NCT04807205
ID: CYN20-ELITEIQ-02
Document Date: October 30, 2020

INVESTIGATIONAL PLAN

PROTOCOL #: CYN20-ELITEIQ-02

POST MARKET STUDY USING THE ELITE IQ DEVICE

CONFIDENTIAL

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POST MARKET STUDY USING THE ELITE IQ DEVICE

INVESTIGATOR AGREEMENT

I agree to conduct the study in accordance with the relevant, current protocol and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation.

I agree to inform any patients, or any persons used as controls if applicable, that the device(s) is/are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in and institutional review board (IRB) review and approval are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigations. I have read and understand the information in the device manual, including the potential risks and side effects of the device.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records and to make those records available for inspection. I further agree that Cynosure, LLC. or their designees shall have access to any source documents from which case report form information may have been generated.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators including providing data and relevant information.

I will comply with the International Conference on Harmonization (ICH), Good Clinical Practice (GCP) guidance E6, FDA Good Clinical Practice Regulations (21 CFR parts 50, 56, and 812), Declaration of Helsinki (DoH) and the Health Human Service (HHS) Belmont Study Principals and Guidelines during the conduct of this study.

I have read the foregoing protocol and agree that it contains all necessary details for carrying out this study. I will conduct the study as outlined herein and will complete the study within the time designated.

I will provide copies of the protocol and all pertinent information to all individuals responsible to me who assist in the conduct of this study. I will discuss this material with them to ensure they are fully informed regarding the study device the conduct of the study.

I will disclose financial arrangements and interests in accordance with Financial Disclosure Rules (21 CFR part 54) and FDA Form 3455.

_____ _____

Investigator's Signature Date

_____

Name of Investigator (Typed or Printed)

_____

_____

_____

Address of Investigator (Typed or Printed)

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1.0 PURPOSE

1.1 Name and Intended Use

The device used in this study is called the Elite iQ device.

The intended use of the Elite iQ device used in this study is for the treatment of hair removal, pseudo folliculitis barbae, and benign vascular and pigmented lesions.

1.2 Objectives

1. Primary Objectives:
   - To assess the safety of the study devices through the collection of side effects throughout the study.
   - To assess efficacy by blinded evaluation of photography.
2. Secondary Objectives:
   - To assess of efficacy of the study device through Investigator and subject questionnaires.
   - To assess the ease of use of the new device.

1.3 Duration of the Investigation

The sponsor anticipates that all subjects can be enrolled within 3 months. If subject participates in all required visits, then the subject's participation in this study may last up to 15 months. It is anticipated that it will take approximately 3 months to analyze the data collected during this study. The total duration of this study is anticipated to last approximately 21 months.

2.0 PROTOCOL

2.1 Protocol Methodology and Analysis

Methodology:
Subjects are to be enrolled in this clinical study if they are a healthy male or female 18 years of age or older. Up to 20 subjects will be enrolled at up to 1 study center. Subjects will attend a screening/pretreatment visit which may be performed on the same day as the treatment visit. Subjects may receive up to 5 treatments on multiple areas of the body such as, but not limited to, the face, legs, and arms. All subjects will be required to return a follow-up visit at 30 - 90 days after the final treatment in each treatment area. An unscheduled visit or phone call may be performed at any time during the study at the request of the subject or as deemed necessary by the site Investigator.

Analysis:
Upcoming generations are proving to have an interest in non-ablative aesthetic treatments and will drive demand for innovated products, procedures, and practice design.[1] Due to this shift in patient base, practices need to evolve to adapt to the newer generational ideologies. This device uses the Alexandrite wavelength (755 nm) and the Nd:YAG wavelength (1064 nm) target hair follicles, unwanted veins, pigmented lesions and treat sun-damaged skin. Although this laser technology is one of the most used, there is a need for a new advanced treatment guidance system that is built into the laser.

Relevance:
According to the 2018 Plastic Surgery Statistics Report, the amount of laser treatments for minimally invasive aesthetic treatments have drastically increased over the past 8 years.[2] There is an increasing demand for new methods and novel laser technology for improved treatment outcomes. Other devices currently on the market cleared for use include, but are not limited to, the Excel and Candela devices.

Testability:
The Elite+ device, the most current approved Elite platform, had been previously cleared for use for hair reduction and the treatment of vascular lesions, benign pigmented lesions, pseudo folliculitis barbae, and wrinkles (FDA K141425). This study will utilize similar evaluation methods to assess prototype software and accessories.

Compatibility:
Although laser technology is a well-known and widely use technique for non-ablative aesthetic treatments, there is still a need to improve technology to reduce the number of treatments and provide a more effective treatment plan.

Predictive power:
Assuming there is significant improvement, it would be appropriate to expect results in different areas where other products and devices have significant results alongside more effective treatments for hair removal, pseudo folliculitis barbae, and benign vascular and pigmented lesions.

2.2 Protocol Study Design

This is a prospective, open label, single-center clinical study to collect safety and efficacy data on the Elite iQ workstation.

2.3 Subject Selection Criteria

Subjects will meet the criteria described below:

Inclusion Criteria:

- A healthy male or female 18 years of age or older.
- Understands and accepts obligation not to receive any other procedures on the treatment area through the length of the study.
- Understands and accepts the obligation and is logistically able to be present for all visits.
- Is willing to comply with all requirements of the study and sign the informed consent document.

Exclusion Criteria:

- The subject is hypersensitive to light in the near infrared wavelength region
- The subject has sun-damaged skin (treatment contraindicated with Alex laser only)
- The subject had recent unprotected sun exposure (for Alex laser within four weeks of treatment; for Nd:YAG laser within one week of treatment), including the use of tanning beds or tanning products, such as creams, lotions and sprays

- The subject is taking medication which is known to increase sensitivity to sunlight
- The subject has seizure disorders triggered by light
- The subject is taking anticoagulants
- The subject is taking or have taken oral isotretinoin, such as Accutane®, within the last six months
- The subject is taking medication that alters the wound-healing response
- The subject has a history of healing problems or history of keloid formation
- The subject has an active localized or systemic infection, or an open wound in area being treated
- The subject has a significant systemic illness or an illness localized in area being treated
- The subject has a history of skin cancer or suspicious lesions
- The subject has an autoimmune disease
- The subject is receiving or have received gold therapy
- The subject is currently enrolled in an investigational drug or device trial, or has received an investigational drug or been treated with an investigational device within in the area to be treated 6 months to entering this study.
- The subject has any condition or is in a situation which in the investigators opinion may put the subject at significant risk, may confound study results or may interfere significantly with the subject's participation.

Be sure to list all concomitant medications taken or procedures performed before, during and after the trial.

Subjects will be recruited for the study through the existing patient database and may use advertisements.

Subject populations will not be eligible to participate in the study if they are vulnerable populations such as children, pregnant women, prisoners, institutionalized individuals, and any persons requiring a legally authorized representative as part of the consenting process.

Subject population characteristics that will not be eligible to participate in participate in the study include non-English speaking individuals and people who cannot read or comprehend English. Employees of the Investigator will be participating in the study.

2.4 Screening

Subjects will be asked questions about their medical history, may have a limited physical and their inclusion/exclusion criteria will be verified. Discontinuation of any concomitant medications, pretreatment instructions and post treatment instruction will be reviewed with the subject.

Procedure for the Limited Physical Exam:
If the investigator determines that a limited exam is necessary, the exam will be like a basic annual physical exam performed by a primary care doctor to determine general overall health. The limited medical exam may include all or any of the following; vital signs such as blood pressure, heart

rate, respiratory rate and body temperature, general appearance, listening to the heart, lungs and abdomen with a stethoscope, head and neck exam, in addition to examining the throat, tonsils, teeth, ears, eyes and nose as well as a neurological exam such as testing muscle strength, reflexes, balance, sensory changes of the extremities and mental state.

2.5 Informed Consent Process and Enrollment

Subjects will be asked to review the pre and post treatment instructions prior to signing the informed consent form and their involvement in the study. Subjects who sign the informed consent will be screened to confirm eligibility and, if eligible, will be assigned a subject identification number. Subjects will be de-identified through their subject identification number, which will be stored in a secure location. Subject identification numbers will be generated chronologically and assigned only to subjects who have met all the study selection criteria and have signed the informed consent form. The informed consent will be obtained prior to a subject's involvement in any study related procedures. A subject will be considered enrolled in the study once they have signed the informed consent form.

2.6 Pre-Treatment Procedures

If the subject is of childbearing potential (i.e. females not post-menopausal or not surgically sterile), they will be asked if they are pregnant, the date of their last menstrual cycle, and perform a urine pregnancy test. A urine pregnancy test will be performed on all women of childbearing potential prior to each treatment only if the treatment is on the abdomen. A urine pregnancy test may also be conducted at the Investigator's discretion at any time during the study. If a urine pregnancy test is conducted, then a negative result must be obtained within 24 hours prior to the treatment.

Urine Pregnancy Test Procedure:

1. A urine sample is tested mid-stream or by cup sample with an indicator stick.
2. Negative results are indicated on the indicator stick.

- Photographs will be taken prior to the first treatment and may be taken prior to each subsequent treatment.
- The following Pre-Treatment instructions will be reviewed:
  - For hair removal subjects, you will be asked to grow hair in the treatment area for a minimum of 5-7 days prior to the baseline photos.
  - For all other treatments and subsequent hair removal treatments, shave any visible hair on the area to be treated 24 hours before treatment.
  - Avoid sun exposure, including tanning beds, self-tanning lotions/creams/sprays for a at least 4 (four) weeks before, and during and after (at least one week) the course of laser treatments.
  - Remove all makeup, lotions, deodorant, and oil from the area to be treated.

2.7 Treatment Procedures

- The defined study area will be identified and may be marked with a white or yellow, washable marker.
- A topical anesthetic may be applied to the treatment area prior to treatment.

- To avoid eye injury, appropriate eye protection for the wavelength being used must be worn by all individuals in the room during treatment.
- Test spots should be performed prior to each treatment.
- The Skintel Melanin Reader will be used for objective measurement of the melanin content of skin. The Skintel Reader will provide guidance to help select test spot settings.
- Procedures for the Elite iQ treatment:
    - The device will be used in accordance with the Operator's Manual.
    - Pulses will be delivered in a linear fashion with no more than a 10% overlap between pulses.
    - An air-cooling system may be used during treatment. The air-cooling system allows for the continuous flow of cold air on the treatment area to ease the sensation from the laser pulse.
    - A thin coating of gel, aqueous or surgical lubricant, clear aloe, clear ultrasonic gel, or water can be used in conjunction with the system as a conduit for the laser energy and to increase cooling efficiency of the treatment site.
    - Parameters may be adjusted throughout the treatment in order to increase subject comfort.
    - Subjects will be asked to report the general level of treatment discomfort/pain on a scale of 0 (none) to 10 (maximum intolerable pain).
    - Parameters and skin reaction will be continuously monitored and recorded during treatment.
- The additional treatments will follow the same procedure.
- Subjects may receive between 1-5 treatments on each treatment area. Subjects may return for a treatment visit every 2-10 weeks.

2.8 Post Treatment Procedures

- Adverse events will be documented after treatment.
- Following treatment, an aloe-based gel, chiller, and/or cold pack may be applied to soothe the skin.
- Photographs may be taken post treatment.
- The following post treatment instructions will be reviewed with subject:
    - Wash the treatment area gently with soap and water. Do not soak. Gently pat area to dry.
    - Following treatment, apply an aloe-based gel or equivalent (such as a cold pack) to soothe and moisturize the skin.
    - Do not shave the treated area if blistering or crusting is evident.
    - Avoid contact sports or any other activity that could cause bruising of the treated area.
    - Following the laser treatment, activities, such as swimming, sports, or strenuous exercise should be avoided for the first 2–3 days, or until any redness, crusting, or blisters have resolved.
    - For vein treatment, avoid exercises that can cause vasodilatation for 1-week posttreatment. Walking is encouraged after vein treatment.
    - Avoid sun exposure throughout the course of treatment and use a broad-spectrum (UVA/UVB) sun block SPF 30 or greater when treatment area is exposed to the sun.

- Avoid sun exposure as delayed secondary blistering has been noted up to 72 hours posttreatment.
- Contact physician if there is any sign of blistering or infection (redness, tenderness, or pus).
- An antibiotic cream should be used if there is any blistering or break in the skin.
- Do not use tanning beds.
- Avoid hot baths/whirlpools for 1 week following treatment (vein treatment).
- Normal skin care regimens, i.e., makeup, moisturizers, deodorant, and shaving may be resumed the day after treatment if there is no redness, blistering, or crusting present. If makeup is allowed, apply and remove it delicately. Excess rubbing can open the area and increase the chance of scarring. If the area blisters, extreme caution should be used when applying or removing makeup. The treated area is very delicate and should be treated with care.
- For vein treatment, discomfort, such as swelling or redness (lasting from a few hours to a couple of days), can be relieved with acetaminophen (such as Tylenol) or ice packs.
- Apply lotion to the area to prevent drying and crusting. Lotion applied following the laser treatment can have a soothing effect. If a crust develops, allow it to fall off naturally. Do not scratch or pick (vein treatment).
- Treated pigmented lesions will likely crust then slough over the course of several days or weeks. Do not scratch or pick at crusts.

2.9 Follow Up

- The study subjects are required to return to Investigator site for a follow up evaluation between 30 - 90 days post last treatment.
- Subject and Investigator questionnaires may be performed at these visits.
- Photographs will be taken, and adverse events will be documented at all follow up visits.
- Some subjects may have an incomplete response or no response by the end of the study. At the end of the study, treatments using an FDA approved/cleared treatment method may be discussed with the subject and obtained at the cost of the subject.

2.10 Unscheduled Visits

An unscheduled visit may be performed at any time during the study at the subject's request or as deemed necessary by the site Investigator. The date and reason for the unscheduled visit will be recorded in the source documentation.

2.11 Replacement of Subjects

Replacement of subjects who have withdrawn or been withdrawn from the study will be allowed to be replaced with prior approval from the sponsor and/or IRB.

2.12 Schedule of Visits and Procedures

	Visit #1*	Visit #2-6	Visit #7
Procedure	Screening and Pretreatment Procedures	Treatment Visit(s) #1 (required) #2-5 (optional) (2 – 10 Weeks Apart)	Follow Up 60 Days Post Last Tx (+/- 30 Days)
Medical History	X		
Pregnancy Verification	X		
Informed Consent	X		
Photographs	X	X	X
Treatment		X	
Treatment Discomfort/ Pain Evaluation		X	
Subject Questionnaires			X
Investigator Questionnaire			X
Adverse Events Assessment		X	X

*Screening and Pretreatment Procedures may occur at the same time as the first Treatment Visit.

2.13 Evaluation Methods

Photographs:
Photographs will be taken at all visits and will be used to assess safety and efficacy of treatment.

Treatment Discomfort/Pain Evaluation:
Subjects will be asked to report the general level of treatment discomfort on a scale of 0 (none) to 10 (maximum intolerable pain) using the universal pain assessment tool (Appendix B)

Subject Questionnaire:
The subject will be asked their level of satisfaction using a 6-point Likert scale that ranges from "extremely satisfied" to "extremely unsatisfied."

Subject Satisfaction	
Rating	Description
6	Extremely Satisfied
5	Satisfied
4	Slightly Satisfied
3	Slightly Unsatisfied
2	Dissatisfied
1	Extremely Unsatisfied

Physician Questionnaire:
The Clinical Global Aesthetic Improvement Scale (CGAIS) ranging from "worse" to "very much improved" will be used to judge the improvement as seen by the treating Investigator.

Global Aesthetic Improvement Scale Assessment	
Rating	Description
1	**Very Much Improved-** Optimal cosmetic result in this subject
2	**Much Improved-** Marked improvement in appearance form the initial condition, but not completely optimal for this subject.
3	**Improved-** Obvious improvement in appearance from initial condition, but a re-treatment is indicated.
4	**No Change-** The appearance is essentially the same as the original condition.
5	**Worse-** The appearance is worse than the original condition.

2.14 Adverse Event Recording

All data captured must be supported by the Investigator's timely assessment and documentation of the adverse event in the case report forms or source documents. All documented adverse events will be reviewed by the Sponsor or designee to determine whether the adverse event meets regulatory reporting requirements and to ensure timely adverse event reporting to meet local and global regulatory requirements. All adverse events must be followed until their resolution.

Adverse Events Pertaining to the Elite iQ Device:

- Subjects may experience some temporary erythema, edema, bruising, or irritation of the skin around the treatment site.
- Scarring, though rare, can occur following any laser procedure.
- Blistering during treatment may be an indication of sun exposure or an excessive fluence setting for the skin type. Blistering can occur during the first three days following the laser procedure.
- Other acute changes may include scaling or scabbing. These changes are often associated with higher energies and their incidence decrease when treatment energies are reduced.
- Histamine/Hives: some subjects may develop raised papules similar to hives. This irritation usually subsides in a few hours.
- Pustules, pimples, or folliculitis may develop in the first few days following treatment.
- Hyperpigmentation or hypopigmentation can occur following the laser treatment. Pigmentary changes have been reported to be transient although they may last for several months or longer.
- Hemosiderin Staining- The treated vessel may leak tiny amounts blood into the tissue. When the red blood cells die, iron released from the hemoglobin is converted into hemosiderin and stored in the tissue beneath the skin. This shows up as a brown/purple stain on the skin. It usually will fade over time, but some may require further treatment to resolve.

Adverse Events Pertaining to Gel:
The gel is a water-based gel that may be placed on the skin during the Elite iQ treatment. No known adverse events are documented. However, an allergic reaction is always possible when placing a topical gel onto the skin. Allergic reaction may include a mild reaction such as skin redness, irritation or hives.

Adverse Events Pertaining to Anesthesia:
Topical anesthesia, such as but not limited to; EMLA, LMX and Lidocaine/Tetracaine, will be used. The most common side effects for most anesthetics include redness, blanching, swelling and application site reaction.

Less common side effects include large swellings that look like hives on the skin or in the mouth or throat, pain, burning, paleness and altered temperature sensation. Subjects may be allergic to the contents of any anesthetic which may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people.

Adverse Events Pertaining to the Marker:
Using surgical marker has minimal risks and may produce effects on the body such as redness or a rash.

Other Cautions:
Incomplete response or no response may occur since some subjects may not respond to treatment.

2.15 Statistical Analysis

2.15.1 Hypothesis

For this study to be considered a success, parameters are developed, and the side effect profile is acceptable to the Physician as it relates to this type of treatment.

For secondary objectives to be considered a success, the results from any assessments will need to be statistically significant or have ≥80% response rate. In cases where the subject's improvement is being graded on a scale, such as the GAIS scale, we will test the statistical significance of our results against a hypothetical population that would have no change (average score of 4).

2.15.2 Sample Size Rationale

The primary outcome will be the development of the practicality of the device. Based on the need for data collected from this study, it was determined that a total of 20 subjects will be required, including departures.

2.15.3 Patient Populations

Interim results may be collected and reported. All data will be analyzed at the end of the study. The primary analysis will be performed by the intention-to-treat approach. Everyone who begins the treatment is part of the study whether he or she completes the study or not. Additional per-protocol analysis may also be performed on subjects who complete the entire clinical trial according to the protocol. The most appropriate method of handling missing values will be chosen based on the individual trial goals, endpoints and context.

The analysis of demographic, medical history, and efficacy variables will be based on all patients who are randomized and receive at least one treatment. The analysis of safety data will be based on all patients who are randomized, receive at least one treatment, and have at least some safety data.

2.15.4 Analysis of Demographic and Medical History Variables

Summaries will be prepared for all important demographic and medical history variables. For quantitative variables summaries will include the sample size, mean, median, standard deviation, minimum, and maximum. For these variables the treatment groups will be compared using either a t-test or a Wilcoxon Rank Sum test, as appropriate. For categorical variables the summaries will include the sample size and the number and percent of patients for each outcome. For these variables the treatment groups will be compared using Fisher's Exact test. Statistical significance will be declared if the two-sided p-value is < 0.05.

2.15.5 Analysis of Efficacy Variables

The primary efficacy variable is the change from baseline to visit 7 (60 days post last treatment, +/- 30 days) with respect to the indication being treated as evaluated by physician grading with CGAIS. Baseline is defined as the last assessment prior to the first treatment. The change from baseline to visit 13 will be analyzed using a Mixed Model Repeated Measures Analysis of Variance. A pairwise treatment group comparison at visit 7 will be performed using the results of this analysis. If a patient has no post-baseline assessment of the primary efficacy variable the patient data will be excluded from the statistical analysis of the improvement. Statistical

significance with respect to the treatment group comparison at visit 7 will be declared if the two-sided p-value is < 0.05. For each treatment group summaries will be prepared for both the observed assessment and the change from baseline. Subject satisfaction results from Visits 12 and 13 will also be included in the summary. The summaries will include the sample size, mean, median, standard deviation, minimum, and maximum. Categorical variables will also include a summary which will include the number and percent of patients for each outcome. The statistical significance of the mean change from baseline for each treatment group will be determined using a student's paired t-test.

2.15.6 Analysis of Safety Variables

Safety will be assessed through the degree of pain/discomfort related to the procedure (universal pain scale) and the collection of Adverse Events throughout the course of the study. For each treatment group these variables will be summarized. The summaries will include the number and percent of patients for each outcome. No statistical comparisons will be performed for any of these variables.

3.0 RISK ANALYSIS AND MANAGEMENT

3.1 Risk Determination

This device study used in this study does not meet the FDA definition for a Significant Risk Device study per 21 CFR 812.3(m). Therefore, the sponsor determines that this is a non-significant risk device study.

Significant risk device means an investigational device that:
(1) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
(2) Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
(3) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
(4) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

3.2 Risk Management

The Investigator in this clinical trial has been invited to participate based on his/her previous experience with the use of the system and/or similar systems and industry experience. Experience with treatments is the most critical element in managing subject risk in this trial.

In addition, as with any study, there is a risk of bias. Objective evaluation methods may be used in conjunction with subjective evaluation methods when feasible. The value of the compensation to the clinical investigator for conducting the study is not influenced by the study outcome. If photographic results are listed as the primary objective, they are to be evaluated by blinded evaluators who did not partake in the study. If information concerning investigator assessment of improvement or investigator satisfaction is collected, then it is not listed as an objective for the study.

All other known risks will be disclosed to the subject via the informed consent process. Since this is an elective procedure and the subjects are volunteers, it can be assumed that their signature on the informed consent is indicative of their agreement to accept the risks involved.

The risks to the subjects who participate in this study are the same as those for the subject undergoing similar non-ablative radiofrequency treatment. It is possible to have an adverse reaction to the Elite iQ device use. There may be some side effects that we don't know about yet.

3.3 Risk Analysis

CONTEXT OF THE PROPOSED INVESTIGATION:
The Alexandrite wavelength (755 nm) and the Nd:YAG wavelength (1064 nm) target hair follicles, unwanted veins, pigmented lesions and treat sun-damaged skin. The Elite iQ laser system delivers the correct combination of wavelengths (755 and 1064 nm), high fluences (up to 600 J/cm2) and long pulses (up to 300 ms) for its clinical applications. Further investigation of parameter optimization is necessary to achieve safe and efficacious results.

ASSESSMENT OF RISKS OF THE PROPOSED INVESTIGATION:
There is one risk identified with the Elite iQ device used in this study. The risk identified is the lack of clinical data using this software for evidence of effectiveness. Parameters need to be further investigated to be optimized for efficacious results.

The risk identified with the overall clinical investigation is the integrity of the data collected.

There are multiple clinical mitigation strategies for the risks identified. Proper training on the device and protocol will be performed. Data from prior investigations will be utilized to minimize side effects and optimize treatment outcomes. Monitoring of the study will be implemented to minimize subject and data risks.

ASSESSMENT OF BENEFITS OF THE PROPOSED INVESTIGATION:
The subject may or may not have improvement for the indication treated.

CONSIDERATION OF PATIENT PREFERENCE INFORMATION:
Many physicians support the use of laser devices for non-invasive cosmetic treatments due to current patient satisfaction of cosmetic results with the currently available devices. However, there is still a level of interest in novel technologies that could reduce the need for future treatments with better treatment outcomes.

ASSESSMENT OF UNCERTAINTY:
There is uncertainty of the efficacy of the treatment with the use of the Elite iQ system.

CONCLUSION:
The Elite iQ device is determined to be a non-significant risk study and has been FDA cleared for use. This device poses similar risks to its predicate device, the Elite+, which is also currently FDA cleared for use. The risks posed to the subjects and integrity of data are acceptable.

Patient population to be enrolled in this clinical study:
Total anticipated population: 20 Subjects
Age Range: 18 years of age or older
Gender: Male or Female
Condition: Hair removal and benign vascular and pigmented lesions.

4.0 DEVICE DESCRIPTION AND SPECIFICATIONS

On March 9th, 2020, the Elite iQ device used in this study was cleared for use by the U.S. Food and Drug Administration (the FDA) under K193426 for the following indications:

755nm:
The Elite iQ Laser System is indicated for stable long-term or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing when measured at 6, 9 or 12 months after the completion of a treatment regime. It is used for skin types (Fitzpatrick I-VI) including tanned skin. It is also indicated for the treatment of vascular lesi ons, benign pigmented lesions , and wrinkles.

1064nm:
The Elite iQ Laser System is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas , warts, telangiectasia, rosacea, venous lakes, leg vein s, spider veins and poikiloderma of Civatte; and treatment of benign cutaneous lesions such as warts , scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigines (age spots), solar lentigines (sunsp ots), cafe au lait macules , seborrheic keratoses, nevi, chloasma, ver rucae , skin tags, keratosis and plaques.

The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

Additionally, the laser is indicated for the treatment of pseudo folliculitis barbae (PFB) and for stable long-term or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

The Skintel Reader is intended as an objective measurement tool for examining skin melanin content for determining and setting a test spot starting fluence

The Elite iQ Device Specifications are:

Specification	Alexandrite (755nm) For Both the M122B1 and M122D1 Models	Nd:YAG (1064nm) For the M122B1 Model Only
Wavelength	**755 nm +10/-5 nm**	**1064 nm ± 1.0 nm**
Pulse Width	**≤300 ms (max discrepancy -2%)**	≤300 ms (max discrepancy -2%)
System Cooling Method	**Water (internally circulated with heat exchanger to air)**	
Mode of Operation	**On/Off: 3 min/5 min**	
Nominal Ocular Hazard Distance (NOHD)	**448m**	**239.5m**
Protective Eyewear Specification for diffuse viewing, 300mm distance, 5s exposure time	**OD≥4 DLB5 ILB7 @755nm**	**OD≥4 DLB5 ILB7 @1064nm**
Fluence Incident on Eyewear Surface for Diffuse Viewing Resistance Determination	**0.3 J/cm²**	**0.5 J/cm²**
Protective Eyewear Specification for direct intra-beam viewing, 100mm distance, 5s exposure time*	**OD≥6** DLB7 ILB9 @755nm	**OD>6 DLB7 ILB9 @1064nm**
Fluence Incident on Eyewear surface for intra-beam resistance determination	**104.3 J/cm²**	**156.5 J/cm²**
Corneal Maximum Permissible Exposure (MPE)	**77.54mJ/m²**	**254.6mJ/m²**
Optical Density (min)	**OD≥6**	**OD≥6**
Maximum Output Power (from handpiece)	**106 W ±20%**	**154 W ±20%**
Maximum Output Energy (from handpiece)	**63.5 J**	**91.2 J**
Aiming Beam Source/Wavelength	**Diode laser, 532 nm, green** Selectable intensity between 1% and 100%	
Aiming Beam Max. Delivered Output Power	**4.0 mW**	

Changes to the Elite iQ device are not anticipated during the investigation.

5.0 MONITORING PROCEDURES

The Sponsor Standard Operating Procedure (SOP) for monitoring the investigative site will be followed. The sponsor will train the site following sponsor SOP's and may be present at initiation of treatment. The sponsor will also monitor the site periodically. The Investigator/Institution will permit trial-related monitoring, audits, IRB/IEC review, and regulatory inspections by providing direct access to source documents. The sponsor may request intermediate data following each visit to evaluate treatment progress. Case Report Forms will be reviewed for current data and Regulatory Binders will also be reviewed for correct documents. The sponsor will collect data at

the end of the follow up period. The sponsor will list the study on clinicaltrials.gov when required by FDA regulations.

The monitoring plan for this study is outlined in the Cynosure Monitoring Plan.

ASSIGNED CLINICAL RESEARCH MONITOR:
Monitor #1
Name: Kristy Luis
Institution: Cynosure, LLC
Address: 5 Carlisle Rd. Westford, Ma

6.0 LABELING

Sample labeling will follow FDA regulations and the sponsor standard operating procedure. If applicable, the Elite iQ device label will include, (in accordance with 801.1):

Statement: "CAUTION--Investigational device. Limited by Federal (or United States) law to investigational use."

Additionally, the label or other labeling will describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.

Directions for use are contained in the Elite iQ Operator's Manual

7.0 CONSENT MATERIALS

Forms and informational materials which are provided to the subject during the informed consent process are listed below:

Form/Informational Material Description
Pre and Post Treatment Instructions
Informed Consent Form

8.0 INSTITUTIONAL REVIEW BOARD INFORMATION

This protocol, informed consent forms, and any amendments to the protocol will be reviewed by the appropriate Institutional Review Board prior to initiation. The study will not be initiated without the approval from the Institutional Review Board.

9.0 OTHER INSTITUTIONS

If a part of the study is conducted by an institution that has not previously been identified within the Investigational plan each institution's contact information will be documented below;

No other institutions will be part of this study.

10.0 ADDITIONAL RECORDS AND REPORTS

If this is an IDE study, additional records and reports will be maintained on the investigation in addition to those prescribed in 21 CFR 812 sub-part G. If this is a non-IDE study, the study summary will be maintained on the investigation and may include those prescribed in 21 CFR 812 sub-part G.

Additional Records and Reports:

Report	Submit To	Description/Constraints
N/A	N/A	This is a non-IDE study; no additional records or reports will be maintained.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law in accordance with the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11). The sponsor will be responsible for the submission and maintenance of http://www.ClinicalTrials.gov records. The Principle Investigator will be responsible for providing accurate data in a timely manner for compliance.

11.0 PREGNANCY

Females may not participate in this study if they are pregnant, breastfeeding, were pregnant within the last three months or are planning a pregnancy during the study.

If the subject thinks they have become pregnant during the study, it is important that they inform the Investigator immediately. If she becomes pregnant or thinks that she may be pregnant, she will be removed from the study and will be asked to perform a final evaluation similar to the final follow-up visit. The Investigator may request to track the pregnancy and will report the pregnancy to the Sponsor.

12.0 SUBJECT WITHDRAWAL

The subject is free to withdraw from this study at any time. The subject must inform the Investigator immediately if they intend to withdraw. To terminate the subject's participation in this study, they must contact the Investigator at the contact information listed on page one of the informed consent form. They will be asked to come to the study clinic or Investigators office to complete a final follow up visit and may be asked to perform end of study procedures. Their decision to participate in this study or to withdraw from this study will not influence the availability of their future medical care and will involve no penalty or loss of benefits to which they are otherwise entitled.

The Investigator in charge of the study can remove the subject from this study without their consent for any reason, including, but not limited to:

a) His/her judgment that any condition or circumstance may jeopardize their welfare or the integrity of the study.
b) Their failure to follow the instructions of the Investigator(s).
c) If the study is stopped by the sponsor and/or Investigators participating in the study prior to completion.

Data collected prior to withdrawal will be used in data analysis but after withdrawal no further data will be collected.

13.0 PHOTOGRAPHY

Standardized photographs will be taken of the treatment area. The subject will be asked to remove jewelry, make-up, and lotions prior to each photo session. Photographs will be taken with an appropriate high-resolution digital camera. Camera settings (lighting, distance, background, polarization, etc.) will be reproduced at each visit, so that photographs are suitable for comparison. Photographs will be taken of the treatment area for study purposes. If the subject does not wish to have their photographs taken, they cannot be in the study.

14.0 ADVERSE REACTIONS DEFINITIONS AND REPORTING REQUIREMENTS

All adverse events that occur, starting from the time of the first treatment, will be recorded in the source documents and Case Report Forms (CRF).

Adverse Events (AE) occurring will be captured and followed until the condition resolves, stabilizes, is otherwise explained, or the subject is lost to follow-up. Subjects will be instructed that they may contact the Investigator at any time throughout the course of the study.

The Investigator and/or designated study staff will review each event and assess its relationship to the study device (not related, unlikely, possible, probable, and highly probable). The following definitions will be used for rating relationship to the Elite iQ treatments:

- Not related – The event is clearly related to other factors such as the subject's clinical state, therapeutic interventions, or concomitant medications administered to the subject.
- Unlikely – The event was most likely produced by other factors such as the subject's clinical state, therapeutic interventions, or a concomitant medication administered to the subject; and does not follow a known response pattern to the investigational product.
- Possible – The event follows a reasonable temporal sequence from the time of investigational product administration; **and/or** follows a known response pattern to the study sampling sessions; **but** could have been produced by other factors such as the subject's clinical state, therapeutic interventions, or concomitant medications administered to the subject.
- Probable – The event follows a reasonable temporal sequence from the time of investigational product administration; **and** follows a known response pattern to the investigational product; **and** cannot be reasonably explained by other factors such as the subject's clinical state, therapeutic interventions, or concomitant medications administered to the subject.

- Highly Probable – The event follows a reasonable temporal sequence from the time of investigational product administration; **and** follows a known response pattern to the investigational product; **and** cannot be reasonably explained by other factors such as the subject's clinical state, therapeutic interventions, or concomitant medications administered to the subject; **and** either occurs immediately following investigational product administration, **or** improves on stopping the investigational product, **or** reappears on repeat exposure, **or** there is a positive reaction at the application site.

  Each adverse event reported will be graded on a 3-point severity. Using the following definitions for rating severity will be used:
- Mild – easily tolerated, causing minimal discomfort, and not interfering with normal everyday activities.
- Moderate – sufficiently discomforting and may interfere with normal everyday activities.
- Severe – incapacitating and/or preventing normal everyday activities.

A Serious Adverse Event (SAE) is any adverse device experience that results in any of the following outcomes: death, a life-threatening adverse device experience, in-patient hospitalization or prolongation of hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may or may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse device experience when, based upon appropriate medical judgment, they may jeopardize the subject or subject may require medical or surgical intervention to prevent one of the outcomes listed in this definition

If any of the above adverse events are serious as defined by the FDA Code of Federal Regulations (CFR), Title 21, special procedures will be followed. All serious adverse events will be reported within 24 hours of acknowledgment to the Sponsor whether or not the serious events are deemed sampling session-related. All serious event reporting will adhere to 21 CFR part 812 and the IRB will be notified accordingly.

The SAE information will be entered into the database and a desk copy of the complete SAE report will be submitted to the study file.

Adverse events, whether serious or non-serious, will be followed until the condition is resolved, stabilized, otherwise explained or the subject is lost to follow-up. Adverse events will be captured throughout the study and where appropriate, medical tests and examinations will be performed to document the resolution of event(s). Outcomes may be classified as resolved, improved, unchanged, worse, fatal, unknown or lost to follow-up. Following the resolution of any study-associated adverse events there will be no further adverse event reports for that subject.

Reporting Adverse Events:

Report	Submit To	Description/Constraints

Adverse Events, Unanticipated Adverse Device Effect	IRB and Sponsor	If an unforeseen complication is determined to be an unanticipated adverse device effect, the investigator's report must be submitted within 10 working days after the investigator first learns of the effect.
Serious Adverse Events	IRB and Sponsor	The sponsor must be notified within 24 hours of serious adverse events. The IRB must be notified within 1 working day of serious adverse events as defined by FDA guidelines.

15.0 PROTOCOL DEVIATIONS

All requests for protocol deviations by the Investigator must be communicated to the sponsor in writing and if accepted by the Sponsor must be approved by the IRB. If a deviation occurs, the Investigator must inform the Sponsor as soon as possible. The Sponsor will notify the IRB in accordance with IRB specific policies.

16.0 CONFIDENTIALITY AND DISCLOSURE OF MEDICAL INFORMATION

As part of this study the Investigator and the team at the research facility will keep records of subject participation in the study. These study records will include personal information that the subjects provide including age, sex, etc., the results of the study, information about response to treatments, photographs taken during the study and other medical information relating to participation in the study.

Under federal law the study records cannot be used or disclosed by the Investigator for research purposes unless subjects sign the informed consent authorization.

Some or all of the test results, photographs and other information will be reported to Cynosure, LLC, the manufacturer of the test device (Sponsor), and consultants that are helping conduct the study. The Sponsor and its consultants will analyze and evaluate these results and information and may report them to the U.S. Food Administration and the FDA, Institutional Review Board or other regulatory agencies in the United States and/or foreign countries. The subject's study records will be assigned a code number by the study team and they will ordinarily not be identified by name in the study records that are sent to the Sponsor and its consultants. However, The Sponsor, the Institutional Review Board and its consultants will have the right to see the complete study records, including the subject's name, and might choose to do so. If reports or articles are written about the study, the subject will not be identified by name in them however your study information and photographs may be used.

The research facility will review and use the study records only for purposes of this study. They will keep the subject's identity confidential and, except for the disclosures described above, will not disclose the study records to other parties unless disclosure is required by law. Once the research facility discloses information in the study records, photographs or medical records to the Sponsor or

its consultants, the information will no longer be protected by federal law. Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. However, the Sponsor and its consultants will only use information for purposes of the study and will not disclose your study records to parties other than; the FDA or other regulatory agencies in the United States and/or foreign countries, unless disclosure is required by law. If reports or articles are written about the study, subjects will not be identified by name in them however, subject study information and photographs may be used.

Study records will be kept at the research facility according to applicable regulations and policies and may be kept indefinitely following the completion of the study. Subjects will not have the right to review their records while the research is in progress. However, they will be able to review their records after the research has been completed.

17.0 CLINICAL RESEARCH CONDUCT

The study will be conducted in accordance with the protocol, International Conference on Harmonization (ICH) GCP guidelines, applicable regulations and guidelines governing clinical study conduct and ethical principles that have their origin in the Declaration of Helsinki. The investigator must ensure that the study is conducted in accordance with the provisions as stated in the FDA regulations and complies with the applicable local or regional regulatory requirements.

18.0 REPORTING FOR THE STUDY

A study summary report will be generated. It will include a description of the clinical conduct of the study and results.

Study Summary Reporting:

Report	Submit To	Description/Constraints
Deviation from Investigational Plan	IRB and Sponsor	A deviation performed in an emergency to protect the life or physical well-being of a patient necessitates notification of the IRB and sponsor. The Investigator's report must be submitted within 5 working days after the emergency occurred. Deviations in a non-emergency situation require notification to sponsor prior to implementation
Failure to Obtain Informed Consent	IRB and Sponsor	The Investigator must make notification within 5 working days after device use, using the Protocol Deviation CRF. The report must include a brief description of the circumstances justifying the failure to obtain informed consent.
Final Report	IRB and Sponsor	The Investigator must submit a final report within 3 months after termination or completion of the investigation.

Withdrawal of IRB approval	Sponsor	The Investigator must report a withdrawal of the reviewing IRB approval within 5 working days.
Progress Report	IRB, Monitor and Sponsor	The Investigator must submit progress reports at regular intervals, and as required by the IRB, but in no event less than annually.

19.0 DISCLOSURE

The Principal Investigator and Cynosure employees and consultants have signed confidentiality agreements with the sponsor. This confidentiality agreement ensures that all information provided to the Investigator or Data Management and Statistics group dealing with the study and information obtained during the study will be regarded as confidential.

20.0 RESPONSIBILITY OF THE INVESTIGATOR

The Investigator is responsible for ensuring that the clinical study is performed in accordance with the International Conference on Harmonization (ICH), Good Clinical Practice (GCP) guidance E6, FDA Good Clinical Practice Regulations, Declaration of Helsinki (DoH) and the Health Human Service (HHS) Belmont Study. Investigators will supply information to the sponsor such that the sponsor can comply with the Financial Disclosure Rules.

21.0 PROCEDURE FOR AMMENDMENTS TO PROTOCOL

No deviations from this protocol will be permitted, except in a medical emergency, without the approval of the Sponsor. Any amendment to this study will be discussed by the Investigator and the Sponsor. If agreement is reached concerning the need for modification, this will be made in a formal amendment to the protocol.

All revisions and/or amendments to the protocol must be approved in writing by the appropriate Institutional Review Board.

22.0 TERMINATION OF STUDY

The Sponsor reserves the right to discontinue this study for administrative reasons at any time. The Investigator reserves the right to discontinue the study for safety reasons at any time in collaboration with the Sponsor.

23.0 DATA SECURITY

To ensure the privacy and confidentiality of data for this protocol, the data will be stored on a restricted access location on a company server. Access to the project directory containing the data will be limited to the Investigators and research staff. Information about data security awareness is promoted through user training and education, supplemented by policies and procedures. Password protection will be used for all transactions that allow viewing, editing, and analysis of data, or that provide access to data fields derived from the original source documents.

24.0 REPORT OF PRIOR INVESTIGATIONS

The report of prior investigations or predicates are:

Device	**Determination**	**510(k)**
Elite+	Meets the criteria for exemption from IDE regulations, non-significant risk	K141425

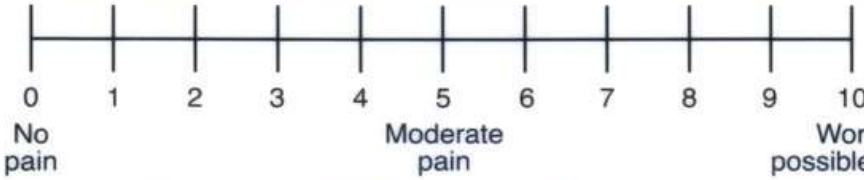
APPENDIX A:
Protocol Revisions Tracker

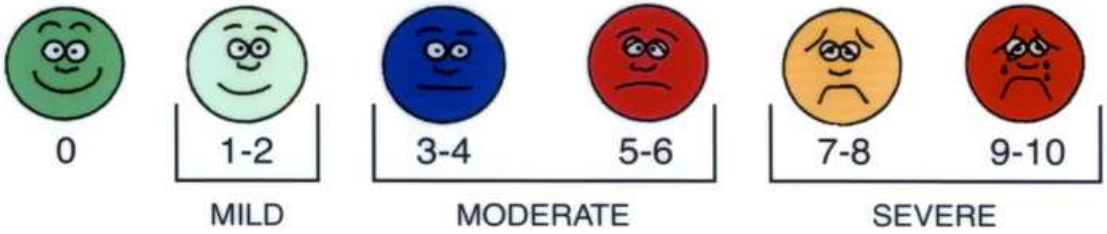
Version Date	Editor	Description
June 30, 2020	Kristy Luis	Version 1.0

APPENDIX B:

UNIVERSAL PAIN ASSESSMENT TOOL

This pain assessment tool is intended to help patient care providers assess pain according to individual patient needs. Explain and use 0-10 Scale for patient self-assessment. Use the faces or behavioral observations to interpret expressed pain when patient cannot communicate his/her pain intensity.





ACTIVITY TOLERANCE SCALE	NO PAIN	CAN BE IGNORED	INTERFERES WITH TASKS	INTERFERES WITH CONCENTRATION	INTERFERES WITH BASIC NEEDS	BEDREST REQUIRED
SPANISH	NADA DE DOLOR	UN POQUITO DE DOLOR	UN DOLOR LEVE	DOLOR FUERTE	DOLOR DEMASIADO FUERTE	UN DOLOR INSOPORTABLE
FRENCH	AUCUNE DOULEUR	LÉGÈRE DOULEUR	DOULEUR MODÉRÉE	FORTE DOULEUR	TRÈS FORTE DOULEUR	DOULEUR EXTRÊME
GERMAN	KEINE SCHMERZEN	LEICHTE SCHMERZEN	MÄSSIGE SCHMERZEN	STARKE SCHMERZEN	SEHR STARKE SCHMERZEN	EXTREME SCHMERZEN
JAPANESE	痛みなし	軽い痛み	中程度の痛み	ひどい痛み	非常にひどい痛み	最悪の痛み

REFERENCES

[1] Sherber, N. S., MD FAAD. (2018). The Millennial Mindset. *Journal of Drugs in Dermatology, 17*(12), 1340-1342.

[2] "2018 Plastic Surgery Statistic Report." American Society of Plastic Surgeons, https://www.plasticsurgery.org/documents/News/Statistics/2018/plastic-surgery-statistics-full-report-2018.pdf. Accessed 13 November 2019.