that the randomization methodology and the generated allocation sequence is concealed from the study investigators and subjects.

Concealment will be insured as follows:

(i) Each computer generated randomization sequence is unique and will therefore not be able to be replicated.
(ii) Randomization will occur to either 'Procedure Group A' or to 'Procedure Group B' rather than to a test or placebo group, and only the sole study Sponsor representative will know which assignment (A or B) corresponds to the active device and which corresponds to the fake device. The Sponsor representative will not reveal this information to any source (investigators, subjects, or study Monitor) until the final study data analysis is complete.

SUBJECTS

Subjects will be overweight/obese individuals who are voluntarily seeking assistance to reduce circumference around the hips, waist and upper abdomen body area.

<u>Recruitment</u>

The recruitment process will work as follows:

1. An individual voluntarily schedules an appointment at the physician's office (that in the context of this study also functions as the investigator's test site) to discuss his or her desire for body shaping in the area of the hips, waist and upper abdomen.
2. Through this initial patient consultation visit, if the physician perceives that the subject may be a potentially likely candidate for enrollment in this clinical study, then the physician will present to the patient the option of being a subject in the study.
3. If the patient is interested in possibly taking part in the study, the physician – now in the role of study investigator – will personally review the informed consent form with the individual and answer his or her questions. The individual may sign the informed consent form at that visit or he or she may think about it for a while and sign the informed consent form at a later time (taking as long as desired, from hours to days to sign as long as study enrollment is continuing at the time the decision to sign is made) or he or she may refuse to participate.
4. An individual who signs the study consent form will receive a subject ID and proceed to the study qualification evaluation phase of the study.
5. An individual who decides not to participate in the study will continue to work with the physician to determine a treatment plan for his or her goals.

Compensation
A subject will not be offered money or any other form of compensation to participate in this clinical study; however, he or she will also not be charged for the cost of the study procedures administered with the Erchonia® Obesity Laser or for the cost of any other directly-related evaluations or measurements that occur as part of his or her participation in the study.

Sample size
There will be 48 qualified subjects enrolled in this clinical study:

- 24subjects in the test group
- 24 subjects in the control group

Rationale for sample size
Based on the following parameters established for the purposes of assessing efficacy of the Erchonia® Obesity Laser device in this clinical study …:

- ✓ Overall study success criteria of at least a 40% difference between groups, comparing the proportion of individual successes in each group. Individual subject success criteria is defined as a 3.0 inch or greater reduction in combined circumference measurements for the hips, waist and upper abdomen combined, from Baseline (pre-treatment) to study Endpoint (four weeks after Baseline, after the final laser treatment administration). It is anticipated that about 55% of subjects in the test group and about 15% of subjects in the control group will meet the individual success criteria, and
- ✓ Intended application of a one-tailed test for results analysis with an alpha value of 0.05 and Power of 0.8.

  …the sample size of 22 subjects per procedure group (test and control, separately) has been determined using the following reference calculator: *Hypothesis Testing: Categorical Data - Estimation of Sample Size and Power for Comparing Two Binomial Proportions* in Bernard Rosner's *Fundamentals of Biostatistics.*

From here, it is anticipated that about one-twelfth of subjects overall may withdraw from the study prior to completion for various reasons. Therefore, the following formula is used to determine the final needed starting sample size for each group:

Final sample size = sample size X 1/(1-d); where d = # expected dropouts/# subjects enrolled.
Final sample size = 22 X 1/(1-0.083)
Final sample size = 22 X 1/0.917 = 27 X 1.0905 = 24 subjects per group.

Therefore, a minimum starting total study sample size of 48 subjects is needed to insure that a sufficient number remains at the end of the trial (44 subjects) for any significant differences found between groups to be considered statistically valid and representative of the general population being sampled.

The parameters for determining this sample size are derived from those employed and results attained and considered to be positive for statistically significant and clinically meaningful change by the FDA for the three prior clinical trials employing Erchonia® low level light lasers to evaluate circumference reduction indications and whose results were accepted in support of the respective FDA clearances for those indications ((K121695 & K082609; K121690 & K120257; and K123237), as presented above in this clinical study protocol document under the section titled: DEVICE INFORMATION: ERCHONIA® OBESITY LASER: REGULATORY BACKGROUND.

STUDY PROCEDURE

STUDY TEST BATTERY

The following is a listing of the study measurement tools to be used in this study. For each study phase, the precise tools from this list that will be employed will be specified.

BODY MASS INDEX (BMI): BMI is calculated as the ratio of a person's weight in kilograms (kg) to his or her height in meters squared (m^2).

PHOTOGRAPHS: High-resolution digital photographs of the subject's hips/waist/upper abdomen area, frontal view and back view, separately will be taken. The photographs will be taken in a standardized manner in the same room under the same lighting conditions, by the same individual, with the same camera (settings fixed) fixed at the same location, with all subjects situated at the same distance from the camera for each photograph, and wearing comparable undergarments at each photographic evaluation point.

HIPS, WAIST AND UPPER ABDOMEN CIRCUMFERENCE: The circumference in inches (ins.) will be measured for the subject's hips waist and upper abdomen, as follows, to ensure consistency of measurements across all evaluation time points:

- ✓ Hips circumference measurement: The hips circumference measurement will be made such that both hip bones are encircled.

- ✓ Waist (mid-abdomen) circumference measurement: The distance in inches from the hip bone to the point at which the circumference of the waist is measured (at the subject's natural waist formation) will be recorded after first measurement to allow for consistent subsequent post-procedure measurements.

- ✓ Upper Abdomen: The distance in inches from the natural waist to the point at which the upper abdomen is measured will be recorded after first measurement to allow for consistent subsequent post-procedure measurements.

In addition, the same individual will be responsible for all circumference measurement recordings for all subjects for additional consistency and removal of potential inter-investigator variability. This individual will have been previously trained in this procedure routinely performed at the test site for patients undergoing body contouring procedures.

BASELINE DIET AND EXERCISE PATTERNS: Details of a subject's typical daily diet (food and drink consumption) and exercise patterns are recorded at baseline assessment.

BASELINE CONCOMITANT MEDICATION AND THERAPY USE: Medications (OTC and prescription) routinely taken by the subject and other therapies or treatments routinely engaged in by the subject (non-study excluded) at the time of baseline assessment are recorded.

DEMOGRAPHICS: The subject's age, gender and ethnicity are recorded.

SKIN MARKERS NOTATION: The Assessment Investigator records the presence and location of any existing skin markers on the subject's hips, waist and upper abdomen area to be treated with the Erchonia® Obesity Laser, under the following categories:

- ✓ notation of hernias, scars, asymmetries, cellulite, stretch marks, discoloration, etc.
- ✓ presence of stria and dimpling
- ✓ underlying abdominal musculofacial system and presence/absence of flaccidity and diastasis recti
- ✓ quality of the skin and its elasticity

SUBJECT SATISFACTION WITH OVERALL OUTCOME RATING: The subject is asked to indicate how satisfied he or she is with any change in the appearance of his or her hips/waist/ upper abdomen area following the procedures with the Erchonia® Obesity Laser in response to the following question, using the accompanying five-point Likert scale:

"How satisfied or dissatisfied are you with any change you may have noticed in the appearance of your hips, waist and upper abdomen area after having received the procedures with the Erchonia® Obesity Laser?"

- ✓ Very Satisfied
- ✓ Somewhat Satisfied
- ✓ Neither Satisfied nor Dissatisfied
- ✓ Not Very Satisfied
- ✓ Not at All Satisfied

SUBJECT PERCEIVED GROUP ALLOCATION AND RATIONALE: The subject records whether he or she believes that he or she received the study procedures with the true or fake Erchonia® Obesity Laser and records verbatim his or her reasoning or rationale for this perceived determination.

ASSESSMENT INVESTIGATOR PERCEIVED GROUP ALLOCATION AND RATIONALE: The Assessment Investigator records whether he or she believes the subject to have received the study procedures with the true or fake Erchonia® Obesity Laser and records verbatim his or her reasoning or rationale for this perceived determination.

SUBJECT DAILY DIARY: On each of the 28 days of the procedure administration phase, the subject will record at home the following information on the case report forms provided by the test site, as applicable:

- ➢ *Diet and exercise deviation:* Subjects will record any instance where their diet and exercise pattern for that day deviated notably from that which is typical for them (and as reported during the pre-procedure phase). For example, a subject who reported at baseline that he or she typically never engages in any form of exercise partakes in a 10-mile bike ride would record this as an exercise deviation for that day.
- ➢ *Concomitant medication and therapy use deviation:* Subjects will record any use of over-the-counter and prescription medication and any therapy engaged in that is different than that reported as typical during the pre-procedure phase.
- ➢ *Adverse Events* recording, as applicable.
- ➢ *Additional comments*, as desired

STUDY PROCEDURE PROTOCOL

PRE-PROCEDURE PHASE ACTIVITIES

All pre-procedure phase activities will take place on the same day. The successive progression of subject pre-procedure phase activities is as follows:

STUDY QUALIFICATION

SIGNING OF INFORMED CONSENT FORM
The investigator will commence by presenting and reviewing in detail the items in the informed consent form with the individual and answer any questions. To proceed further in the study protocol, the individual must willingly sign the informed consent form at this time.

ASSIGNMENT OF SUBJECT ID
The subject will be assigned a unique non-identifying Subject ID composed of the PI's first and last name initials and a 3-digit number based upon the subject's order of entry into the study. Additional information on subject ID assignment is contained in the PRIVACY AND CONFIDENTIALITY section further along in the protocol.

INCLUSION/EXCLUSION CRITERIA EVALUATION
If the individual remains interested in participating and has voluntarily signed the consent form, he or she will undergo the study qualification inclusion/exclusion criteria evaluation, as follows.

INCLUSION CRITERIA

To be eligible for study participation, a subject must satisfy each of the following criteria.

- Body Mass Index (BMI) is between 30 kg/m² and 40 kg/m², inclusive.
- Subject indicated for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that do not respond to diet and exercise; specifically for the indication of body contouring in the areas of the hips, waist and upper abdomen. (As per the American Academy of Cosmetic Surgery's 2006 Guidelines for Liposuction Surgery developed by *A joint Ad Hoc Committee of the American Society of Lipo-Suction Surgery (ASLSS) and the American Academy of Cosmetic Surgery (AACS))*
- Subject is willing and able to abstain from partaking in <u>any treatment other than the study procedure (existing or new)</u> to promote body contouring/circumference reduction/weight loss during the course of study participation. Such treatments include, but are not limited to:
  - ✓ over-the-counter and/or prescription medications indicated to promote body sculpting/weight loss, including dietary/herbal supplements/minerals and appetite suppressants such as Xenical (orlistat), Meridia (sibutramine), Alli, etc.
  - ✓ weight loss programs/diet plans such Weight Watchers, LA Weight Loss, SlimFast, Atkin's, etc.
  - ✓ surgical procedures to promote body sculpting/weight loss, such as liposuction, abdominoplasty, stomach stapling, lap bands, etc.
  - ✓ alternative therapies such as acupuncture, body wraps, hypnotherapy, mesotherapy.
- Subject is willing and able to maintain his or her regular (typical pre-study) diet and exercise regimen without effecting significant change in either direction during study participation.
- 18 years to 65 years of age, inclusive.
- Male or female.

EXCLUSION CRITERIA

A subject will be ineligible for study participation if satisfying any one or more of the following.

- Body Mass Index (BMI) is less than 30 kg/m² or greater than 40 kg/m².
- Known cardiovascular disease such as cardiac arrhythmias, congestive heart failure.
- Cardiac surgeries such as cardiac bypass, heart transplant surgery, pacemakers.
- Prior surgical intervention for body sculpting/weight loss, such as liposuction, abdominoplasty, stomach stapling, lap band surgery, etc.
- Medical, physical, or other contraindications for body sculpting/weight loss.
- Current use of medication(s) known to affect weight levels/cause bloating or swelling and for which abstinence during the course of study participation is not safe or medically prudent.
- Any medical condition known to affect weight levels and/or to cause bloating or swelling.
- Diagnosis of, and/or taking medication for, irritable bowel syndrome.
- Active infection, wound or other external trauma to the areas to be treated with the laser.
- Known photosensitivity disorder.
- Current active cancer or currently receiving treatment for cancer.
- Pregnant or planning pregnancy prior to the end of study participation.
- Serious mental health illness such as dementia or schizophrenia; psychiatric hospitalization in past two years.
- Developmental disability or cognitive impairment that in the opinion of the investigator would preclude adequate comprehension of the informed consent form and/or ability to record the necessary study measurements.
- Involvement in litigation and/or a worker's compensation claim and/or receiving disability benefits related to weight-related and/or body shape issues.
- Participation in a clinical study or other type of research in the past 30 days.

PROCEDURE GROUP RANDOMIZATION

A fully qualified subject will be randomly assigned to Procedure Group A or to Procedure Group B, following the methodology outlined above in the STUDY DESIGN section of the protocol.

PRE-PROCEDURE PHASE MEASURES AND RECORDINGS

PRE-PROCEDURE PHASE MEASURES

The following pre-procedure measures will be recorded according to the procedures outlined in the STUDY PROCEDURE: STUDY TEST BATTERY section above in this protocol document.

- Body Mass Index (BMI)
- Photographs
- Hips, Waist and Upper Abdomen Circumference measurements

PRE-PROCEDURE PHASE RECORDINGS

The following pre-procedure recordings will be made according to the procedures outlined in the STUDY PROCEDURE: STUDY TEST BATTERY section above in this protocol document.

- Baseline Diet and Exercise Patterns.
- Baseline Concomitant Medication and Therapy Use:
- Skin Markers Notations
- Demographics

PROCEDURE ADMINISTRATION PHASE ACTIVITIES

The procedure administration phase of the study will commence on the same day as the pre-procedure phase activities are completed, right after the pre-procedure phase activities are completed.

PROCEDURE ADMINISTRATION PROTOCOL

- The procedure administration phase will extend over 4 consecutive weeks.
- Each subject will receive 12 total procedure administrations with the Erchonia® Obesity Laser across the consecutive 4-week procedure administration phase, 3 procedure administrations per week.
- Each procedure administration will be approximately evenly spaced.
- Each procedure administration with the Erchonia® Obesity Laser will be administered at the test site by the Administration Investigator.
- The procedure administration protocol for each session is as follows:

1. The subject enters the procedure room and lies comfortably flat on his or her back on the table such that the front area of the subject's body is facing upwards.
2. The subject is correctly fitted with the safety glasses.
3. The center diodes of the Erchonia® Obesity Laser (Laser A or B according to subject Procedure Group assignments) are positioned at a distance of 6 inches above the subject's abdomen (stomach), centered along the body's midline (the "line" that vertically "dissects" the body into two equal halves) and focused on the navel.
4. The Erchonia® Obesity Laser is then activated for 15 minutes over the subject's frontal region. Each scanner emits to the subject a laser beam of approximately 17 mW with a wavelength of 532 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 (the subject's hips, waist and upper abdomen). The target area is approximately 8.00 x 10.00 inches or 80 square inches (approximately 516 square centimeters).
5. The subject turns over to lie flat on his or her stomach such that the back area of the subject's body encompassing the region spanning from the subjects' back down though the hips and back aspect of both thighs, is facing upwards.
6. The center diode of the Erchonia® Obesity Laser (Laser A or B according to subject Procedure Group assignment) is positioned at a distance of 6.00 inches above the subject's back, centered along the body's midline (the "line" that vertically "dissects" the body into two equal halves) and focused on the equivalent spot to the navel's location on the stomach, as if along a line dissecting the body horizontally from front to back at the navel.
7. The Erchonia® Obesity Laser is then activated for 15 minutes over the subject's back region. Each scanner emits to the subject a laser beam of approximately 17 mW with a wavelength of 532 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 (the subject's hips, waist and upper abdomen). The target area is approximately 8.00 x 10.00 inches or 80 square inches (approximately 516 square centimeters).
8. The subject's safety glasses are removed and the procedure administration session is over.

PROCEDURE ADMINISTRATION PHASE MEASURES

DAILY MEASURES: On each of the 28 days of the four-week procedure administration phase, the subject will record at home all applicable information on the SUBJECT DAILY DIARY case report forms provided by the test site, as outlined in the STUDY PROCEDURE: STUDY TEST BATTERY section above.

EACH PROCEDURE ADMINISTRATION VISIT: At each of the 12 procedure administration visits, the Assessment Investigator will evaluate the subject for any potential adverse events.

END OF WEEK TWO EVALUATION: INTERIM EVALUATION
The following measures will be recorded at the test site by the Assessment Investigator following completion of the second procedure administration week (after the 6th procedure administration is completed), according to the procedures outlined in the STUDY PROCEDURE: STUDY TEST BATTERY section above.

- Body Mass Index (BMI)
- Hips, Waist and Upper Abdomen Circumference measurements
- Skin Marker's Notation
- Adverse Events Evaluation

END OF WEEK FOUR EVALUATION: STUDY ENDPOINT EVALUATION
The following measures will be recorded at the test site by the Assessment Investigator following completion of the fourth and final procedure administration week (after the 12th and final procedure administration is completed), according to the procedures outlined in the STUDY PROCEDURE: STUDY TEST BATTERY section above.

- Body Mass Index (BMI)
- Photographs
- Hips, Waist and Upper Abdomen Circumference measurements
- Skin Marker's Notation
- Adverse Event's Evaluation
- Subject Satisfaction With Overall Outcome Rating
- Subject Perceived Group Allocation and Rationale
- Assessment Investigator Perceived Group Allocation and Rationale

POST-PROCEDURE PHASE ACTIVITIES

Two weeks after the final procedure administration, the following measures will be recorded at the test site by the Assessment Investigator according to the procedures outlined in the STUDY PROCEDURE: STUDY TEST BATTERY section above.

- Body Mass Index (BMI)
- Photographs
- Hips, Waist and Upper Abdomen Circumference measurements
- Skin Marker's Notation
- Adverse Event's Evaluation

TABLE OF PROGRESSIVE STUDY EVENTS

PRE-PROCEDURE PHASE ACTIVITIES

The following activities are conducted:

1) Study Qualification:
   - Review and signing of informed consent form
   - Assignment of Subject ID
   - Inclusion/exclusion criteria evaluation
2) Procedure Group Randomization
3) Pre-Procedure Phase Measures and Recordings:
   - *Pre-Procedure Measures*: BMI; Photographs; Circumference measurements
   - *Pre-Procedure Recordings*: Baseline diet and exercise patterns; baseline concomitant medication and therapy use; skin marker's notation; demographics

PROCEDURE ADMINISTRATION PHASE ACTIVITIES

1) Procedure Administration Protocol: The subject received 12 30-minute procedure administrations with the Erchonia® Obesity Laser over 4 consecutive weeks, three procedure administration per week, administered by the Administration Investigator at the test site.
2) Procedure Administration Phase Measures:
   - Daily Measures: Subject Daily Diary
   - Each Procedure Administration Visit: Adverse events evaluation
   - *End of Week 2 Evaluation: Interim Evaluation:* BMI; Circumference measurements; Skin marker's notation; Adverse events
   - *End of Week 4 Evaluation: Study Endpoint Evaluation:* BMI; Photographs Circumference measurements; Skin marker's notation; Adverse events; Subject Satisfaction rating; Subject and Assessment Investigator Perceived Group Allocation and rationale

POST-PROCEDURE ADMINISTRATION PHASE ACTIVITIES

Two weeks after the final study procedure administration, the following is recorded:

- Body Mass Index (BMI)
- Photographs
- Circumference measurements of the hips, waist and upper abdomen
- Skin markers notation
- Adverse events evaluation

ADVERSE EVENTS

At each evaluation and measurement point throughout the study and at any other time throughout the duration of the trial that is necessary, any and all potential adverse events and/or reactions reported by a subject or observed by an investigator will be recorded on the case report form, and subsequently evaluated by the investigator for its relation to the study procedure and whether or not any corrective action needs to be taken. All potential adverse events and reactions recorded will be appropriately reported to the governing IRB.

It is unlikely and not expected that any adverse events and/or reactions will result from implementation of this study protocol. Prior clinical trials using Erchonia® low level lasers have not yielded any adverse events or reactions. However, potential adverse events that may feasibly occur from application of the Erchonia® Obesity Laser include, but are not necessarily limited to: skin irritation, discoloring, rash, indentations and infection.

PRIVACY AND CONFIDENTIALITY

Records for each subject in the study will be maintained in separate files in a locked filing cabinet at the test site. The investigator will be responsible for ensuring that all records for a subject pertaining to his or her participation in the study are stored in that subject's file at all times other than when information is being recorded on them.

Once a subject's participation in the study is complete and all of the required records are in the subject's file, copies of the documents will be made and supplied to the study Sponsor who will then store them in a locked filing cabinet. Copies of subjects' case report forms will also be sent to Regulatory Insight, Inc. for the purposes of monitoring the data collection process and analysis of results. Regulatory Insight, Inc. will also maintain these copies in a separate study file kept in a locked filing cabinet. The original records will be maintained at the test site upon completion of the study in their original files and stored in a locked filing cabinet.

Subjects' identities will be kept confidential by assigning each subject a subject ID upon acceptance into the study. The subject ID will comprise the investigator's two initials and a three-digit number ranging from 001 to 100 for the first test site (Dr. Gregory Roche); 101 to 200 for the second test site (Dr. Robert Jackson) and 201 to 300 for the third test site (Dr. Joseph Gosevitz) that will be determined based on the subject's order of entry into the study. For example, the eighth subject to be enrolled at Dr. Roche's site will have a subject ID of GR008. Neither the study Sponsor nor Regulatory Insight, Inc. will receive any additional identifying information about a subject and will therefore have no way of linking a subject ID to a particular subject and his or her results.

MONITORING OF THE STUDY

The study Monitor(s) will assure that the investigator is executing the protocol exactly as outlined and intended. This includes insuring that a signed informed consent form has been attained from each subject prior to commencing the protocol, that study procedure protocol is administered as specified, and that all pre- and post-procedure evaluations are taken using the specified methods and correctly and fully recorded on the appropriate case report forms.

STATISTICAL ANALYSIS PLAN

PRIMARY EFFICACY OUTCOME MEASURE: CHANGE IN COMBINED CIRCUMFERENCE IN INCHES OF THE HIPS, WAIST AND UPPER ABDOMEN FOLLOWING THE FOUR-WEEK PROCEDURE ADMINISTRATION PROTOCOL WITH THE ERCHONIA® OBESITY LASER

Primary efficacy outcome measure for this clinical study will be a statistically significant difference in the proportion of subjects who demonstrate a reduction of at least 3.0 inches in their combined hips-waist-upper abdomen circumference (in ins) between test and control group subjects, following completion of the four-week study procedure administration protocol.

The 3.0 inch criterion was determined from that which was accepted and considered positive for statistically significant and clinically meaningful change by the FDA in the following clinical studies whose data was used to successfully support the following subsequent FDA 510(k) clearances to market Erchonia® laser devices for circumference reduction indications comparable to that being sought trough the results of this current clinical study protocol:

- **K123237:** (532 nm green light diodes)
  Erchonia® Zerona™ 2.0 Laser: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

- **K121695 & K082609** (635 nm red light diodes)
  Erchonia® ML Scanner (MLS) & Erchonia® Zerona: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

- **K121690 & K120257** (635 nm red light diodes)
  Erchonia® MLS, Zerona, Zerona-AD: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of the upper arms.

Subjects meeting Individual Success Criteria
The individual subject success criteria is defined as at least a 3.0 inch reduction in combined circumference measurements for the hips, waist and upper abdomen from baseline to after completion of the four-week study procedure administration protocol with the Erchonia® Obesity Laser.

Overall Study Success Criteria.
Overall study success criteria is defined as at least a 40% difference between procedure groups, comparing the proportion of individual successes in each group. It is anticipated that about 55% of subjects in the test group will meet the individual success criteria and about 15% of subjects in the control group will meet the individual success criteria.

Evaluation Time Point
The evaluation time point for primary success will be following completion of the four-week study procedure administration phase (study endpoint) relative to baseline.

Null Hypothesis: There will be no statistically significant difference in the proportion of individual successes as defined between the test and control groups.

Alternative Hypothesis: There will be a statistically significant difference in the proportion of individual successes as defined between the test and control groups.

Statistical Procedures
The following statistical methods will be used to evaluate the primary study endpoint:

1) The primary statistical method to analyze the primary endpoint will be **Fisher's exact test** to compare the proportion of success between the test and the control groups, considering that randomization has been diligently conducted and important covariates between the two groups are well balanced.

2) A **two-sample T-test** will be used to compare the two independent group means for the continuous variable of mean change in number of inches in total circumference attained from study baseline to end point.

Populations Examined

For the primary outcome measure, two analyses will be performed:

- Intent-to-treat analysis: including all randomized subjects who had measures recorded at baseline, and
- Per-protocol analysis: excluding subjects with major protocol deviations, incompletes, etc.

Handling of missing data will be according time point the Last Observation Carried Forward (LOCF) method.

Covariates
The potential covariate continuous baseline variables of BMI and combined hips-waist-upper abdomen circumference will be adjusted through application of ANCOVA analysis.

SECONDARY EFFICACY OUTCOME MEASURES
The following secondary efficacy outcome measures will be evaluated for change across and between all measurement points, as applicable, using t-test and ANOVA statistical techniques:

a) Circumference measurements of the hips, waist and upper abdomen, individually.
b) Body Mass Index (BMI).

ADDITIONAL OUTCOME MEASURES
The following additional outcome measures will be evaluated:

a) Subject self-reported satisfaction with study outcome by procedure group rating will be evaluated between treatment groups using Fischer's Exact Test to evaluate the significance of the difference in the proportion of test versus placebo group subjects who reported being 'Very Satisfied' or 'Somewhat Satisfied' with the study procedure outcome.
b) Reported deviations in subject daily diet and exercise compliance and the relation to study outcome.
c) Reported deviations in subject daily concomitant medication and therapy use compliance and the relation to study outcome.
d) Changes in skin marker notations.
e) Reported or observed adverse events.

BLINDING EFFICACY EVALUATION

Statistical evaluation of blinding efficacy will be performed as follows:

(i) The percentage of subjects who correctly perceived their procedure group allocation and the percentage of subjects who did not correctly perceive their procedure group allocation will be calculated.
(ii) The percentage of times the assessment investigators correctly perceived subjects' procedure group allocation and the percentage of times the assessment investigators did not correctly perceive subjects' procedure group allocation will be calculated.
(iii) The Fischer's Exact categorical analysis technique for comparison of proportion of successes (accurate procedure group allocation determination) between actual active and placebo subject groups will be performed.

It is anticipated that the results of the Fischer's Exact analysis will not be statistically significant; that is, it is anticipated that both subjects assigned to the active procedure group and subjects assigned to the placebo procedure group will demonstrate a high percentage of accuracy of group allocation determination if the study treatment proves efficacious. Similarly, it is anticipated that assessment investigators will demonstrate a high percentage of accuracy of group allocation determination for both subjects assigned to the active procedure group and subjects assigned to the placebo procedure group, if the study treatment proves efficacious. Therefore, it should be noted that lack of a statistically significant Fischer's Exact analysis result will be considered an indicator of study blinding efficacy, providing additional support to study outcome efficacy, particularly if appropriately supported by the reasoning statements, as explained below.

Positive blinding efficacy will be supported by comments provided to support perceived group allocation that pertain to the determination being made based on treatment efficacy or lack thereof; e.g.: 'I think I look a lot better than I used to and my clothes fit much better now than they used to, so I believe I got the real treatment' or 'I haven't noticed any difference in the way I look, and my clothes fit me pretty much the same as they did before the study, so I believe I got the fake treatment.'

Blinding will be determined to have failed if comments provided to support perceived group allocation pertain to factors such as sensation/visual clues (e.g. I saw/didn't see a light go on, etc.) or other factors that pertain to blinding having been compromised such as 'I overheard the doctor saying I wasn't getting the real treatment.'

INFORMED CONSENT

- Informed consent will be an agreement between the individual investigator and each subject, having the capacity to understand and make an informed decision. Consent will be obtained prior to each potential subject's participation in this study.
- Each subject participating in this study will be made aware of the fact that his or her participation involves research and the intent of the research, the expected duration of participation and a description of the procedures that will be followed.
- Each subject will be made aware of the reasonably expected benefits he or she might receive, as well as any risks or potential discomfort that are involved.
- Each subject will also be made aware of alternative treatments available to him or her.
- Each subject will be made aware that his or her records will remain confidential, but that the FDA and the IRB has the right to inspect his or her records.
- Each subject will be told that his or her participation in the study is voluntary, without force or influence from the investigator or sponsor.
- Each subject will be given the name and method of contacting the appropriate person(s) to answer questions about the research and in the event of a research-related injury.

CASE REPORT FORMS

The case report forms that will be used to collect the data from each subject in this study can be found in **Appendix B**.

APPENDIX A
LETTER OF APPLICATION FOR NONSIGNIFICANT RISK DETERMINATION

ERCHONIA CORPORATION
LETTER OF APPLICATION FOR NONSIGNIFICANT RISK DETERMINATION
FOR THE ERCHONIA® OBESITY LASER
FOR REDUCTION OF CIRCUMFERENCE
OF THE HIPS, WAIST AND UPPER ABDOMEN
FOR INDIVIDUALS WITH BMI BETWEEN 30 AND 40 KG/M²
CLINICAL STUDY V1.0 02.20.13

DEVICE NAME: Erchonia® Obesity Laser

INVESTIGATIONAL INDICATION: The purpose of this clinical study is to determine the effectiveness of the Erchonia® Obesity Laser, manufactured by ERCHONIA CORPORATION (the Company), for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals with a Body Mass Index (BMI) between 30 kg/m² and 40 kg/m² intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and upper abdomen by applying green diode (532 nm) energy around the waist, hips and thighs for 30 minutes, twelve (12) times across four (4) weeks.

INDICATION FOR USE: The results of this clinical study will be used to support the following indication for use statement: "The Erchonia® Obesity Laser is indicated for use for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals with Body Mass Index (BMI) between 30 kg/m² and 40 kg/m² intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and upper abdomen."

DEVICE DESCRIPTION & SPECIFICATIONS: The Erchonia® Obesity Laser to be used in this study is made up of 10 independent 17 mW, 532 nm green laser diodes, each diode positioned 120 degrees apart from the next with each titled at a 30 degree angle.

The Erchonia® Obesity Laser is a variable frequency device. The variable frequency feature of the Erchonia® Obesity Laser is a pulsed wave, defined as containing a selected series of breaks, variances that are preprogrammed.

The Erchonia® Obesity Laser utilizes internal mechanics that collects the light emitted from 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® Obesity Laser has the following specifications:

- ✓ Configuration: 6 Class 2 Line Generated Laser Diode Modules
- ✓ Wavelength: 532 nm
- ✓ Power Output (Mean): 17 mW
- ✓ Modulation: Constant Wave (CW)
- ✓ Display: Full Color TFT Touch Screen Control Center
- ✓ Adjustments:
    - 44" Vertical Arm Height Adjustment.
    - Ten Independent Adjustable Arms
- ✓ Power Source: 100-240 VAC 50-60 Hz

- ✓ Chassis:
    - Metal Frame Powder Coated for Ease of Cleaning
    - 4 Anti-Static Casters (4 Locking)
- ✓ Housing: Black Carbon Fiber Finish Thermoformed from Non-Allergen Material/Plastic
- ✓ Weight: 70 lbs.

The Erchonia® Obesity Laser is shown if Figure 1 below.

Figure 1: The Erchonia® Obesity Laser

DETERMINATION OF DEVICE SAFETY
RISK AND PREVENTION OF EYE INJURY

The Erchonia® Obesity Laser is classified by the FDA/IEC as a Class 2 laser device. This designation represents a current standard for use in order to ensure the safety of the patient. A Class 2 laser is determined to have a chronic viewing hazard. Pointing the laser beam directly into the eye and maintaining it there for an extended period of time could prove to be damaging.

To ensure there is no possible instance of residual effect, a pair of specialty glasses (shown in Figures 2 and 3 below) is provided for use during procedure applications with the Erchonia® Obesity Laser device for both the Administration Investigator and the subject.

These safety glasses are KenTek Corporation KenTek C22-KMT-6101 light blue safety glasses. These safety glasses have the following specifications:

- ✓ OD 0.47 @ 532 nm
- ✓ VLT 63%
- ✓ 635D LB2
- ✓ KTK CE 2056

Figure 2: KenTek Corporation KenTek C22-KMT-6101 Light Blue Safety Glasses

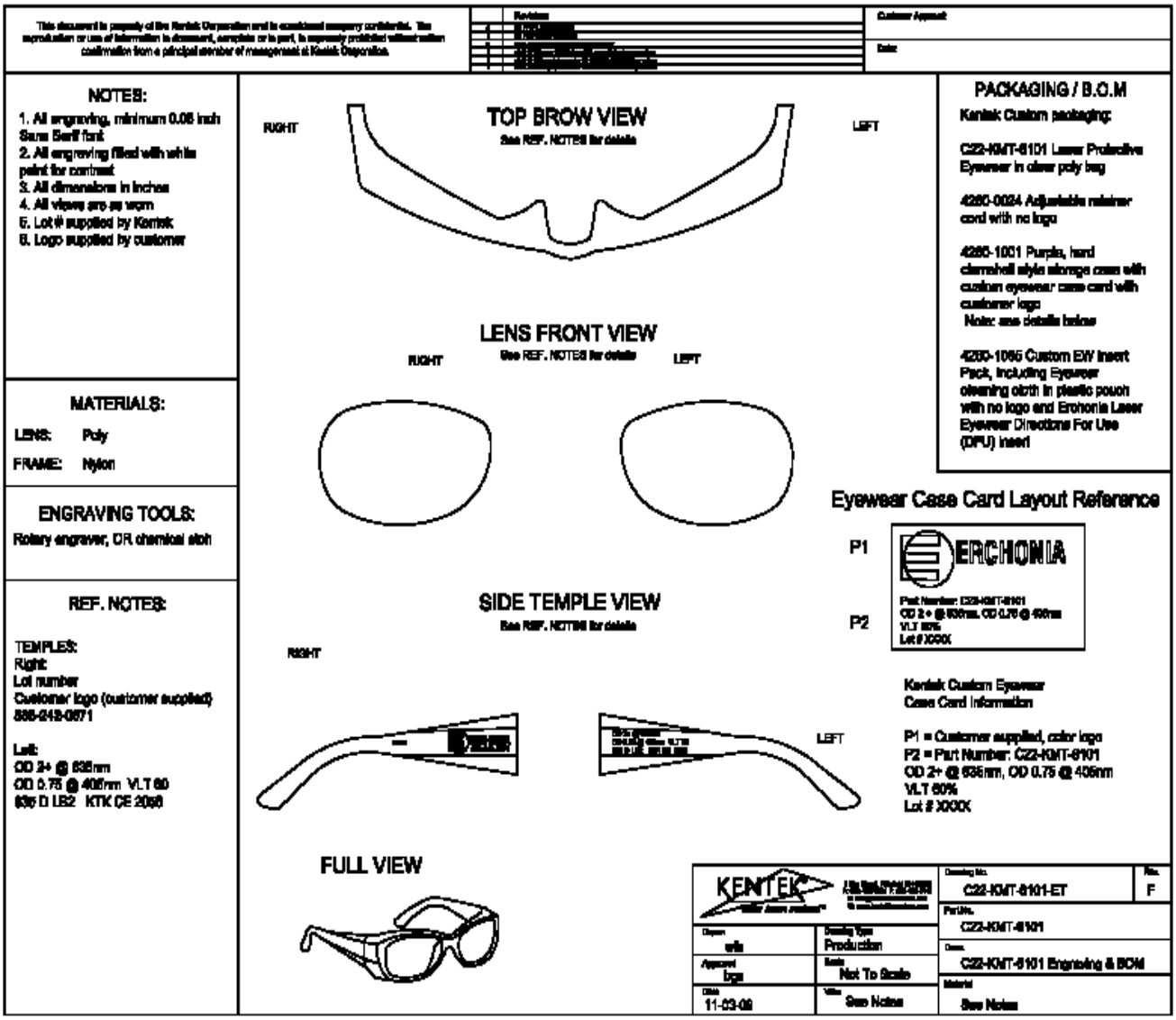


Figure 3: KenTek Corporation KenTek C22-KMT-6101 Safety Glasses Specifications

FOOD AND DRUG ADMINISTRATION (FDA) DETERMINATION OF NON-SIGNIFICANT RISK (NSR) STATUS

(i) Regulatory Clearances**:** The Food and Drug Administration (FDA) has determined the family of Erchonia® low level laser devices, including those employing 532 nm green diodes, to be non-significant risk (NSR) through numerous **510(k) clearances**, as follows.

4. K123237: (532 nm green light diodes)
Erchonia® Zerona™ 2.0 Laser: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

5. K121695 & K082609 (635 nm red light diodes)
Erchonia® ML Scanner (MLS) & Erchonia® Zerona: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist, and thighs.

6. K121690 & K120257 (635 nm red light diodes)
Erchonia® MLS, Zerona, Zerona-AD: is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of the upper arms.

4. K101430
MLS-AC Derma Scanner™: is indicated while using the red diodes for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin, and while using the blue diode, to treat moderate inflammatory Acne Vulgaris.

5. K082609
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.

6. K072206
Erchonia® EML Laser: is indicated for the temporary reduction in post-surgery pain at 24 hours after surgery following bilateral breast augmentation surgery.

7. K062792
Erchonia IOTO_240: is a galvanic generator that is indicated for use in tap water iontophoresis to treat palmer hyperhidrosis and plantar hyperhidrosis.

8. K050672
Erchonia® EVRL Laser: The Erchonia EVRL Laser is generally indicated:

c. while using the red diode, for adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin, and
d. while using the blue diode, to treat dermatological conditions, and specifically indicated to treat moderate inflammatory Acne Vulgaris.

9. K041139
Erchonia® EML Laser: is indicated as an adjunct to liposuction procedures of the thighs, hips and stomach for reduction of pain associated with the recovery process.

10. K100509
Erchonia® *THL1 Laser*: is indicated for use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.

(ii) Pre-IDE Reviews**:** FDA has previously reviewed numerous clinical study protocols employing various Erchonia® Corporation low level laser devices, including all of the clinical studies conducted in support of the above 510(k) clearances and employing 532 nm green diodes. For all of the FDA's pre-IDE reviews of Erchonia low level laser clinical study protocols, there was concurrence from FDA that the clinical study protocols and application of the Erchonia laser devices therein were considered non-significant risk (NSR).

INSTITUTIONAL REVIEW BOARD (IRB) DETERMINATION OF NON-SIGNIFICANT RISK (NSR) STATUS

Erchonia® Corporation low level laser devices have been determined to be non-significant risk (NSR) when applied in various clinical studies through several IRBs, including those involving application of 532 nm green diode energy and application for circumference reduction indications, as follows:

- Western Institutional Review Board (WIRB®) has previously determined Erchonia low level laser devices to be non-significant risk (NSR) when applied in the following clinical studies:

1. **WIRB PRO NUM: 20110331:** Erchonia® 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

2. **WIRB PRO NUM: 20120911:** Erchonia® MLS: 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 five-day treatment protocol clinical study protocol

3. **WIRB PRO NUM: 20110758**: Erchonia® MLS: A pilot evaluation of the effect of the Erchonia® ML Scanner (MLS) laser device on enhancing body weight loss, fat loss and circumference reduction of the waist, hips and thighs clinical study protocol

4. **WIRB PRO NUM: 20121548:** Erchonia® MLS: A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) laser on reducing pain associated with degenerative arthritis (osteoarthritis) of the midfoot clinical study protocol

5. **WIRB PRO NUM: 20121330:** Erchonia LUNULA™**:** An Evaluation of the Effect of the Erchonia LUNULA™ on Treating Toenail Onychomycosis Clinical Study Protocol; Version 6.0 August 7, 2012
6. **WIRB PRO NUM: 20110461:** Erchonia FX-405™**:** An Evaluation of the Effect of the Erchonia FX-405™ on Treating Toenail Onychomycosis Clinical Study Protocol; Version 3.0 March 19, 2011

7. **WIRB PRO NUM: 20120787:** Erchonia® MLS: A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) on low back pain clinical study protocol

8. **WIRB PRO NUM: 20120489:** Erchonia® MLS: A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) on lipid panel levels clinical study protocol

9. **WIRB PRO NUM: 20111793:** Erchonia® MLS: A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) laser on chronic heel pain clinical study protocol

- Independent Review Consulting, Inc.'s/Ethical and Independent Review Services has previously determined Erchonia low level laser devices to be non-significant risk (NSR) when applied in the following clinical studies:

5. **IRC# 07150, NSR# DER-006:** Erchonia® MLS**:** A double blind, placebo-controlled randomied evaluation of the effect of the Erchonia® ML Scanner (MLS) on body contouring of the waist, hips and thighs clinical study protocol.

6. **IRC# 09120, NSR# DER-015:** Erchonia® MLS**:** A double-blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) on reducing the appearance of cellulite clinical study protocol.

7. **IRC# 08167, NSR# DER-009:** Erchonia® MLS**:** A double blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) on capsular contracture clinical study protocol.

8. **IRC# 09059, NSR# DER-010:** Erchonia® MLS**:** A double blind, placebo-controlled randomized evaluation of the effect of the Erchonia® ML Scanner (MLS) in combination with silicone sheets on cellulite pilot study protocol.

- Chesapeake Research Review, Inc. determined the Erchonia® MLS laser device to be a non-significant risk (NSR) device when applied in the following study:

1. **Pro. # 00006393:** Erchonia® MLS**:** A pilot evaluation of the effect of the Erchonia® ML Scanner (MLS) as applied to the abdomen on reducing visceral abdominal fat in patients with HIV-associated lipodystrophy.

OTHER POTENTIAL RISKS
Other potential risks and their mitigation include:

(i) Electric shock: operator risk only: mitigated through electrical safety testing.
(ii) Electromagnetic interference: mitigated through EMC/EMI testing.
(iii) User error: mitigated through instructions for use documentation.

LABELING: The device used in this clinical study was labeled with the following statement:

"CAUTION – Investigational device. Limited by United States law to Investigational use."

Do you contend that this device as used in this protocol is an NSR device?
_✓_ Yes ___No

Has another IRB decided this device is SR?
___ Yes _✓_ No

Does this type of device appear as SR on the FDA Information Sheet?
___ Yes _✓_ No

APPENDIX B
INFORMED CONSENT FORM

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	A Double-Blind, Placebo-Controlled Randomized Evaluation of the Effect of the Erchonia® Obesity Laser on the Reduction of the Circumference of the Hips, Waist and Upper Abdomen for Individuals With Body Mass Index (BMI) of 30 to 40 kg/m² Clinical Study
SPONSOR:	Erchonia Corporation McKinney, Texas United States
INVESTIGATOR:	< >
SITE(S):	< >
STUDY-RELATED PHONE NUMBER(S):	<PI Name>. <PI phone> (24 hours)

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this form carefully. To be in a research study you must give your informed consent. "Informed consent" includes:

- Reading this consent form,
- Having the study doctor or study staff explain the research study to you,
- Asking questions about anything that is not clear, and
- Taking home an unsigned copy of this consent form. This gives you time to think about it and to talk to family or friends before you make your decision.

You should not join this research study until all of your questions are answered.
Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- No one can promise that a research study will help you.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- If you decide to take part, you can change your mind later on and withdraw from the research study.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your study doctor will continue to treat you.
- This study involves experimental (investigational) device procedures that are being tested for a certain condition or illness. An investigational device is one that has not been approved by the U.S. Food & Drug Administration (FDA).

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the research;
- What device and procedures will be used;
- Any possible benefits to you;
- The possible risks to you;
- The other medical procedures, drugs or devices that could be used instead of being in this research study; and
- How problems will be treated during the study and after the study is over.

PURPOSE OF THE STUDY

In this study, the Sponsor, Erchonia Corporation, and investigators are studying the use of a device called the Erchonia® Obesity Laser that gives off a low level laser light. This study is to see if using the Erchonia Obesity Laser can help to reduce the circumference of the hips, waist and upper abdomen in individuals with a Body Mass Index (BMI) of between 30 and 40 kg/m^2.

The Erchonia® Obesity Laser is an investigational device in this study. An investigational device is one that is not approved by the U.S. Food and Drug Administration (FDA) for this use.

PROCEDURES

- If you agree to take part in this study, you will be one of about forty-eight (48) subjects taking part.
- This is a randomized, double-blind, placebo-controlled study. This means that if you choose to take part in this study, it will be determined by chance (like the flip of a coin) whether you are in the group of subjects who will get the active study treatment or the placebo study treatment. If you are in the group of subjects who will get a placebo treatment, the study treatments will be 'fake,' as if the Erchonia® Obesity Laser were turned off.

  Since there are two groups of subjects in this study, you have:
  - About a 50% chance of receiving active study treatments
  - About a 50% chance of receiving a placebo treatment (no active laser therapy).

  Neither you nor the investigator will know what treatment you get until the study is over. The light will look the same on both the real and fake Erchonia® Obesity Laser devices and there is no noise or heat or anything else you can hear, see or feel, so no one will be able to guess which group you are in.

Both the real and the fake Erchonia® Obesity Laser devices will be called "study device" in the rest of this consent form.

- If you agree to take part in this study, you must also agree to not do any other treatments to try to change your body shape or to lose weight while in the study. This includes treatments such as over-the-counter or prescription medicines or supplements, weight loss programs and diet plans, surgical procedures, and alternative therapies like acupuncture or body wraps.
- If you agree to take part in this study, you must also agree to maintain your usual diet and exercise patterns without any big changes while in the study.
- The entire study takes about 6 weeks to complete.
- The study visits are as follows:

Screening Visit

If you agree to take part in this research study, we will conduct a screening visit at the test site. At this visit, we will review this informed consent document. Then we will:

- Measure your height and weight
- Get information about your medical history, including information about current medical conditions you may have and about medicines you are now taking

This should take about 10 minutes.

Pre-Study Treatment Phase

The pre-study treatment phase will start once you have successfully completed the screening visit, and we can confirm that you are eligible for this study, on the same day. At this visit, we will

- Measure around your hips, waist and upper abdomen flexible tape measure
- Take photographs of your hips, waist and upper abdomen area from the front and back. Your face will not be included in any of the photographs. Your subject ID will be used on the photographs. Your subject ID cannot be linked to you or your name. If the photographs are used for medical journal or other publications, there will not be any information connecting you or your name to the photographs. Photographs taken during the study will not be used to market the laser for sale
- Check the skin around your hips, waist and upper abdomen area
- Get information about medicines you are taking now for any reason
- Get information about the types of foods you usually eat and the types of exercise you usually do
- Record your age, gender, and ethnicity

The pre-study treatment phase should take about 20 minutes.

Study Treatment Phase

- The study treatment phase will start right after the pre-study treatment phase is done
- There are 12 study treatments with the study device in this study
- The first study treatment will happen on the same day as the pre-study treatment phase
- You will need to go to the test site again 11 more times over 4 weeks for another study treatment
- Each study treatment lasts 30 minutes
- You will lie on a study treatment table, on your back for 15 minutes. The laser light will be centered on your middle and will shine on your body, but will not touch your body
- Then you will line on the study treatment table on your stomach for 15 minutes. The laser light will be centered on the middle of your back and will shine on your body, but will not touch your body
- You will wear protective glasses to block out the laser light
- On each day of the 4 weeks of the study treatment phase, you will need to record some measures at home. You will need to write down:

    - Any time the foods you eat or your exercise patterns are very different than usual for you
    - Any time you take medications that are different than usual for you

- After the first 2 weeks of the study treatment phase (right after the sixth study treatment visit), we will take some more measures at the test site. We will again:

    - Measure your height and weight
    - Measure around your hips, waist and upper abdomen with a flexible tape measure
    - Check the skin around your hips, waist and upper abdomen area

- After the last study treatment, we will take some more measures at the test site. We will again:

  - Measure your height and weight
  - Measure around your hips, waist and upper abdomen with a flexible tape measure
  - Take photographs of your hips, waist and upper abdomen area from the front and back
  - Check the skin around your hips, waist and upper abdomen area
  - Ask you to rate how satisfied you are with how your hips, waist and upper abdomen area looks after completing the study treatments on a scale from 1 to 5
  - Ask you if you think you got the study treatments with the real or fake Erchonia® Obesity Laser and why you think this

Post-Study Treatment Phase

The post-study treatment phase will last for 2 weeks right after the study treatment phase is finished. At the end of these 2 weeks, you will need to come to the test for a visit. We will again:

- Measure your height and weight
- Measure around your hips, waist and upper abdomen with a flexible tape measure
- Take photographs of your hips, waist and upper abdomen area from the front and back
- Check the skin around your hips, waist and upper abdomen area

RISKS AND DISCOMFORTS

- There have been other research studies using Erchonia low level light lasers. In these studies, no serious medical events resulted from use of the device.

- The only known or anticipated risk with the use of the laser device is that long-term exposure to laser light could cause damage to eyesight. As a precaution, when you are given the treatments with the Erchonia® Obesity Laser, you will be fitted with special darkened protective glasses to block out the light.

- However, there may be unknown risks to using the laser device with this study treatment such as skin irritation, discoloring, rash, indentations and infection. There may be side effects that are not known at this time.

- It is possible that you will not get any improvement in your body shape or that it may even get worse.

PREGNANCY

Women who are pregnant may not take part in this study. If you are trying to get pregnant, you should not volunteer for this study. Before entering the study, you and your study doctor must agree on the method of birth control you will use during the entire study. If you think that you have gotten pregnant during the study, you must tell your study doctor immediately. Pregnant women will be taken out of the study.

NEW INFORMATION
You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS
The shape of your hips, waist and upper abdomen may improve while you are in this study; however, this cannot be promised. The results of this study may help people to improve the shapes of their hips. waist and upper abdomen in the future.

COSTS
It will not cost you anything to be part of the study. Erchonia Corporation, the sponsor of this research will provide the treatments with the Erchonia® Obesity Laser free of charge during this study. The cost for all study related procedures and measurements will also be covered by Erchonia Corporation. Nothing will be billed to you or to your insurance company.

PAYMENT FOR PARTICIPATION
You will not be paid for your part in this research study.

ALTERNATIVE TREATMENT
If you decide not to enter this study, there is other care available to you, such as over-the-counter and prescription medications such as Xenical Meridia and Alli; diet and exercise programs such as Weight Watchers, LA Weight Loss, SimFast, and Atkin's; surgical procedures such as liposuction, abdominoplasty, stomach stapling and lap bands; and alternative therapies such as acupuncture, body wraps, hypnotherapy and mesotherapy. The study doctor will discuss these with you. You do not have to be in this study to be treated for improving your body shape.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Research records including photographs
- Records about your study visits

Who may use and give out information about you?
The study doctor and the study staff

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to see if the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

COMPENSATION FOR INJURY

If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide emergency medical treatment. Your insurance will be billed for this treatment. The sponsor will pay any charges that your insurance does not cover. No other payment is routinely available from the study doctor or sponsor.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- or for any other reason.

If you leave the study before the planned final visit, you may be asked by the study doctor to have some of the end of study procedures done.

SOURCE OF FUNDING FOR THE STUDY
The sponsor, Erchonia Corporation, will pay for this research study.

QUESTIONS
Contact <PI name>, at <PI phone> (24 hours) for any of the following reasons:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study treatment, or
- if you have questions, concerns or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT
I have read this consent form. All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____
Subject Name (printed)

CONSENT SIGNATURE:

_____ _____
Signature of Subject (18 years and older) Date

_____ _____
Signature of Person Conducting Informed Consent Discussion Date

APPENDIX C

CASE REPORT FORMS

ERCHONIA® OBESITY LASER CIRCUMFERENCE REDUCTION CLINICAL STUDY

PRE-PROCEDURE PHASE ACTIVITIES: STUDY QUALIFICATION

Subject ID:	Investigator initials:	Date:

INCLUSION CRITERIA EVALUATION

Mark each box that applies:

☐	Signed informed consent form
☐	18-65 years of age, inclusive
☐	Subject is indicated for liposuction or use of liposuction techniques for the removal of localized deposits of adipose tissues that do not respond to diet and exercise, specifically for the indication of body contouring in the areas of the hips, waist and upper abdomen, as per the AACS Guidelines
☐	Subject's Body Mass index (BMI) is between 30 kg/m² and 40 kg/m², inclusive: weight (in kg) _____ height (in meters) _____ **BMI** (kg/m²) _____
☐	Subject is willing and able to abstain from partaking in any treatment other than the study procedure (existing or new) to promote body contouring/circumference reduction/weight loss during the course of study participation
☐	Subject is willing and able to maintain his or her regular (typical pre-study) diet and exercise regimen without effecting significant change in either direction during study participation.

Mark the appropriate box:

☐	All of the above boxes are marked	**=>** Continue with the evaluation
☐	One or more of the above boxes IS NOT marked	**=>** End subject's evaluation and participation in the study

EXCLUSION CRITERIA EVALUATION

Mark each box that applies:

☐	Subject's Body Mass index (BMI) is not less than 30 kg/m² or greater than 40 kg/m²: weight (in kg) _____ height (in meters) _____ **BMI** (kg/m²) _____
☐	No known cardiovascular disease such as cardiac arrhythmias, congestive heart failure

☐	No prior cardiac surgeries such as cardiac bypass, heart transplant surgery, pacemakers
☐	No prior surgical intervention for body sculpting/weight loss such as liposuction, abdominoplasty, stomach stapling, lap band surgery, etc.
☐	No medical, physical or other contraindications for body sculpting/weight loss
☐	Not consuming any medication known to affect weight levels/cause bloating or swelling, from which study abstinence is not safe or medically prudent
☐	No medical condition known to affect weight levels and/or to cause bloating/swelling
☐	No diagnosis, and not taking medication for, irritable bowel syndrome
☐	No active infection/wound/trauma to intended laser treatment areas
☐	No known photosensitivity disorder
☐	No active cancer or not currently receiving treatment for cancer
☐	Not pregnant or planning pregnancy prior to study participation end
☐	No developmental disabilities/cognitive impairments that in the opinion of the investigator would preclude adequate comprehension of the informed consent form and/or ability to record the necessary study measurements
☐	No serious mental health illness; psychiatric hospitalization in past 2 years
☐	No litigation/disability benefits/worker's compensation related to weight-related and/or body shape issues
☐	Subject is not less than 18 years of age or older than 65 years of age
☐	No other research participation in the past 30 days

Mark the appropriate box:

☐	All of the above boxes are marked	**=>** Continue with the evaluation
☐	One or more of the above boxes IS NOT marked	**=>** End subject's evaluation and participation in the study

QUALIFICATION FOR STUDY PARTICIPATION DETERMINATION

This subject:

☐	Qualifies on all criteria for participation in this clinical study => proceed to Pre-Procedure Phase
☐	Does not qualify for participation in this clinical study => end subject's participation in this study

ERCHONIA® OBESITY LASER CIRCUMFERENCE REDUCTION CLINICAL STUDY

Subject ID:	Investigator initials:	Date:

PROCEDURE GROUP ASSIGNMENT RECORD

The subject has been randomized to Procedure Group:

❑	Procedure Group A
❑	Procedure Group B

ERCHONIA® OBESITY LASER CIRCUMFERENCE REDUCTION CLINICAL STUDY

Subject ID:	Investigator initials:	Date:

PRE-PROCEDURE PHASE ACTIVITIES:

PRE-PROCEDURE PHASE MEASURES AND RECORDINGS

PRE-PROCEDURE PHASE MEASURES

BODY MASS INDEX: ***N.B.: REPEAT ONLY IF PRE-PROCEDURE ACTIVITIES OCCUR ON A DIFFERENT DAY TO STUDY QUALIFICATION.***

weight (in kg)	
height (in meters)	
BMI (kg/m²)	

PHOTOGRAPHS

❑	Frontal view photograph of the hips/waist/upper abdomen area has been taken
❑	Back view photograph of the hips/waist/upper abdomen area has been taken

CIRCUMFERENCE MEASUREMENTS (inches)

Hip circumference (ins.)	
Waist circumference (ins.)	
Upper abdomen circumference (ins)	

Distance from hip bone to point where waist circumference is measured on the right body side (ins.)	
Distance from hip bone to point where waist circumference is measured on the left body side (ins.)	
Distance from natural waist to point where upper abdomen circumference is measured on the right body side (ins.)	
Distance from natural waist to point where upper abdomen circumference is measured on the left body side (ins.)	

N.B.: Use the above measures to insure consistency of subsequent circumference measurements.

PRE-PROCEDURE PHASE RECORDINGS

DIET PATTERNS

Please record information about the subject's typical daily diet, such as approximate calories consumed, types of food eaten and drinks consumed (sodas, milk, coffee/tea, alcohol, water, etc).

EXERCISE PATTERNS

Please record information about the subject's typical exercise regimens, such as type of exercise activities engaged in (e.g. cycling, tennis, weight lifting), how frequently and t what capacity, or if the subject does not typically engage consistently in any form of exercise.

CONCOMITANT MEDICATION/THERAPY USE

Please record information on subject's regular use of medication (OTC and prescription) and/therapies.

SKIN MARKERS NOTATIONS

Please record the presence and location of any existing skin markers on the areas to be treated (front and back).

hernias, scars, asymmetries, cellulite and stretch marks

presence of stria and dimpling

underlying abdominal musculofacial system and the presence/absence of flaccidity and diastasis recti

quality of the skin and its elasticity

DEMOGRAPHICS

AGE

	years

GENDER

☐	Male	☐	Female

ETHNICITY

☐	Caucasian	☐	African American	☐	Asian/Pacific Islander
☐	Hispanic	☐	American Indian	☐	Other _____

ERCHONIA® OBESITY LASER CIRCUMFERENCE REDUCTION CLINICAL STUDY

Subject ID:	Investigator initials:

PROCEDURE ADMINISTRATION PHASE ACTIVITIES: PROCEDURE ADMINISTRATION PROTOCOL INVESTIGATOR RECORD SHEET

PROCEDURE ADMINISTRATION RECORD

Record below each time that a procedure with the Erchonia ® Obesity Laser is administered to the subject. Record the date of the procedure administration and whether or not it was completed according to the specified protocol.

Procedure administration #	Date	Administered according to protocol?
1	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
2	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
3	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
4	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
5	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
6	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
7	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
8	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
9	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
10	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
11	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
12	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No

COMMENTS

ERCHONIA® OBESITY LASER CIRCUMFERENCE REDUCTION CLINICAL STUDY

PROCEDURE ADMINISTRATION PHASE MEASURES:
END OF WEEK TWO EVALUATION : INTERIM EVALUATION

Subject ID:	Investigator initials:	Date:

BODY MASS INDEX

weight (in kg)	
height (in meters)	
BMI (kg/m²)	

CIRCUMFERENCE MEASUREMENTS (inches)

Hip circumference (ins.)	
Waist circumference (ins.)	
Upper abdomen circumference (ins)	

SKIN MARKERS NOTATIONS

Please record the presence and location of any existing skin markers on the treated areas (front and back). If there has been no change in skin markers since the last evaluation, please write in 'no change'.

<u>hernias, scars, asymmetries, cellulite and stretch marks</u>

<u>presence of stria and dimpling</u>

underlying abdominal musculofacial system and the presence/absence of flaccidity and diastasis recti

quality of the skin and its elasticity

ADVERSE EVENTS

☐	Yes => complete investigator's adverse events form
☐	no

COMMENTS

ERCHONIA® OBESITY LASER CIRCUMFERENCE REDUCTION CLINICAL STUDY

PROCEDURE ADMINISTRATION PHASE MEASURES:
END OF WEEK FOUR EVALUATION : STUDY ENDPOINT EVALUATION

Subject ID:	Investigator initials:	Date:

BODY MASS INDEX

weight (in kg)	
height (in meters)	
BMI (kg/m²)	

PHOTOGRAPHS

❑	Frontal view photograph of the hips/waist/upper abdomen area has been taken
❑	Back view photograph of the hips/waist/upper abdomen area has been taken

CIRCUMFERENCE MEASUREMENTS (inches)

Hip circumference (ins.)	
Waist circumference (ins.)	
Upper abdomen circumference (ins)	

SKIN MARKERS NOTATIONS

Please record the presence and location of any existing skin markers on the treated areas (front and back). If there has been no change in skin markers since the last evaluation, please write in 'no change'.

hernias, scars, asymmetries, cellulite and stretch marks

presence of stria and dimpling

underlying abdominal musculofacial system and the presence/absence of flaccidity and diastasis recti

quality of the skin and its elasticity

SUBJECT SATISFACTION: Please have the subject answer the following question using the five-point scale below: "How satisfied or dissatisfied are you with any change you may have noticed I the appearance of your hips, waist and upper abdomen area after having received the procedures with the Erchonia® Obesity Laser?"

☐	Very Satisfied
☐	Somewhat Satisfied
☐	Neither Satisfied nor Dissatisfied
☐	Not Very Satisfied
☐	Not at all Satisfied

SUBJECT PERCEIVED GROUP ALLOCATION AND RATIONALE: Does the subject believe that he or she received the study procedures with the real (active) Erchonia® Obesity Laser or the fake (placebo) Erchonia® Obesity Laser?

☐	Real (active) Erchonia® Obesity Laser
☐	Fake (placebo) Erchonia® Obesity Laser

Please record verbatim below the subject's reasoning or rationale for his or her perceived group allocation

ASSESSMENT INVESTIGATOR PERCEIVED GROUP ALLOCATION AND RATIONALE: Does the Assessment Investigator believe that the subject received the study procedures with the real (active) Erchonia® Obesity Laser or the fake (placebo) Erchonia® Obesity Laser?

☐	Real (active) Erchonia® Obesity Laser
☐	Fake (placebo) Erchonia® Obesity Laser

Please record verbatim below the Assessment Investigator's reasoning or rationale for his or her perceived group allocation for the subject

ADVERSE EVENTS

☐	Yes => complete investigator's adverse events form
☐	no

COMMENTS

ERCHONIA® OBESITY LASER CIRCUMFERENCE REDUCTION CLINICAL STUDY

PROCEDURE ADMINISTRATION PHASE MEASURES: SUBJECT DAILY DIARY MEASURES

Subject ID:	Investigator initials:

SUBJECT DAILY DIARY RECORD: Record below any time your diet or exercise pattern or your medication/other therapy use is different than you told the investigator at the start of the study. Please write in exactly what the difference is. Also write in any time that you think you may be experiencing an adverse event from use of the study laser and call the investigator right away.

**Week One: Dates: / / **(dd/mm/yy) **to / / **(dd/mm/yy)

Day	Date	Diet & Exercise Changes	Medication and other treatment changes	Adverse event?
1				❑ Yes ❑ No
2				❑ Yes ❑ No
3				❑ Yes ❑ No
4				❑ Yes ❑ No
5				❑ Yes ❑ No
6				❑ Yes ❑ No
7				❑ Yes ❑ No

COMMENTS

Week Two: Dates: / / (dd/mm/yy) to / / (dd/mm/yy)

Day	Date	Diet & Exercise Changes	Medication and other treatment changes	Adverse event?
8				❑ Yes ❑ No
9				❑ Yes ❑ No
10				❑ Yes ❑ No
11				❑ Yes ❑ No
12				❑ Yes ❑ No
13				❑ Yes ❑ No
14				❑ Yes ❑ No

COMMENTS

Week Three: Dates: / / (dd/mm/yy) to / / (dd/mm/yy)

Day	Date	Diet & Exercise Changes	Medication and other treatment changes	Adverse event?
15				❑ Yes ❑ No
16				❑ Yes ❑ No
17				❑ Yes ❑ No
18				❑ Yes ❑ No
19				❑ Yes ❑ No
20				❑ Yes ❑ No
21				❑ Yes ❑ No

COMMENTS

Week Four: Dates: / / (dd/mm/yy) to / / (dd/mm/yy)

Day	Date	Diet & Exercise Changes	Medication and other treatment changes	Adverse event?
22				❑ Yes ❑ No
23				❑ Yes ❑ No
24				❑ Yes ❑ No
25				❑ Yes ❑ No
26				❑ Yes ❑ No
27				❑ Yes ❑ No
28				❑ Yes ❑ No

COMMENTS

ERCHONIA® OBESITY LASER CIRCUMFERENCE REDUCTION CLINICAL STUDY

Subject ID:	Investigator initials:

PROCEDURE ADMINISTRATION PHASE MEASURES: EACH PROCEDURE ADMINISTRATION VISIT ADVERSE EVENTS EVALUATION RECORD SHEET

PROCEDURE ADMINISTRATION VISIT ADVERSE EVENTS EVALUATION

At each procedure administration visit, record whether or not a potential adverse event has occurred or is reported by the subject. If yes, proceed with formal evaluation of the potential adverse event by completing the Assessment Investigator's Adverse Events Evaluation case report form and proceed accordingly.

Procedure administration #	Date	Potential Adverse Event?
1	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
2	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
3	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
4	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
5	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
6	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
7	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
8	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
9	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
10	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
11	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No
12	_____/_____/_____ (dd/mm/yy)	❑ Yes ❑ No

COMMENTS

ERCHONIA® OBESITY LASER CIRCUMFERENCE REDUCTION CLINICAL STUDY

POST-PROCEDURE PHASE ACTIVITIES: TWO WEEKS POST-PROCEDURE END

Subject ID:	Investigator initials:	Date:

BODY MASS INDEX

weight (in kg)	
height (in meters)	
BMI (kg/m²)	

PHOTOGRAPHS

❑	Frontal view photograph of the hips/waist/upper abdomen area has been taken
❑	Back view photograph of the hips/waist/upper abdomen area has been taken

CIRCUMFERENCE MEASUREMENTS (inches)

Hip circumference (ins.)	
Waist circumference (ins.)	
Upper abdomen circumference (ins)	

SKIN MARKERS NOTATIONS

Please record the presence and location of any existing skin markers on the treated areas (front and back). If there has been no change in skin markers since the last evaluation, please write in 'no change'.

hernias, scars, asymmetries, cellulite and stretch marks

presence of stria and dimpling

underlying abdominal musculofacial system and the presence/absence of flaccidity and diastasis recti

quality of the skin and its elasticity

ADVERSE EVENTS

☐	Yes => complete investigator's adverse events form
☐	no

COMMENTS

ERCHONIA® OBESITY LASER CIRCUMFERENCE REDUCTION CLINICAL STUDY

ASSESSMENT INVESTIGATOR'S ADVERSE EVENTS EVALUATION RECORD SHEET

Subject ID:	Investigator initials:	Date:

Please record the following information for any adverse event(s) that you or the subject believes he or she may have experienced because of the study procedures with the Erchonia® Obesity Laser.

Please mark any of the boxes below that are applicable, if any:
The subject's reported adverse event is as follows:

☐	skin irritation
☐	discoloring
☐	rash
☐	indentations
☐	infection

Please describe the event in detail in your words:

Would you say that the event the subject is experiencing is:

☐	Mild
☐	Moderate
☐	Severe

Please explain why you believe that the event <u>is or is not</u> a result of the study treatment.

Please describe the action that you have taken to resolve the event. If no action is taken, please explain why not.

When do you anticipate that the event will resolve?

Please describe any follow-up treatment that you may be recommending as result of the event.