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ERCHONIA CORPORATION

VIOLET ZERONA® Z6 OTC

An Evaluation of the Effect of the Erchonia Corporation Violet ZERONA® Z6 for Body Contouring

Version 1.0
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PURPOSE OF STUDY

The purpose of this clinical study is to determine the effectiveness of the Erchonia Violet ZERONA® Z6 OTC (manufactured by Erchonia Corporation (the Company), an over-the-counter (OTC) laser device, in providing noninvasive body circumference reduction.

STUDY DURATION

The estimated total duration of the study is 2 weeks.

INDICATION FOR USE

The indication (claim) being sought through support of the results of this clinical study is:

"The Erchonia Violet ZERONA® Z6 OTC is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference."

The Erchonia Violet ZERONA® Z6 OTC is intended for Over-the-Counter (OTC) use.

The indication for use and intended use of the Erchonia Violet ZERONA® Z6 OTC is identical to the predicate device, the Erchonia ZERONA® Z6 OTC, as FDA cleared under K162578:

"The Erchonia ZERONA Z6 OTC is indicated for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference."

It is cleared for Over-the-Counter (OTC) use.

It is intended that the results of this clinical study be used to support a 510(k) submission to seek FDA clearance to market the Erchonia Violet ZERONA® Z6 OTC for the same indication for use as that cleared for the predicate device, the Erchonia ZERONA® Z6 OTC (K162578), by demonstrating that the efficacy of application of the Erchonia Violet ZERONA® Z6 OTC is non-inferior to the efficacy of application of the Erchonia ZERONA® Z6 OTC (K162578) for the reduction of body circumference of the waist, hips, and bilateral thighs when applied in the over-the-counter setting.

EXPECTED RESULTS

Following completion of the study treatment administration protocol, it is anticipated that compared with the Erchonia ZERONA® Z6 OTC red diode laser, application of treatment administration with the Erchonia Violet ZERONA® Z6 OTC will yield non-inferior (equivalent or superior) results with respect to mean decrease in subjects' combined waist-hips-bilateral thighs circumference measurements relative to baseline.

REGULATORY BACKGROUND AND JUSTIFICATION FOR THE CURRENT STUDY

The intended regulatory pathway to seek clearance for the Erchonia Violet ZERONA® Z6 OTC for the intended indication is through a 510(k) submission with supportive clinical data from the outcome of this clinical study protocol.

The intended predicate device is the Erchonia ZERONA® Z6 OTC, previously FDA cleared under K162578.

The Erchonia ZERONA® Z6 OTC is currently FDA cleared under K162578 for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference. It is cleared for Over-the-Counter (OTC) use.

Preceding its clearance under K162578, the Erchonia Zerona® Z6 OTC received FDA clearance under K143007 for use as a non-invasive dermatological aesthetic treatment for the reduction of circumference of hips, waist, and thighs. K143007 was supported by the results of a Human Factors Validation and Testing Study that evaluated the lay user's ability to operate the device safely, correctly, and effectively per the instructions in the User's Manual. In that study, 22 lay user subjects administered the treatment with the Zerona® Z6 OTC to 22 client subjects. The outcome of that study demonstrated that the lay users successfully understood the information in the User's Manual and were able to follow the instructions to operate the device and administer treatments safely, correctly, and effectively. All treated subjects in that study received an active course of 6 treatments across 2 weeks administered by the lay users. The mean circumference reduction across the waist, hips and bilateral thighs for those subjects was -3.7 inches, a statistically significant finding of equivalency to the precedent prospective randomized controlled trial (RCT) evaluating efficacy of the Erchonia ZERONA® for noninvasive circumference reduction of the waist, hips, and bilateral thighs. In that prior study, 67 males and females aged 18 to 65 years received the identical treatment protocol of 6 treatments with the Zerona® equally spaced across 2 weeks to the waist, hips, and bilateral thighs. The 35 subjects who received the active laser treatment attained an average total circumference reduction of 3.5 inches compared with a mean decrease of 0.68 inches for the 32 subjects who received the sham treatment.

In 2016, the above-mentioned predicate device, the Erchonia® ZERONA® Z6 OTC, received FDA market clearance "for use as a non-invasive dermatological aesthetic treatment for the reduction of body circumference", under 510(k) K162578.

It is intended that the results of the current proposed clinical study be used to support a 510(k) submission to FDA for clearance to market the Erchonia Violet ZERONA® Z6 OTC for the same indication for use as for the Erchonia ZERONA® Z6 OTC as cleared under K162578 by demonstrating that efficacy of application of the two devices are equivalent.

The current clinical study protocol evaluating efficacy of the Erchonia Violet ZERONA® Z6 for the reduction of body circumference is based on the efficacy protocol for the clinical study whose results were submitted in support of clearance of the predicate device, the Erchonia Zerona® Z6 OTC, under K143007.

The 510(k) submitted under K143007 additionally included a successful evaluation of Human Factors Testing and Validation. It is determined that a Human Factors Validation and Testing

study is not applicable for the Erchonia Violet ZERONA® Z6 OTC as the Operational Instructions for Use for the Erchonia Violet ZERONA® Z6 OTC and additional safety and other information contained in the Violet ZERONA® Z6 OTC Installation and Proper Use Reference Guide are identical to those for use of the predicate laser, the Erchonia ZERONA® Z6 OTC, with the only differences being the visible light output (violet compared to red) and the duration of treatment administrations (20 minutes compared to 40 minutes, which is automatically programmed into the device and cannot be altered by the user), neither of which therefore impacts the user's operation of the Violet ZERONA® Z6 OTC versus the ZERONA® Z6 OTC laser device, and therefore has no impact on the user's ability to understand or apply the instructions for use contained in the Violet ZERONA® Z6 OTC Installation and Proper Use Reference Guide or to safely or effectively apply treatments with the device relative to that demonstrated for the predicate device. The study population and all elements of the device protocol and the Violet ZERONA® Z6 OTC Installation and Proper Use Reference Guide other than the pre-programmed administration timing duration (as explained above) will be identical to that employed in evaluation of the Erchonia ZERONA® Z6 OTC device in support of K143007.

Both the predicate and the subject laser devices have the same treatment protocol as will be evaluated for the Violet ZERONA® Z6 OTC in this current study: 6 treatments occurring over 2 weeks: 3 treatments per week; each treatment every other day.

Therefore, as usability has already been established, and all other variables of device user, use, and application are held constant, the goal of this study is solely to demonstrate that efficacy of application of violet light over 20 minutes per treatment administration procedure using the Erchonia ZERONA® Violet Z6 OTC is equivalent to application of red light over 40 minutes per treatment administration procedure using the Erchonia ZERONA® Z6 OTC with respect to reduction in body circumference attained.

The rationale for evaluating efficacy of the application of violet diodes in this current study is that prior research and preliminary testing has demonstrated that non-inferior (equivalent or superior) results with respect to body circumference reduction can be attained with application of violet light compared with application of red light using the same treatment administration protocol but with lesser treatment administration time per treatment administration – 20 minutes versus 40 minutes, respectively, which is a significant time savings to the patient.

STUDY DEVICE

DEVICE DESCRIPTION

The Violet ZERONA® Z6 OTC laser is designed for client's seeking noninvasive fat loss without invasive surgery. Violet ZERONA® Z6 OTC allows the patient to continue their daily activities without interruptions from surgery, pain, wounds or garments. The Violet ZERONA® Z6 OTC works by emulsifying adipose tissue which then releases into the interstitial space. The excess fat is then passed through the body during its normal course of detoxification. The Violet ZERONA® Z6 was built on the clinical foundation of its predecessors, Zerona® and Zerona®-AD, and ZERONA® Z6 OTC, which were proven through clinical studies to be safe and effective in the application of circumference reduction and noninvasive fat loss.

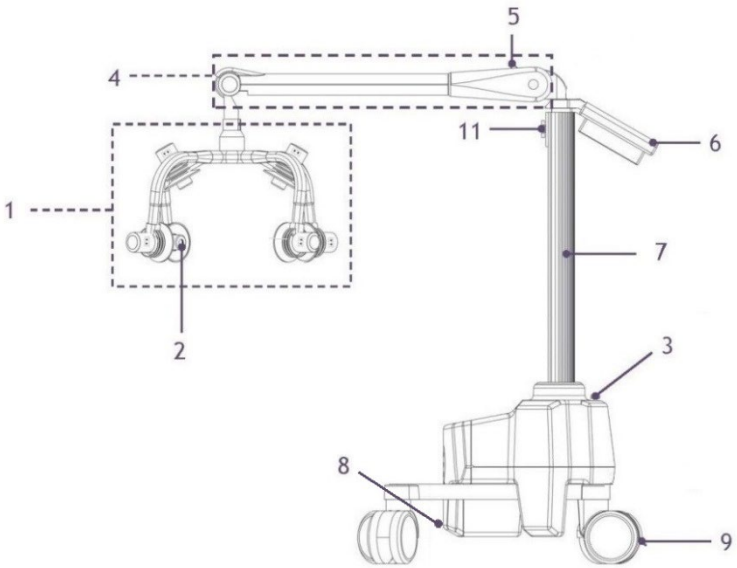
The Erchonia Violet ZERONA® Z6 OTC is identical to the predecessor device, the Erchonia ZERONA® Z6 OTC cleared under K162578, with the differences being light output (visible violet compared to visible red) and duration of treatment administrations (20 minutes compared to 40 minutes, which is automatically programmed into the device). The Installation and Proper Use Reference Guide for use for the Erchonia® Violet ZERONA® Z6 OTC are identical to those for use of the predecessor laser, the Erchonia® ZERONA® Z6 OTC; consisting of the same device set-up and same treatment protocol involving 6 treatments occurring over 2 weeks: 3 treatments per week; each treatment every other day.

The Violet ZERONA® Z6 OTC emits a 405-nanometer wavelength with a tolerance of ±10 nanometer, from each of the six specially created and patented electronic diodes. Laser devices are typically constructed to emit a "spot" of light. The Violet ZERONA® Z6 OTC laser utilizes internal mechanics that collects the light emitted from the laser diode and processes it through a proprietary patented lens, and then redirects the beam with a line refractor. The laser applicator heads, each produce an output power of 23mW (± 2mW) measured. Laser diodes and adjustable laser arms are positioned no greater than 3-4 inches away from the client's target treatment areas.

The Violet ZERONA® Z6 OTC Laser device has been classified by the FDA/EC as a Class II/IIa device and a Class II/2 Laser. This designation represents a current standard for use in order to ensure the safety of the patient. A Class II/IIa Laser is determined to have a chronic viewing hazard. The Violet ZERONA® Z6 OTC Laser device has been classified by the FDA Class II device and a Class 2 laser in accordance IEC 60825-1 (Complies with 21CFR 1040.10 and 21 CFR 1040.11 by Laser Notice #50). The performance parameters and intended use of the Erchonia Violet ZERONA® Z6 OTC are compliant to the internationally recognized safety testing standards for medical devices. The testing of the Violet ZERONA® Z6 OTC device includes functional performance, electrical, safety and component verification, in accordance with the FDA QS requirement, validated annually through ISO 13485 audits. The software incorporated into the operation of the Violet ZERONA® Z6 OTC complies with FDA and ISO Software Development and Validation regulations.

The Violet ZERONA® Z6 OTC laser package is comprised of (1) Violet ZERONA® Z6 OTC Laser device, (1) Pair of Safety Glasses, (1) Power Cord, (1) Power Supply, (1) Tape Measure, and (1) Installation and Proper Use Reference Guide.

DEVICE SPECIFICATIONS



1. Laser Head Assembly
2. Laser Output Head
3. Power Pushbutton
4. Boom Arm
5. Arm Lock
6. Touch Screen
7. Main Upright of Base
8. Power Inlet
9. Wheel Locks
10. Electrical Connector
11. Locking Knob
12. Power Cord
13. External Power Supply

Fig. 1

Device

- Weight: 71lbs / 32kg
- Height: 70 in / 177.8 cm (Average – Adjustable)
- Full Color Touch Screen Control Center
- Four independent Adjustable Arms
- 4 locking Anti-static casters
- Powder coated metal frame
- Non-allergenic material finished with black carbon fiber
- Applied Part: Type B
- Leakage Current 0.3 -0.5 µA (Micro Amps)

Laser

- Six line generating diode modules
- Output: 23mW +/- 2mW
- Wavelength: 405 nm +/- 10nm
- Duty Cycle: CW (Continuous 100%)

Power

- Source: 100-240VAC 50-60Hz

Temperature

- Operating Temp: 59 to 85°F (15 to 29°C) <50% Relative Humidity
- Transporting: -22 to 158°F (-30 to 70°C) <75% Relative Humidity

LASER HEAD ASSEMBLY [1]
This six head assembly located on the end of the boom arm accommodates the lens, laser diodes and their associated electronics.

LASER OUTPUT HEAD [2]
The aluminum housing located on the end of the flex arms accommodates the lens, laser diodes, motors, and their associated electronics.

POWER BUTTON (ON/OFF) [3]
The Power Pushbutton allows the end user to turn the device ON "|" or OFF "O". To turn the device ON the Power Supply (13) must be plugged into the device Power Inlet (8) and the Power Cord (12), with the other end of the power cord plugged into a wall socket. Once connected, the pushbutton will need to be pushed to the ON "|" position to power the device ON. When the pushbutton is in the ON "|" position an LED on the pushbutton will illuminate.

LASER ARM [4]
The Laser Arm serves to position the Laser Head Assembly [1] vertically only. It is designed to be adjusted by intentional force from the end user. This allows the end user to lower and raise the Laser Output Heads for proper positioning to the client for accurate treatment distance.

ARM LOCK [5]
The Arm Lock is the black lever attached to the side of the Laser Arm. This is a secondary locking mechanism for the laser arm. The arm tension can be adjusted or locked into position with the Arm Lock lever. The lever is pulled out to place it in the desired position then locked back in place before turning.

TOUCH SCREEN [6]
The touch screen functions as a display screen and an input panel, providing information to the user and a means to operate the device by touching the appropriate icon.

MAIN UPRIGHT OF BASE [7]
The main upright of base supports the laser arm and contains the electrical connector [10] and the Locking Knob [11].

POWER INLET/FUSE HOLDER [8]
The device contains an appliance coupler (Power Inlet) and a flexible detachable power cord. This is the location on the device where the power cord is connected. **NOTE:** The power cord must be plugged into the device at this location prior to plugging it into a wall socket. The Power Inlet module also contains a fuse holder. Replacing the fuses is the only service that can be conducted by the end-user.

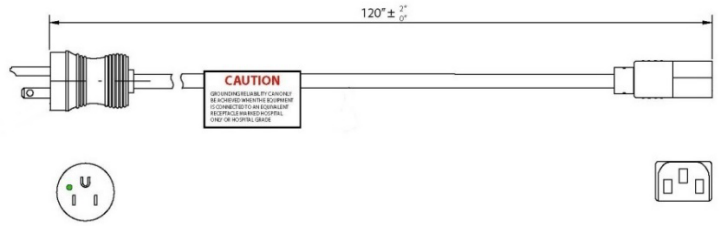
The device includes a transformer which converts AC input power to match the required DC power output. Only a 3-prong power cord is required (Hospital Grade Only). Once the power cord is affixed to the power inlet, the opposite end is plugged into a wall socket. Input: 100-240V~0.5-1.5A, 50-60 Hz.

WHEEL LOCKS [9]
The device includes four antistatic wheels that enable ease for maneuverability. Once the device is transported to the desired location, the wheel locks can be engaged to eliminate excessive movement of the device.

ELECTRICAL CONNECTOR [10]
The electrical connector is a two-piece assembly. The electrical connector connects the main head assembly to the base assembly to transfer data and power.

LOCKING KNOB [11]
The locking knob is utilized to secure the two-piece assembly [4] & [7], also preventing the laser arm assembly from unwanted rotation during use.

POWER CORD [12]
The device contains a hospital grade flexible detachable power cord. The power cord plugs into the external power supply [13] prior to plugging the other end into a wall socket.



EXTERNAL POWER SUPPLY [13]
The power supply is an external AC/DC convertor that is required to power the device. The power supply must be plugged into the device power inlet (8) and the power cord (12), with the other end of the power cord plugged into a wall socket, to power the device.

Protective Wear

The Violet ZERONA® Z6 OTC is classified by the FDA/IEC as a Class 2 laser device. This represents a current standard for use to ensure the safety of the client. 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 could prove to be damaging.

To ensure there is no possible instance of residual effect, we have included a pair of specialty glasses for use by the client during protocol. The Laser safety glasses sufficiently and effectively block the laser light spectrum at OD 2+ @ 635nm, OD 0.75 @ 405nm VLT60.

Height: 40 mm
Width: 145 mm
Length: 165 mm

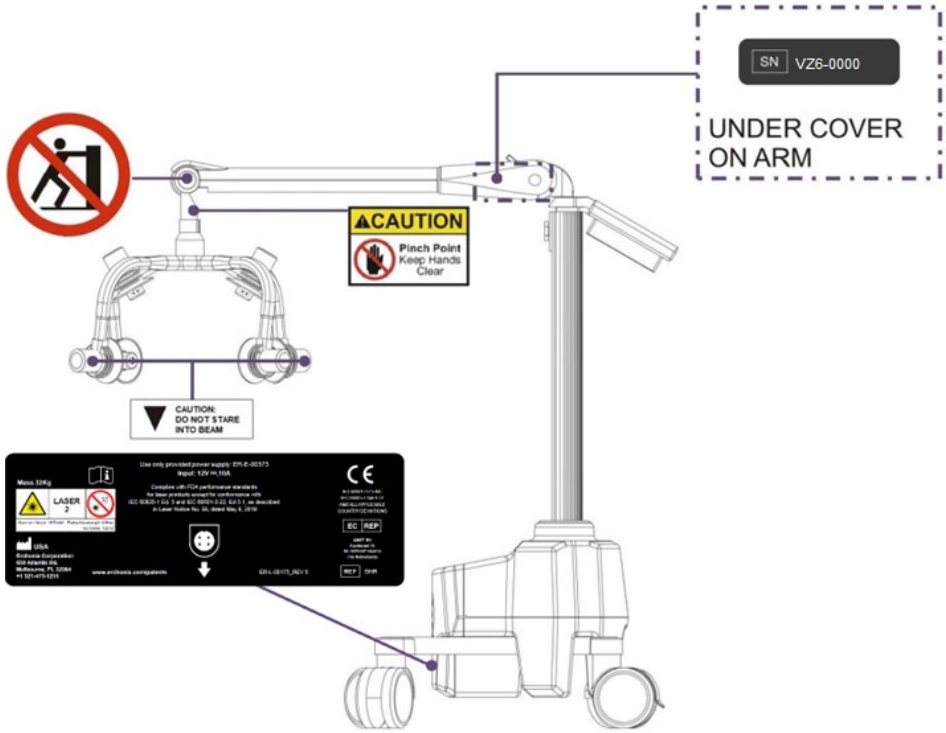
Labeling
The Violet ZERONA® Z6 OTC used in this clinical study is regulated as an investigational device, and as such, will be labeled as follows:

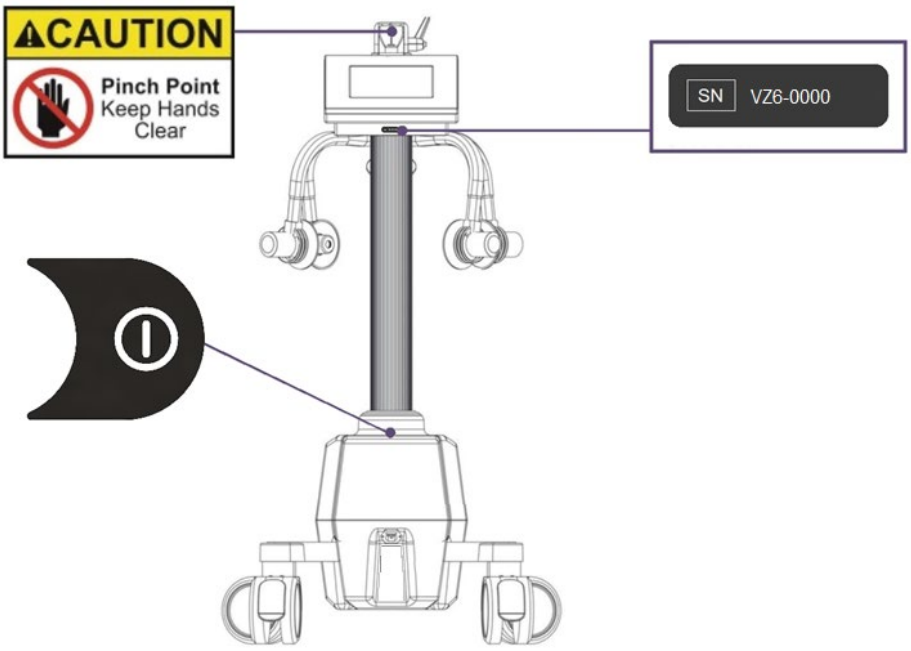
CAUTION – Investigational Device.
Limited by Federal (or United States) law to investigational use

Additionally, the diagrams below show the device labeling and their placement and is an excerpt from the Installation and Proper Use Reference Guide.

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

The following diagram shows the location of the power supply label, serial number label, power pushbutton label and one of the (2) identified pinch point labels.





SAFETY

Protective Wear

The Violet ZERONA® Z6 OTC is classified by the FDA/IEC as a Class 2 laser device. This represents a current standard for use to ensure the safety of the client. 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 could prove to be damaging.

To ensure there is no possible instance of residual effect, we have included a pair of specialty glasses for use by the client during protocol. The Laser safety glasses sufficiently and effectively block the laser light spectrum at OD 2+ @ 635nm, OD 0.75 @ 405nm VLT60.

Height: 40 mm
Width: 145 mm
Length: 165 mm

STUDY DESIGN

This clinical study is an open-label single-arm non-inferiority design to evaluate the efficacy of the Erchonia Violet ZERONA® Z6 OTC in providing noninvasive body circumference reduction. As such, all enrolled subjects will receive the active study treatment, and therefore, neither randomization to procedure group nor blinding of the subjects nor investigative parties is applicable.

STUDY BLINDING

As all subjects in this study will receive the active procedure administration with the Erchonia Violet ZERONA® Z6 OTC, it is not possible to blind either subjects or investigators (device users).

However, there are two aspects of this study design that assist in supporting elements of blinding:

(i) The primary efficacy study outcome assessment of body circumference measurements is objective; and

(ii) As the outcome data from this current study will be comparatively assessed to that of the active treatment group in the predicate device clinical study (the clinical data for the Zerona® Z6 OTC submitted in support of K143007), it is possible to blind the study statistician as to which data set pertains to which study, as the variables for each will be identical. The data from each study will be de-identified and presented to the study statistician simply as 'Group A' and 'Group B' data. The statistician will not be aware of which group – A or B – contains the current study data and which contains the comparative data. The study statistician will also not be made aware of sample sizes for either analysis group if there is a difference. In this way, study success analysis by the statistician cannot be biased.

INVESTIGATORS / DEVICE USERS

The respective investigator/device user sample population, defined as those who will be administering the treatments with the Erchonia Zerona® Violet Z6 OTC, will be representative of the population of users (non-medical professionals) who may potentially purchase and operate the Violet ZERONA® Z6 OTC device following clearance. The respective investigators / device users will be the identical user population as that enrolled in the study evaluating efficacy and usability of the Zerona® Z6 OTC device in the 2014 comparative study (predicate) and for whom OTC market clearance of the device was subsequently attained through K143007.

SUBJECTS

The study sample population, defined as those who will be receiving the study treatments with the Erchonia Zerona® Violet Z6 OTC, will be identical to the study sample population as defined and enrolled in the reference study and as intended to be the real-world patient population recipients of the device treatments.

Subject Sample

Subjects will be males and females 18 years or older who are potential candidates for receiving the course of treatment using the Violet ZERONA® Z6 OTC device and who subsequently satisfy all criteria on the Client Qualification Checklist as verified by the device user.

Sample Size
There will be a minimum of 22 qualified subjects enrolled in and completing this study.

Rationale for Sample Size
Sample size is determined to be identical to the final sample size treated and evaluated in the 2014 Zerona® Z6 OTC comparative study to enable clinically meaningful statistical comparison of outcomes to be performed.

Recruitment
Subjects will be recruited from among:
(i) The test sites' pool of existing and new clients
(ii) Subjects who respond to the following IRB-approved recruitment materials:

WANTED

ADULTS WHO WISH TO REDUCE THE CIRCUMFERENCE OF THEIR HIPS, WAIST, AND THIGHS FOR A STUDY OF THE EFFECTS OF LOW-LEVEL LASER LIGHT ON REDUCING BODY CIRCUMFERENCE

THIS STUDY INVOLVES SIX LASER LIGHT PROCEDURES WITH THE ERCHONIA® VIOLET ZERONA® Z6 LASER OVER 2 WEEKS AT THE TEST SITE.

FOR MORE INFORMATION PLEASE CONTACT:

<name>
<test site name & location>
<phone # and/or e-mail>

You may be eligible to participate in a clinical research study with an investigational device.

- **Non-Invasive laser light treatments (no pills, no needles)**
- **The study involves 6 laser light treatment over 2 weeks at the test site.**

For more information please contact:

(Investigator Name)
(Phone)
(Email)

Compensation
Subjects will not receive financial payment or any other form of compensation to participate in this study. Subject will not be charged for the cost of the Violet ZERONA® Z6 OTC treatments or for the cost of any other evaluations or measurements that occur as part of his or her participation in the study.

STUDY PROCEDURES

Investigators / device user in this clinical study will be required to follow all procedures contained within SECTION 3: VIOLET ZERONA Z6 OTC OPERATION of the Violet ZERONA® Z6 OTC Installation and Proper Use Reference Guide, pages 15 through 27, without any additional guidance, materials, instruction, whether verbal or written or otherwise, from any source, as per real-life intended use.

SECTION 3 of the Violet ZERONA® Z6 OTC Installation and Proper Use Reference Guide includes the following:

1. Violet ZERONA Z6 OTC Operation: pages 15 - 23
2. Violet ZERONAT Z6 OTC Treatment Protocol: page 24
3. Violet ZERONA Z6 OTC Client Qualification Checklist: pages 25 – 28: includes protocols for calculation of:
   - Body Mass Index (BMI): pages 26 - 27; and
   - Body circumference measurements (waist, hips, and thighs): page 28

PRE-PROCEDURE ACTIVITIES

All pre-procedure activities will take place on the same day and proceed successively as follows:

SIGNING OF INFORMED CONSENT FORM

The investigator / device user 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 Investigator's / user's first and last name initials and a 3-digit number based upon the subject's order of entry into the study.

INCLUSION/ EXCLUSION CATERIA

The investigator / user conducts the CLIENT QUALIFICATION CHECKLIST as contained in the Installation and Proper Use Reference Guide, to determine if the client is suitable for the Violet ZERONA® Z6 OTC treatment. As part of this assessment, the investigator / user conducts the BMI evaluation. The CLIENT QUALIFICATION CHECKLIST includes PART A and PART B as follows:

A. CLIENT QUESTIONS: The client will be asked to respond "YES or NO" to the following questions:

- Are you under 18 years of age?
- (Female clients only): Are you pregnant or do you think you might be pregnant? Not applicable, client is male
- Do you have any open wounds (sores, cuts, ulcers, etc.)?
- Do you have or are you being treated for any cancerous growths?

A client that answers **"YES"** to one or more of the client questions is not suitable for the treatment with the Violet ZERONA® Z6 OTC. A client that answers **"NO"** to ALL the questions will proceed to the Body Mass Index (BMI) Calculation.

B. BODY MASS INDEX (BMI) CALCULATION:

- BMI is 30 or less => the client qualifies for Violet ZERONA Z6 OTC treatment.
- BMI is more than 30 => the client does not qualify for Violet ZERONA Z6 OTC

PRE-PROCEDURE STUDY MEASUREMENTS

A subject who satisfies the criteria to receive the study treatment per the Client Qualification Checklist will complete the following pre-procedure study assessments:

Circumference Measurements of the waist, hips, and thighs per the instructions contained in SECTION 3: VIOLET ZERONA® Z6 OTC OPERATION of the Installation and Proper Use Reference Guide, under the MEASUREMENT PROTOCOL & MEASUREMENT AREAS header on page 28.

PROCEDURE ADMINISTRATION ACTIVITIES

The procedure administration phase of the study will commence immediately following completion of the pre-procedure activities, on the same day. The first treatment administration with the Violet ZERONA® Z6 OTC will be administered that day.

The investigator / device user is required to follow the instructions in SECTION 3: VIOLET ZERONA® Z6 OTC OPERATION of the Erchonia Violet ZERONA® Z6 OTC Installation and Proper Use Reference Guide to correctly administer a procedure.

The procedure administration protocol in this current study is identical to that evaluated in the 2014 comparative study, with the exception being that the treatment time with the violet laser is 20 minutes compared to 40 minutes with the red laser. However, as the timing is automatically pre-programmed in the laser device, and it beeps and pauses automatically mid-treatment to enable the individual to turn-over and the laser arms to be resituated to the posterior aspect of the patient, and subsequently automatically shuts off when the second half of the treatment is completed, this has no impact on the user's operation of the Violet ZERONA® Z6 OTC device compared with the ZERONA® Z6 OTC device.

Both the predicate and the currently evaluated laser devices have the same treatment protocol: 6 treatments occurring over 2 weeks: 3 treatments per week; each treatment every other day.

PROCEDURE ASSESSMENTS

After completion of the sixth and final scheduled Violet ZERONA® Z6 OTC treatment administration, the investigator / user will again record the subject's BMI and waist, hips and thighs circumference following the protocols in the Installation and Proper Use Reference Guide.

This is considered the study endpoint evaluation at which change relative to pre-procedure measurements will be assessed. Evaluation for and recording of any observed or reported adverse events will be conducted at each study visit.

STATISTICAL ANALYSIS PLAN

STUDY POPULATIONS

The following two study populations will be evaluated:

1. Modified Intent-to-Treat (mITT) Population

Primary analysis of efficacy will be according to the modified intent to treat (ITT) analysis, including all enrolled subjects who had a valid baseline visit and received at least the first study treatment with the Erchonia Violet ZERONA® Z6 OTC.

Missing data for the mITT population will be handled through Last Observation Carried Forward (LOCF) methodology. Sensitivity analysis may be applied if missing data is extensive.

2. Per Protocol Population.

Secondary analysis of efficacy to confirm the findings of the primary analysis will be conducted on the per protocol population, comprised of all subjects who completed the study per protocol through to the final treatment administration and outcomes measures recording visit.

PRIMARY EFFICACY OUTCOME

The primary efficacy outcome for this clinical study is the mean change in combined waist-hips-bilateral thighs circumference measurement at study endpoint (following completion of the sixth and final treatment administration procedure) relative to baseline (pre-procedure).

PRIMARY EFFICACY OUTCOME EVALUATION

To determine primary efficacy outcome success, the mean change across all subjects enrolled in this study in combined waist-hips-bilateral thighs circumference measurements at study endpoint relative to baseline will be calculated and compared to the relative mean change attained for treated subjects in the reference study.

As this study is a non-inferiority design, the research hypothesis is that violet diode therapy with the Erchonia Violet ZERONA® Z6 OTC is either equivalent to, or superior to, red diode therapy with the Erchonia Zerona® Z6 OTC in effecting a clinically meaningful reduction in body circumference.

The selected equivalence margin (δ) is ±5%. Therefore, non-inferiority will be established if the mean change in combined circumference measurement for subjects treated with the violet diode laser in the current study is no more than 5% less than the subject group who received treatment with the red diode laser in the predicate reference trial that supported efficacy of the Zerona® Z6 OTC device (K143007).

In the predicate reference study, the mean change in combined circumference measurements across the same 6-treatment 2-week evaluation period was a decrease of 3.72 inches. Therefore, success for the current study will be determined as having been met if the mean change in combined circumference measurements for the subject group in the current study is -3.72±5% inches (-3.53 to -3.91 inches). This is defined as the maximally clinically acceptable difference for which the range of efficacy values (±5%) are “close enough” to be considered equivalent.

Hypotheses

• *Null Hypothesis*: Treatment application of the Erchonia Violet ZERONA® Z6 OTC is inferior to treatment application of the Erchonia® Zerona® Z6 OTC in effecting a clinically meaningful reduction in body circumference.

H_o: $\mu < -3.53$ inches

• *Alternative Hypotheses*: Treatment application of the Erchonia® Violet ZERONA® Z6 OTC is NOT inferior to treatment application of the Zerona® Z6 OTC in effecting a clinically meaningful reduction in body circumference.

H_1: $\mu \geq -3.53$ inches

SUPPORTIVE SECONDARY EVALUATIONS

The following two secondary evaluations will be performed to provide direct support for the primary efficacy evaluation outcome are will therefore be assessed with respect to statistical significance of change and/or against pre-determined non-inferiority success criteria.

(i) T-test for independent samples will be performed to compare the mean change in combined circumference measurements across study evaluation (at endpoint relative to baseline) for subjects treated with the Violet ZERONA® Z6 OTC in the current study to the relative mean change for subjects treated with the ZERONA® Z6 OTC in the reference study treatment group. i.e., between device treatment groups. A finding of the difference being not statistically significant ($p>0.05$) will provide statistically significant and clinically meaningful support for the equivalency of the efficacy of the two devices.

(ii) Responder rate analysis will be conducted wherein individual responder success is defined per the reference study as at least a 3.0-inch reduction (≥-3.0 inches) in combined circumference measurements for the waist, hips, and bilateral thighs from baseline to after study treatment completion. The maximally clinically acceptable difference for which the responder rate for the current study subject group is defined is (±5%), that is, 73% +/- 5% (68% - 78%), as the responder rate attained in the reference study was 73%.

ADDITIONAL SECONDARY EFFICACY ANALYSIS

Additional secondary efficacy analysis will comprise descriptive only presentation of the mean, standard deviation, and range of circumference measurements (inches) for each individual treatment area of the waist, hips, and right and left thighs, separately, at baseline, and endpoint, and the change between the two assessment points, in table format. As no additional claims are intended to be supported based on the additional secondary efficacy analysis, no statistical analysis of findings will be performed.

INDIVIDUAL TEST SITE EFFICACY ANALYSIS

Comparison of the primary efficacy outcome of mean change in combined waist-hips-bilateral thighs circumference measurements at study endpoint relative to baseline for subjects treated in the current study with the Violet Zerona® Z6 between each of the two study test sites will be conducted to support poolability of the study results.

SAFETY ANALYSES

Safety analyses will be based on all enrolled subjects and will be assessed by evaluating and comparing frequency and incidence of observed and/or reported adverse events between subjects who received treatments with the Erchonia Violet ZERONA® Z6 OTC in the current study and subjects who received treatments with the Erchonia ZERONA® Z6 OTC treatment in the predicate reference study. A chi-square test with a continuity correction will be performed to compare the percentage of subjects who had adverse events between the two subject groups.

APPENDIX B

INFORMED CONSENT FORM

SUBJECT INFORMATION AND CONSENT FORM

TITLE:	An Evaluation of the Effect of the Erchonia Corporation Violet Zerona® Z6 for Body Contouring
SPONSOR:	Erchonia Corporation Melbourne, FL United States
SITE(S):	< >
STUDY-RELATED PHONE NUMBER(S):	<Investigator Name>. <Investigator phone> (24 hours)

Subject ID:_____

This consent form may contain words that you do not understand. Please ask the study investigator 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 researchstudy you must give your informed consent. "Informed consent" includes:

- Reading this consent form,
- Having the 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 itand 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 clients in the future.
- The main goal of regular medical care is to help each client.
- 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 theresearch study.
- The decision to join or not join the research study will not cause you to lose any medicalbenefits. If you decide not to take part in this study, your study doctor will continue to treat you.
- This study involves use of a device that has been approved by the U.S. Food & DrugAdministration (FDA) for this use.

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 thisresearch study; and
- How problems will be treated during the study and after the study is over.

Subject ID:_____

PURPOSE OF THE STUDY

In this study, the Sponsor, Erchonia Corporation, is studying the use of a device called the Erchonia Violet Zerona® Z6 that gives off a low-level laser light.

This study is to see if using the Violet Zerona® Z6 can help to reduce the circumference of the hips, waist, and thighs. Use of the Erchonia® Violet Zerona® Z6 in this study is investigational, as the Erchonia® Violet Zerona® Z6 has not been cleared for market by the U.S. Food and Drug Administration (FDA).

PROCEDURES

- If you agree to take part in this study, you will be one of about twenty-two (22) subjects taking part.
- This is a test group only study. This means that if you choose to take part in this study, you willget the active (true) study treatment.
- If you agree to take part in this study, you must also agree to not do any other treatments to tryto 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 2 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
- Ask you a few simple questions

This should take about 5 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 time, we will measure around your hips, waist, and thighs using a flexible tape measure.

This should take about 5 minutes.

Study Treatment Phase

- The study treatment phase will start right after the pre-study treatment phase is done
- There are 6 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 5 more times over 2 weeks, every second day, for another studytreatment

Subject ID:_____

- Each study treatment lasts 20 minutes
- You will lie on a study treatment table on your back for 10 minutes. The device arms will be placed around your body such that the laser light is centered on the middle of your body and shines on your stomach, the side of your waist, your hips and both upper thigh areas, but it will not touch your body
- Then you will turn over and lie on the study treatment table on your stomach for another 10 minutes. The device arms will be again placed around your body such that the laser light is centered on the middle of your back and shines on your lower back, sides of your waist, hips and upper thighs, but does not touch your body
- You will wear protective glasses to block out the laser light throughout the treatment process

After the last study treatment, we will again measure your height and weight, and measure around your hips, waist, and thighs with a flexible tape measure as during the pre-treatment phase.

This should take about 5 minutes.

RISKS AND DISCOMFORTS

- There have also 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 Violet Zerona® Z6, 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 getworse.

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 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 the study investigator immediately. Pregnant women will be takenout 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 thighs may improve while you are in this study;

Subject ID:_____

however, thiscannot be promised. The results of this study may help Erchonia Corporation, the manufacturer of the Violet Zerona® Z6 device to market and sell the device to lay (non-medical professional) people to help others improve the shapes of their bodies 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 Violet Zerona® Z6 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, SlimFast, 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. Your doctor can discuss these with you if you like. You do not have to be in this study to be treated for improving your body shape.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCHPURPOSES

What information may be used and given to others?
The study investigator will get your personal and medical information. For example:
- Research records
- Records about your study visits

Who may use and give out information about you?
The study investigator 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®)
- A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify

you. Atmost, the Web site will include a summary of the results. You can search this Web site at any time.

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 atany time. You do this by sending written notice to the study investigator. If you withdraw yourpermission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gatheredafter 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 investigator immediately. The study investigator 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 investigator 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 youare otherwise entitled.

Your participation in this study may be stopped at any time by the study investigator or the sponsorwithout 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 mayaffect you;

Subject ID:_____

- or for any other reason.

SOURCE OF FUNDING FOR THE STUDY

The sponsor, Erchonia Corporation, will pay for this research study.

QUESTIONS

Contact (Investigator) at (telephone number) (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:

WCG IRB
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 855-818-2289
E-mail: researchquestions@wcgirb.com

The IRB is a group of people who independently review research.

The IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact the IRB 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 electronic copy of this consent form for your records.

Subject ID:_____

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

Subject ID:_____