STATISTICAL ANALYSIS PLAN

STUDY TITLE: A MULTI-CENTER, PROSPECTIVE STUDY TO EVALUATE THE SAFETY AND EFFECTIVENESS OF MULTI-TREATMENT REGIMEN WITH ZELTIQ AESTHETICS, INC. RAPID ACOUSTIC PULSE (RAP)™ DEVICE FOR THE IMPROVEMENT IN THE APPEARANCE OF CELLULITE

PROTOCOL NUMBER: M24-262/2022-01

Protocol Version Rev 01 (11 Jan 2023)

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REVISION HISTORY

Table 1 SAP Version History Summary

SAP Version	Approval Date	Change	Rationale
1.0	11SEP2023	Not Applicable	Original version
2.0	01NOV2023	• Update protocol number to include AbbVie internal study number (M24-262) • 5.3: added text to clarify that the overall average pain score cannot be computed if both questions are not answered • 6.7: updated Cellulite Dimple – At Rest Scale as assessed during the Screening visit values to be Both Sides Grade 2, Both Sides Grade 3, or Side with Different Grades • 10.1: updated summary of all known physiological responses to be for all values as collected on the CRF	Updates made for alignment between 2021-06 SAP and this SAP

ABBREVIATIONS

ABBREVIATION	DEFINITION OR DESCRIPTION
ADE	Adverse Device Effect
AE	Adverse Event
ATC	Anatomical Therapeutic Chemical
CRF	Case Report Form
CSR	Clinical Study Report
ICH	International Conference on Harmonisation
ICF	Informed Consent Form
IPR	Independent Physician Review
MedDRA	Medical Dictionary for Regulatory Activities
PD	Pharmacodynamic
PK	Pharmacokinetic
PT	Preferred Term
RAP™	Rapid Acoustic Pulse
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOC	System Organ Class
WHO	World Health Organization

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1 INTRODUCTION

This statistical analysis plan (SAP) describes the planned analysis and reporting for ZELTIQ Aesthetics protocol number 2022-01: A Multi-center, Prospective Study to Evaluate the Safety and Effectiveness of Multi-treatment Regimen with ZELTIQ Aesthetics, Inc. Rapid Acoustic Pulse (RAP)™ Device for the Improvement in the Appearance of Cellulite version Rev 01 dated 11 Jan 2023.

This SAP will be signed off, at a minimum, before the final database lock and contains detailed information to aid in the performance of the statistical analysis and reporting of the study data for use in the final clinical study report (CSR). This SAP is being written with due consideration of the recommendations outlined in the most recent International Conference on Harmonization (ICH) E9 Guideline entitled Guidance for Industry: Statistical Principles for Clinical Trials and the most recent ICH E3 Guideline and the Guidance for Industry: Structure and Content of Clinical Study.

2 STUDY OBJECTIVES

The purpose of this multi-site clinical study is to evaluate the safety and effectiveness of two (2) treatment sessions with the ZELTIQ Aesthetics, Inc. RAP device for the improvement in the appearance of cellulite.

2.1 PRIMARY EFFECTIVENESS OBJECTIVE

The primary effectiveness objective will demonstrate improvement in the appearance of cellulite as determined by correct identification of baseline vs 12-week post final treatment images.

2.2 SECONDARY OBJECTIVES

- Evaluate the safety of the RAP device for cellulite treatments after each treatment and at each follow-up visit
- Demonstrate improvement in the appearance of cellulite as determined by the study participants completing the Participant Satisfaction Survey (**Assessment 3 in the Protocol**) when comparing side-by-side baseline vs 12-week post final treatment images

3 STUDY DESIGN AND PROCEDURES

This is a non-significant risk, multi-center, multi-treatment (2 treatment sessions) prospective trial for safety, and effectiveness using ZELTIQ Aesthetics, Inc.'s RAP device for the improvement in the appearance of cellulite performed at up to four (4) clinical research sites in the United States.

Up to sixty (60) healthy participants between the age of 18-50 will be enrolled in this study.

Participants who sign the informed consent form and meet all the eligibility criteria will be enrolled in the study. Each participant will undergo acoustic rapid pulse (RAP) treatment sessions on both of their thighs and/or buttocks.

Total study duration is anticipated to be at or less than 60 weeks from the first participant visit to the last participant observation visit. A total of up to six (6) visits are planned for this study as shown in Table 1 of the protocol.

4 DETERMINATION OF SAMPLE SIZE

Up to sixty participants will be enrolled and treated in this study. The sample size is based on clinical and practical exploratory considerations and not on a formal statistical power calculation.

5 STUDY ASSESSMENTS AND SCALES

The following assessments are collected during the study.

5.1 PHOTOGRAPHY

Photographs will be taken under standardized lighting and equipment settings at baseline, and at 4-week post-first treatment, 12, 26, and 52-week post-final treatment visits. Photos taken as baseline will serve as control images for the assessment of post treatment photos. At the visit, the photographer will take multiple photos at each angle (posterior; posterior oblique left; posterior oblique right), but only the single best photo, as determined by the photographer, will be selected for each angle. Three blinded, independent photo reviewers will review the 12-week and baseline photos and identify which photos were taken at which visit, called an Independent Physician Review (IPR). Reviewers will be shown one image per participant that consists of three baseline photos at three different angles and three 12-week post-final treatment photos at the same three different angles. Participants will review the same image as the IPR for their self assessments.

5.2 PARTICIPANT SATISFACTION SURVEY (ASSESSMENT 3 IN THE PROTOCOL)

The Participant Satisfaction Survey is used to grade participant-reported overall improvement of the treatment areas. The questionnaire is divided into two sections (participant's right or left side) of three questions graded on a 5-point Likert scale.

The six questions are scored from 1 to 5, where higher scores indicate higher agreement and more positive response:

- Strongly Agree = 5
- Agree = 4
- Neutral = 3
- Disagree = 2
- Strongly Disagree = 1

Scores of Agree = 4 or Strongly Agree = 5 to questions 1 and 4 will be considered an improved response for treatment effectiveness.

The Participant Satisfaction Survey will be administered at 4-week post-first treatment, 12, 26, and 52-week post-final treatment visits.

5.3 PROCEDURE TOLERABILITY QUESTIONNAIRE (ASSESSMENT 1 IN THE PROTOCOL)

The Procedure Tolerability Questionnaire is used to assess the comfort of the RAP treatment. It is divided into two sections (participant's right or left side) of three questions. The overall average pain per participant will be derived as the average of the responses to "The OVERALL pain score DURING the procedure?" and "The OVERALL pain score AFTER the procedure?" for all treatment sides. The overall average pain score cannot be computed if both questions are not answered. The individual responses are scored from 0 to 10, where higher scores indicated increased pain.

5.4 GLOBAL AESTHETIC IMPROVEMENT (GAIS) (ASSESSMENT 5 IN THE PROTOCOL)

The GAIS is completed by the Investigator to grade the overall improvement of each treatment area (thigh/buttock) by comparing baseline photos to post treatment photos at 4-week post-first treatment, 12, 26, and 52-week post-final treatment visits. The question is scored from 1 to 5, where higher scores indicate worse improvement:

- Very much improved = 1
- Much improved = 2
- Improved = 3
- No Change = 4
- Worse = 5

5.5 BODY-Q™ APPRAISAL OF CELLULITE (ASSESSMENT 4 IN THE PROTOCOL)

This self-administered 11-item scale measures how much someone is bothered by the appearance of cellulite. At each assessment, the raw scores for the set of items in a scale are added together to produce a total raw score. If less than 5 questions are missing, the within person mean for the completed items will be imputed for the missing items prior to computing a total raw score. The total raw score cannot be imputed if 5 or more questions are missing. Total raw scores are then converted to a Rasch transformed score in the range of 0 (worst) to 100 (best) using the Conversion Table. Both total raw scores and Rasch transformed scores will be captured in the CRF. The raw scores are scored from 1 to 4, where higher scores indicate the patient is less bothered:

Extremely bothered = 1

Moderately bothered = 2

A little bothered = 3

Not at all bothered = 4

Sum Score	Equivalent Rasch Transformed Score (0-100)
11	0

12	11
13	16
14	20
15	23
16	25
17	28
18	30
19	32
20	34
21	36
22	38
23	40
24	42
25	44
26	46
27	47
28	49
29	51
30	53
31	55
32	58
33	60
34	62
35	65
36	68
37	71
38	74
39	77
40	80
41	83
42	87
43	93
44	100

5.6 BODY-Q™ SATISFACTION WITH HIPS & OUTER THIGHS AND SATISFACTION WITH BUTTOCKS (ASSESSMENT 4 IN THE PROTOCOL)

Hips & Outer Thighs is a self-administered 5-item scale measuring satisfaction with the appearance of the hips and outer thighs. Buttocks is a self-administered 5-item scale measuring satisfaction with the appearance of the buttocks. At each assessment, for both scales, the raw scores for the set of items in a scale are added together to produce a total raw score. If less than 3 questions are missing, the within person mean for the completed items will be imputed for the missing items prior to computing a total raw score. The total raw score cannot be imputed if 3 or more questions are missing. Total raw scores are then converted to a Rasch transformed score in the range of 0 (worst) to 100 (best) using the Conversion Table. Both total raw scores and Rasch transformed scores will be captured in the CRF. The raw scores are scored from 1 to 4, where higher scores indicate the patient is more satisfied:

Very Dissatisfied = 1

Somewhat Dissatisfied = 2

Somewhat Satisfied = 3

Very Satisfied = 4

Sum Score	Equivalent Rasch Transformed Score (0-100)
5	0
6	13
7	19
8	24
9	29
10	33
11	38
12	43
13	48
14	54
15	63
16	73
17	80
18	86
19	93
20	100

5.7 FITZPATRICK SKIN TYPE SCALE (SCALE 2 IN THE PROTOCOL)

A participant's Fitzpatrick skin type is established by the Investigator at baseline using the six-category scale:

Skin Photo type	Typical Features	Tanning Ability
I	Pale white skin, blue/hazel eyes, blond/red hair	Always burns, does not tan
II	Fair skin, blue eyes	Burns easily, tans poorly
III	Darker white skin	Tans after initial burn
IV	Light brown skin	Burns minimally, tans easily
V	Brown skin	Rarely burns, always tans darkly
VI	Dark brown or black skin	Never burns, always tans darkly

6 GENERAL ANALYSIS AND REPORTING CONSIDERATIONS

Continuous data will be summarized using descriptive statistics: n, mean, standard deviation, median, minimum and maximum, Q1 and Q3, unless otherwise noted.

Categorical variables will be summarized using frequency counts and percentages. When count data are presented, the percentage for zero counts will be suppressed to draw attention to the non-zero counts. The denominator for all percentages will be the number of participants in that treatment group within the population of interest, unless otherwise noted.

The following conventions will be used throughout the study analysis:

- Baseline value is defined as the last valid measurement prior to the first RAP treatment.
- Change from baseline is defined as post-baseline value minus baseline value.
- If duplicate values are obtained at a given visit (e.g., repeated vital sign measurements), the last value will be used.

6.1 ADJUSTMENTS FOR COVARIATES

No adjustments for covariates are needed for this study.

6.2 STUDY HYPOTHESES

No formal hypothesis testing is planned.

6.3 HANDLING OF MISSING DATA

No imputation will be performed for missing data.

6.4 ASSESSMENT TIME WINDOWING

No analysis visit windows will be utilized in this study and all safety and effectiveness assessment summaries will be based on the nominal protocol-specified assessment times.

6.5 POOLING OF INVESTIGATOR SITES

Data from all four sites will be pooled together for reporting in total.

6.6 ADJUSTMENTS FOR MULTIPLICITY

No adjustments for multiplicity will be performed as no formal hypothesis testing is planned.

6.7 EXAMINATION OF SUBGROUPS

Subgroup analyses will consist of gender identity (cisgender, transgender male, transgender female, gender fluid, other*)*, age group (18-24, 25-34, 35-44, 45-50), and the Cellulite Dimple – At Rest Scale as assessed during the Screening visit (Both Sides Grade 2, Both Sides Grade 3, Side with Different Grades) for the primary effectiveness endpoint. Only descriptive statistics will be provided for subgroup analysis.

7 PARTICIPANT SUMMARIES

7.1 ANALYSIS POPULATIONS

7.1.1 Enrolled

The Enrolled population consists of all participants who signed the informed consent form (ICF).

7.1.2 Safety

The Safety population consists of all Enrolled participants who received at least one Resonic treatment session (started or completed).

7.1.3 Evaluable

The Evaluable population consists of participants in the Safety population who completed the Resonic treatment plan (completed two treatment sessions) bilaterally for at least one location.

7.2 PARTICIPANT DISPOSITION

The following will be summarized overall using the Enrolled population. Denominators for percentages will be the number of participants who receive a Resonic treatment session/Safety population:

- The number of participants enrolled (Enrolled population)
- The number of participants who received at least one Resonic treatment session (Safety population)
- The number and percentage of participants who completed the Resonic treatment plan bilaterally for at least one location (Evaluable population)
- The number and percentage of participants who completed the 12 weeks evaluation period after last treatment.
- The number and percentage of participants who completed the study
- The number and percentage of participants who withdrew early and reason for withdrawal

7.3 DEMOGRAPHIC AND BASELINE CHARACTERISTICS

7.3.1 Demographic and Baseline Characteristics

Demographic variables will include age, age group (18-24, 25-34, 35-44, 45-50), sex (reported at birth), gender identity, race, and ethnicity. Baseline characteristics include height (cm), weight (kg), BMI, Fitzpatrick Skin Type, and Cellulite Dimple – At Rest Scale (Grade 2, Grade 3 by left and right side and collectively). Demographics and baseline characteristics will be presented in a by-participant listing and summarized descriptively for the Safety population.

7.3.2 Medical History

Medical history, as collected at screening, will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 26.0 to determine system organ class (SOC) and preferred term (PT). Medical histories will be summarized descriptively in descending order of frequency for the Safety population and presented in a by-participant listing.

7.3.3 Medications

The number and percentage of participants taking medications will be summarized by generic drug name based on ATC drug class 3 for the Safety population. If ATC drug class 3 is not available, the highest-level ATC classification available will be used. Medications will be displayed in descending order of frequency of ATC Class and then descending order of frequency of preferred term within each ATC Class. Medications will be coded using World Health Organization Drug Dictionary Anatomical Therapeutic Chemical (WHO/ATC) classification index version Global B3/C3-format March 1, 2023.

All medications captured on CRFs will appear in by-participant data listings.

7.4 PROTOCOL DEVIATIONS

Protocol deviations will be captured on CRFs and categorized and summarized by type using the Enrolled population. CSR reportable protocol deviations will be summarized for the Enrolled population. CSR reportable status will be determined by AbbVie and then transferred to ARA in a programmable format, such as Excel.

8 MEASUREMENTS OF TREATMENT EXPOSURE AND COMPLIANCE

Counts and percentages of participants that completed only one or both treatments will be provided in the participant disposition summary table. Descriptive statistics summarizing the duration of each treatment session, the number of dimples treated per session, the change in treatment duration and the change in the number of dimples treated for a given participant will be summarized. Treatment duration in minutes will be calculated as the sum of total doses per dimple per session as collected on the Site Treatment Data CRF form since each dose takes 1 min.

9 EFFECTIVENESS EVALUATION

9.1 EFFECTIVENESS ENDPOINT(S)

9.1.1 Primary Effectiveness Endpoint

Binary (yes/no) correct identification of baseline vs 12-week post-final treatment images of the treated body area(s) by at least two out of three blinded independent photo reviewers.

9.1.2 Secondary Effectiveness Endpoint

Improvement in the appearance of cellulite as determined by the study participants selecting “Agree” or “Strongly Agree” as answers to the Participant Satisfaction Survey question(s) “In comparison to the pre-treatment photo, the final photograph of the treatment area appears improved.” at the 12-week post-final treatment visit by side (participant’s left or right).

9.1.3 Exploratory Effectiveness Endpoints

- The number of participants who have improvement in the appearance of cellulite as determined by the study participants selecting “Agree” or “Strongly Agree” as answers to the Participant Satisfaction Survey question(s) “In comparison to the pre-treatment photo, the final photograph of the treatment area appears improved.” on one or two sides at the 4-week post-first treatment, 12, 26, and 52-week post-final treatment visit.
- Binary (yes/no) improvement in the appearance of cellulite as determined by the study participants selecting “Agree” or “Strongly Agree” as answers to the Participant Satisfaction Survey question(s) “In comparison to the pre-treatment photo, the final photograph of the treatment area appears improved.” at the 4-week post-first treatment, 26, and 52-week post-final treatment visits by side (participant’s left or right).
- Overall average pain per participant derived as the average of the responses to “The OVERALL pain score DURING the procedure?” and “The OVERALL pain score AFTER the procedure?” for all treatment sides on the Procedure Tolerability Questionnaire at each treatment visit.
- GAIS as determined by the investigator at the 4-week post-first treatment, 12, 26, and 52-week post-final treatment visits.
- Actual and change from baseline in Body Q™ Appraisal of Cellulite, Satisfaction with Buttocks, and Satisfaction with Hip & Outer Thigh Rausch transformed total scores at the baseline, 4-week post-first treatment, 12, 26, and 52-week post-final treatment visits.

9.2 EFFECTIVENESS ANALYSIS

9.2.1 Primary Effectiveness Analysis

The number and proportion of analyzable images that are correctly identified as baseline or 12-week post-final treatment by at least two out of three blinded IPRs will be summarized using the Evaluable population. The primary effectiveness objective will be met if ≥70% of the baseline vs 12-week post-final treatment images of the treated body area(s) are correctly identified by at least two out of the three blinded IPRs.

9.2.2 Supportive Analysis of the Primary Effectiveness Endpoint

The primary effectiveness analysis will be repeated for subgroup analyses with gender, age, and the Cellulite Dimple – At Rest Scale as assessed at Screening using the Evaluable population.

9.2.3 Secondary Effectiveness Analysis

The number and proportion of analyzable images by side that participants indicate as improved in cellulite using the Participant Satisfaction Survey at the 12-week post-final treatment visit compared to baseline will be summarized using the Evaluable population.

9.2.4 Exploratory Effectiveness Analyses

All exploratory effectiveness analyses will be descriptive and summarized using the Evaluable population.

- Number and proportion of participants who have one or two sides improved at the 4-week post-first treatment, 12, 26, and 52-week post-final treatment visits via the Participant Satisfaction Survey.
- Number and proportion of sides that are improved at the 4-week post-first treatment, 26, and 52-week post-final treatment visits via the Participant Satisfaction Survey.
- Descriptive statistics for overall average pain per participant at the two treatment visits.
- Descriptive statistics for GAIS score at the 4-week post-first treatment, 12, 26, and 52-week post-final treatment visits via the investigator GAIS.
- Descriptive statistics for actual and change from baseline in Body Q™ Appraisal of Cellulite, Satisfaction with Buttocks, and Satisfaction with Hip & Outer Thigh Rausch transformed total scores at the 4-week post-first treatment, 12, 26, and 52-week post-final treatment visits.

10 SAFETY EVALUATIONS

10.1 ADVERSE EVENTS AND ADVERSE DEVICE EFFECTS

An adverse event (AE) is defined as any unfavorable or unintended sign, symptom, or disease that occurs or is reported by the participant to have occurred, or worsening of a pre-existing condition. An AE may or may not be related to the study treatment.

An adverse device effect (ADE) is defined as an AE related to the use of an investigational medical device (Was the event caused by an Investigation Device? = Yes in the CRF).

AEs and ADEs will be coded using MedDRA version 26.0.

An overall summary will present the number and proportion of participants with AEs, serious adverse events (SAEs), ADEs, serious adverse device effects (SADEs), unanticipated AEs, and unanticipated ADEs using the Safety population.

In addition, the number and proportion of participants will be summarized by SOC and PT sorted in decreasing frequency. These summaries will be given by treatment in separate tables for each of the following event sets using the Safety population:

- AEs
- SAEs
- ADEs
- SADEs
- Unanticipated AEs
- Unanticipated ADEs

If a given participant experiences an AE that maps to the same PT/SOC more than once, the participant will be counted only once for the SOC/PT.

All AEs and ADEs will be presented in a by-participant listing.

The number and proportion of participants with known physiological responses (Red/pink hair follicles (folliculitis), Pain/Discomfort, Itchy Skin, Scaly Skin, Erythema, Edema, Purpura, Micro Blistering, Bruising/Contusion, Scabbing, Heat, Scratches, Crusting, Pinpoint Redness/Bleeding (petechiae), Sensation of Cold, Stinging, Tingling, Pinching, Hair removal, or Other) will be summarized for the Safety population based on Physiological Response Assessment collected on the Visit CRF form.

11 PHARMACOKINETIC (PK)/PHARMACODYNAMIC (PD) ANALYSIS

No PK/PD analysis is planned.

12 INTERIM ANALYSIS

An informal interim analysis will be performed after the last participant has completed their 12 week evaluation post the second treatment. An option informal interim analysis may also be performed after the last participant has completed their 26 week evaluation post the second treatment. Results neither interim analyses will not impact study conduct.

13 DATA SAFETY AND MONITORING BOARD

No Data Safety and Monitoring Board involvement is planned.

14 CHANGES TO THE ANALYSES PLANNED IN THE PROTOCOL

The protocol specifies the following additional and exploratory assessments/measurements and their corresponding summaries/endpoints. They will not be evaluated as part of the planned analysis due to lack of availability of data.

Additional Assessments/Measurements	Additional Summaries/Endpoints
Treatment Effectiveness: An additional measurement to demonstrate the	Baseline photos and 12-week follow-up photos of the treatment areas (e.g.,

improvement in the appearance of cellulite, will be performed using the Cellulite Dimple – At Rest Scale.	thighs/buttocks) will be assessed using the Cellulite Dimple – At Rest Scale and will be determined as the score agreed to by at least 2 of 3 IPR or the average, rounded to nearest whole number, of all three IPR Cellulite Scores if there is no agreement. Treatment effectiveness will be met if the treatment areas (e.g., thighs/buttocks), of all participants with a Cellulite Score of ≥ 2 at the baseline visit, have a mean reduction in Cellulite Score of ≥ 1 at the 12-week follow-up visit and optionally at the optionally at the 4 week post first treatment visit and 26 and 52 week follow up visits will be noted.
Exploratory Assessments	Exploratory Endpoints
Skin laxity	An IPR panel will assess and grade baseline laxity using the At Rest Skin Laxity Scale, Buttocks and Posterior Thigh **(Scale 3)** by viewing baseline photos. The IPR will then assess laxity improvement of those participants with confirmed baseline laxity by comparing baseline and post treatment photos. The percentage of participants that demonstrate an improvement in skin laxity of the treated areas (e.g., thighs/buttocks), as graded by IPR when comparing baseline and 12-week post final treatment photos and optionally at the 4, 26 and 52 week follow up visits will be noted.
Dermal layer measurements	Ultra-sound skin analysis may be used to visualize the dermal layer of the skin at baseline, 4 weeks post first treatment and 12, 26 or 52 week post final treatment visit.
Dimple/ depth/volume changes	Dimple/depth/volume which may present as but not limited to, round or oval defects, depressions, valleys, linear depressions, or linear elevations or ridges) may be assessed at baseline, the 4 week post first treatment visit or at the 12, 26 or 52 week post final treatment visit for all or some participants using before and after photos taken with a 3D camera system i.e., Cherry Imaging system.

Any deviations from the final SAP will be described and a justification given in the CSR.

15 TABLES OF CONTENTS FOR APPENDICES

15.1 **TABLES**

Table Number	***Population***	***Title***
14.1.1	Enrolled	Participant Disposition
14.1.2	Enrolled	CSR Reportable Protocol Deviations
14.1.3	Safety	Demographics and Baseline Characteristics
14.1.4	Safety	Medical History: Number of Participants with History
14.1.5	Safety	Medications: Number of Participants with Medications
14.1.6	Safety	Treatment Exposure
14.2.1.1	Evaluable	IPR of Study Images: Summary of Baseline vs. 12-Week Post-Final Treatment
14.2.1.2	Evaluable	IPR of Study Images: Summary of Baseline vs. 12-Week Post-Final Treatment by Subgroup
14.2.2.1	Evaluable	Summary of Improvement in Appearance of Cellulite via Participant Satisfaction Survey by Side and Visit
14.2.2.2	Evaluable	Summary of Number of Participants with Improvement in Appearance of Cellulite via Participant Satisfaction Survey on one side or two by Visit
14.2.3	Evaluable	Summary of Improvement in Appearance of Cellulite via Investigator GAIS by Visit
14.2.4	Evaluable	Summary of Overall Pain by Visit
14.2.5.1	Evaluable	Summary of Participant Body-Q Appraisal of Cellulite Rasch Transformed Total Score
14.2.5.2	Evaluable	Summary of Participant Body-Q Satisfaction with Buttocks Rasch Transformed Total Score
14.2.5.3	Evaluable	Summary of Participant Body-Q Satisfaction with Hip & Outer Thigh Rasch Transformed Total Score
14.3.1.1	Safety	Adverse Events: Overall Number (%) of Participants with Adverse Events
14.3.1.2	Safety	Adverse Events by System Organ Class and Preferred Term
14.3.1.3	Safety	Serious Adverse Events by System Organ Class and Preferred Term
14.3.1.4	Safety	Adverse Device Effects by System Organ Class and Preferred Term

14.3.1.5	Safety	Serious Adverse Device Effects by System Organ Class and Preferred Term
14.3.1.6	Safety	Unanticipated Adverse Events by System Organ Class and Preferred Term
14.3.1.7	Safety	Unanticipated Adverse Device Effects by System Organ Class and Preferred Term
14.3.2	Safety	Known Physiological Responses

15.2 **LISTINGS**

Listings will include all available data.

Listing Number	***Title***
16.2.1	Participant Disposition
16.2.2	CSR Reportable Protocol Deviations
16.2.4.1	Participant Demographics and Baseline Information
16.2.4.2	Medical History
16.2.4.3	Concomitant Medications
16.2.5	Exposure Data
16.2.6.1	IPR of Study Images: Baseline vs. 12-Week Post-Final Treatment
16.2.6.2	Participant Satisfaction Survey
16.2.6.3	Procedure Tolerability Questionnaire
16.2.6.4	Investigator GAIS
16.2.6.5.1	Participant Body-Q Appraisal of Cellulite
16.2.6.5.2	Participant Body-Q Satisfaction with Buttocks
16.2.6.5.3	Participant Body-Q Satisfaction with Hip & Outer Thigh
16.2.7.1.1	Adverse Events
16.2.7.1.2	Serious Adverse Events
16.2.7.1.3	Unanticipated Adverse Events
16.2.7.2.1	Adverse Device Effects
16.2.7.2.2	Serious Adverse Device Effects
16.2.7.2.3	Unanticipated Adverse Device Effects
16.2.8	Known Physiological Responses
16.2.9.1	Participant Diary: Side Effects
16.2.9.2	Participant Diary: Return to Work, Exercise Routine, and/or Daily Activities and Change in Cellulite

16.2.10	Vital Signs