Administration and Product Details			
Document and Version Control			
Document title	CSD-045 Claim support document		
Document version	Version 2		
Date of creation	14/11/2025		
Prepared by	Wiktoria Ratajczak *Medical Writer*		
Initial Review Name: Signature:	 Yasmin Hatt Clinical Biostatistician 18/Dec/2025		
Reviewed/Approved by:		**Date**	**Signature**
Clinical Affairs	Leah Richards		19Dec2025
Design & Development	Stuart Jones		19/12/2025
Marketing	Jette Andersen		19/12/2025
Product Management	Mark Huijsmans	Mark Huijsmans	05/01/2026
Quality Assurance	Wayne Davis		13/01/2026
Research	Mike Kiernan		19/12/2025
Chief Executive Officer	Robin van Rozen	Robin van Rozen	19 Dec 2025
Product Identification			
Product Name:	SmoothSkin Pure Ice and Pure Switch		
Product Function	Hair Removal		
Product Mechanism of action:	IPL		

Document History	
Version 01	Initial Document – 19/12/2024
Version 02	Revision – 14/11/2025

Contents

1. Purpose of the document

This document serves to provide the direct scientific and clinical evidence to support each claim listed in Section 2. The evidence is based on data obtained from specific clinical trials, with a synopsis of the supporting study presented alongside its respective claim.

2. Claims

Claim Number	Claim Statement	Claim Type	Data Study Code
1	Proven to deliver up to 12 months of hair reduction/ Enjoy smoother skin for up to 1 year/ Maintains hair reduction for up to 1 year/ Up to 1 year of sustained smoothness.	Efficacy	CD3028
2	Proven to achieve up to 99% of hair reduction after just 12 weeks. * **When tested on legs.*	Efficacy	CD3137
3	Visible results in just 2 weeks / Effective in just 2 weeks / See and feel the difference in just 2 weeks. * **When tested on axillae.*	Efficacy	CD3191
4	Proven to deliver up to 95% of hair reduction after just 2 treatments/weeks/ Up to 95% hair reduction after just 2 weeks/treatment / See significant results in just 2 weeks/treatment with up to 95% hair reduction*. *When tested on legs.	Efficacy	CD3191
5	Painless and gentle. 97.5% of users found the treatment gentle to their skin. Get professional results with the ease of shaving—92.5% of users felt the treatment was as pain-free as shaving. 95% of users found the treatment on their armpits gentler to the skin than shaving. * **Pure Ice only.*	Tolerability (Subjective Claim)	CD3191

3. Summary of supporting clinical evidence

3.1 Synopsis of Key trials

Study ID/Name	Study Design	Population		Intervention/Comparator		Primary Endpoint(s)	Key Findings
CD3028	Randomized Control Trial (RCT) open label prospective study	**First Enrolled N=**	50	**Treatment type**	IPL (intense pulse light)	The primary effectiveness endpoint was the quantitative hair count reduction compared to the control area, demonstrating sustained efficacy (1-week post-treatment) and long-term stable reduction (6-, 9-, and 12- months).	Achieved 74% median hair reduction one-week post-treatment, with 84% of subjects meeting the ≥30% success threshold. Demonstrated sustained median hair reduction of 44% at 6 months and 35% at 12 -months, both statistically significant. Total Device Related Events (DRE) incidence was minimal (3.0% - 18/564 treatments); all were mild, anticipated side effects.
		Age	18-45	**Study Duration**	61 weeks with 20 visits		
		Gender	Females	**Treatment area**	Axillae, bikini and lower leg		
		Skin tone	I-V	**Comparator**	N/a		
CD3137	RCT open label prospective study	**First Enrolled N=**	36	**Treatment type**	IPL	The primary effectiveness endpoint was the quantitative hair count reduction compared to baseline hair count, aiming for at least a 30.0% reduction at week 9 (4th treatment), week 13 (8th treatment, week 17 (1-week post final treatment) and week 20 (1-month post final treatment).	The results show a significant hair reduction on the lower legs, with the majority of participants achieving ≥ 90.0% hair reduction in the Full Analysis Sample (FAS) population at 12-weeks (68.8% on the Right Lower Leg and 60.0% on the Left Lower Leg).
		Age	18-55	**Study Duration**	20 weeks with 19 visits		
		Gender	Females	**Treatment area**	Axillae and lower leg		
		Skin tone	I-V	**Comparator**	N/a		

Study ID/Name	Study Design	Population		Intervention/Comparator		Primary Endpoint(s)	Key Findings
CD3191	RCT open label prospective study	**First Enrolled N=**	40	**Treatment type**	IPL	The primary endpoint was the measurement of occurrence of moderate to severe side effects or adverse events, as self-reported by subjects in their diaries during the investigation.	Most of users (55.0%–88.0%) achieved visible results (≥30% reduction) after just 2- weeks. The study recorded a maximum hair reduction of 95.5% on the legs after 2-weeks. 97.5% of users agreed the treatment was gentler to the skin than shaving on their legs.
		Age	18-55	**Study Duration**	13 weeks with 13 visits		
		Gender	Females	**Treatment Area**	Axillae and lower leg		
		Skin tone	I-V	**Comparator**	N/a		

3.2 Evidence Summary (per Claim)

3.2.1 Claim 1

Proven to deliver up to 12 months of hair reduction/ Enjoy smoother skin for up to 1 year/ Maintains hair reduction for up to 1 year/ Up to 1 year of sustained smoothness.

Supporting evidence:

	Study Reference: CD3028
Study Design	Multi centre, randomized, controlled, non-blinded, prospective study. The aim of this study was to demonstrate the long-term clinical efficacy, safety, and patient tolerance of the iPulse home-use intense pulsed light hair removal device, in a multiple treatment regimen. • Allocation: Randomized, non-blinded • Endpoint classification: Efficacy and safety study • Intervention Model: IPL with no comparator or sham device with one side of the body used for treatment and second as side control. The subjects were randomized to receive 12-weekly treatments on one side of their body, with the contralateral side serving as the untreated control. Assessments were conducted 1-week after the final treatment, followed by reviews at 6-, 9-, and 12-months post-treatment, with additional review appointments also scheduled one week prior to each follow-up.

	Study Reference: CD3028
Population	50 healthy participants enrolled into the study. Inclusion Criteria (Main points) • Females • Aged 18 to 45 inclusive • I-V skin tone* • Natural brown or black hair in treatment areas- lower leg, axillae and bikini. Exclusion Criteria (Main points) • Have previously undergone any permanent hair removal treatment. • They have used plucking, tweezing, waxing, or chemical depilatories in the anticipated treatment area(s) within 3 months prior to study initiation. • They have used any topical hair lightening products in the test area(s) in the previous 6 months. • They have a history of keloidal scar formation. • They have any potentially confounding or non-indicated skin conditions in the test area(s), such as pre-existing cuts, abrasions, or tattoos. • Certain medications * Equal proportions of skin tones were not required for this study, although a minimum of 10 skin tone V subjects was recruited and enrolled.
Objectives	Primary Objective The primary objective was to demonstrate sustained hair removal with periodic treatments (12-weekly treatments), and substantial long-term hair count reduction at 6-, 9- and 12-months post the final treatment, in all body areas (axillae, bikini and lower leg) and skin tones (I-V) treated. Secondary Objective The secondary objective was to assess the long-term safety and patient tolerance of the iPulse hair removal device when used on various body locations (axillae, bikini and lower leg) and a range of skin tones (I-V).

	Study Reference: CD3028
Endpoints	Primary Endpoint The primary endpoint was the measurement of the hair removal treatment effectiveness, which was assessed by quantitative hair counts performed at pre-determined stages of the clinical investigation. At one week following the final treatment, the study aimed to demonstrate a sustained reduction in hair density. Furthermore, at 6-, 9-, and 12-months post-treatment, the study aimed to demonstrate a long-term, stable (permanent) reduction in the number of hairs regrowing after the completion of the treatment regimen. Secondary Endpoint Secondary efficacy measures were determined from subject-completed consumer questionnaires at pre-determined stages, asking for self-assessments of hair count reduction, hair re-growth characteristics, post-treatment skin texture, and overall satisfaction. The secondary safety endpoint was the possible occurrence of side effects or adverse events, which clinical staff evaluated for every subject at each treatment visit. The incidence of each effect was calculated as a percentage of subjects exhibiting it at any visit.
Methods and Results	**Methods** This data was submitted to the FDA and was used to obtain FDA clearance. Below we present a summary of the results to substantiate claim 1. The primary outcome was the measure of effectiveness assessed by quantitative hair counts, comparing the treatment area versus baseline. Effectiveness was measured by quantitative hair counts using bespoke automated software and assessed by independent assessors. Calculation: Percentage reduction was calculated as: $$\% \text{ Reduction} = \frac{(\text{Baseline Count} - \text{Count at Review Point})}{\text{Baseline Count}} \times 100$$ A paired sample t-test was used to compare the means of hair counts before and after the treatment (at the 6- and 12-month post treatment).

Study Reference: CD3028

Methods and Results

Results

The initial study enrolled 53 female subjects. The final number of subjects included in the efficacy analysis varied by time point due to subject withdrawals and exclusions based on data quality. Total of 50 subjects were included in the 6-months post last treatment analysis and 33 subjects were included in the 12-months post last treatment efficacy analysis.

Table 1. Mean % reduction at 6- and 12- month follow up.

	Mean % reduction	Standard Deviation (SD)	P-value	95% confidence Intervals (CI)
6 months post intervention Visit 18	43.9%	29.80	P=0.000	35.6, 52.5
12 months post intervention Visit 20	36.0%	41.00	P=0.000	21.3, 50.4

Total of 66.7% of subjects met the success criteria (defined as greater than 30% hair reduction at all treatment sites) at 12 months post-treatment.

The long-term stable reduction at 6- and 12-months post-treatment was 43.9% and 36.0% (mean), respectively, with all endpoints being statistically significant when compared to baseline. A high percentage of subjects also met the definition of success (achieving a 30% or greater hair count reduction): 66.7% at 12-months post-treatment.

Sensitivity Analysis:

The following sensitivity analysis was carried out by an independent statistician. It is presented alongside the data presented to the FDA.

	Study Reference: CD3028
Methods and Results	This data is presented for completeness to strengthen the claim. The primary outcome was the measure of effectiveness assessed by quantitative hair counts, comparing the treatment area versus baseline. Effectiveness was measured by quantitative hair counts using bespoke automated software and assessed by independent assessors. Calculation: Percentage reduction was calculated as: $$\%\ \text{Reduction} = \frac{(\text{Baseline Count} - \text{Count at Review Point})}{\text{Baseline Count}} \times 100$$ One-sample t-tests (on log-transformed data) and non-parametric tests (Wilcoxon sign rank test) were used, with an alpha allocation method used to adjust p-values across endpoints. The Relative Reduction Factor (RRF) was included as a core analysis method to quantify the superiority of the IPL treatment over natural hair count changes observed in the control group. An RRF of 1.0 represents the null hypothesis (no difference between Treatment and Control effects). An RRF greater than 1.0 reflects greater efficacy in the treatment group. **Table 2. Mean % reduction at 6- and 12- month follow up in sensitivity population.**

Study Reference: CD3028

Methods and Results

Time Point	Median % Hair Reduction (Efficacy)	Non-parametric P-value (vs. Baseline)	Significance Level (Alpha)	RRF (Treatment vs. Control)
6 -months post intervention Visit 18	44 %	3.7×10^{-9}	P=0.006	1.2
12- months post intervention Visit 20	35%	9.6×10^{-6}	P=0.024	1.3

The long-term stable reduction at 6-, and 12-months post-treatment was 44% and 35% (median), respectively, with all endpoints being statistically significant when compared to baseline. A high percentage of subjects also met the definition of success (achieving a 30% or greater hair count reduction): 68% at 6 months, and 53% at 12- months post-treatment.

Table 3. Subjective outcomes and safety

Outcome	Key Finding (Top-2-Box or Y/N)	Time Points
Willingness to Recommend (Q9)	93% of subjects were willing to recommend the device.	9- Months Post (9MP) - Visit 19.
Noticeable/Visible Hair Reduction (Q4)	77% of subjects agreed they experienced a noticeable, visible hair reduction.	12- Months Post (12MP) - Visit 20.
Overall Satisfaction (Q3)	66% of subjects were satisfied with the hair reduction achieved.	12 -Months Post (12MP) - Visit 20
Safety (DRE Incidence)	The total incidence of Device Related Events (DRE) was minimal (3%).	Total study duration.
Comfort (VAS Score)	The combined average pain score across all eligible subjects and settings was 10mm (on a 100mm scale).	Entire treatment phase.

	Study Reference: CD3028
	The results strongly indicate that the new generation device is an effective, non-invasive, and acceptable method of hair removal. Sustained Efficacy: The median hair reduction values of 44% at 6-months and 35% at 12-months post-treatment demonstrates sustained long-term efficacy. Safety and Tolerance: The minimal 3% incidence of Device Related Events (all mild and anticipated (18/564 treatments) and the very high measure of patient satisfaction (secondary objective met) support the device's acceptable safety and tolerance profile for consumer use. <u>Median value use substantiation</u> The selection of the median over the mean was necessitated by the presence of significant outliers within the dataset. As the mean is highly sensitive to extreme values, its use would have resulted in outcomes that were not truly representative of the typical performance of most of the sample. The median, being resistant to outliers, provides a more robust and accurate indication of the centre of the data distribution. To enhance the reliability of the analysis, these median results are presented alongside the RRF, which establishes the precision and consistency of the methodology. It was this comprehensive and robust presentation of median results, specifically addressing the data's inherent variability. Please note: The sensitivity analysis included all participants in the analysis. The FDA analysis did not include some participants due to uncertainty in the positioning of the hair count areas. This has been explicitly stated, and this approach was accepted by the FDA. Ultimately, the results from both analyses are similar, and thus bias in results due to this adjustment is highly unlikely. This clinical investigation successfully demonstrated the long-term clinical efficacy, safety, and patient tolerance of the iPulse home-use Intense Pulsed Light hair removal device using a multiple treatment regimen.
Conclusion	The study met its primary objective by showing sustained and statistically significant hair reduction across all key timepoints including 12-months post treatment. The study met its secondary objective by confirming the long-term safety and patient tolerance of the iPulse device. The total incidence of DRE was minimal and consistent with all anticipated and well-known side effects associated with IPL use. The overall patient experience was determined to be highly comfortable, which supports compliance with the treatment regimen and indicates high potential for market acceptance. **In summary, the entirety of the clinical evidence presented above is deemed robust and sufficient to substantiate the clinical and performance claim 1.**

3.2.2 Claim 2

*Proven to achieve up to 99% of hair reduction after just 12 weeks**

** When tested on legs.*

	Study Reference: CD3137
Study Design	Single centre, randomized, controlled, non-blinded, prospective study. The aim of this study was to demonstrate the clinical efficacy, safety, and patient tolerance of the low-fluence, IPL hair removal devices that are already being sold in market; SmoothSkin Gold, and its latest iterative design SmoothSkin Pure and SmoothSkin Pure FIT. • Allocation: Randomized, non-blinded • Endpoint classification: Efficacy and safety study • Intervention Model: Split body design with two treatment groups, both using different configurations of the SmoothSkin Pure device The subjects were randomized to receive 12-weekly treatments with a total of 19 visits over 20-weeks. Eligible female subjects received third-party IPL treatment on one side of their body using SmoothSkin Pure (without the precision head) and on the opposite side using SmoothSkin Pure FIT (with the precision head) to compare the two device configurations. Each participant was treated in 4 areas, right and left axilla; and right and left lower leg.
Population	36 healthy participants enrolled <u>Inclusion Criteria (Main points)</u> • Females • Aged 18 to 55 inclusive • I-V skin tone • Natural brown or black hair in treatment areas- lower leg, axillae and bikini. <u>Exclusion Criteria (Main points)</u> • Have previously undergone any permanent hair removal treatment. • They have used plucking, tweezing, waxing, or chemical depilatories in the anticipated treatment area(s) within 3-months prior to study initiation. • They have used any topical hair lightening products in the test area(s) in the previous 6-months. • They have a history of keloidal scar formation. • They have any potentially confounding or non-indicated skin conditions in the test area(s), such as pre-existing cuts, abrasions, or tattoos. • Certain medications

	Study Reference: CD3137
Objectives	Primary Objective The primary objective was to demonstrate clinical efficacy, defined as achieving a minimum of 30% hair count reduction (though aiming for higher) across all participants at critical time points (Weeks 9, 13, 17, and 20). Primary efficacy was assessed in all treated body areas (axillae and lower leg) and skin tones (I-V) for both the SmoothSkin Pure and SmoothSkin Pure FIT devices, using comparisons both between and within subjects, as well as against baseline. This 30% threshold was set based on prior investigations and FDA guidelines. Secondary Objective The secondary objective was to assess the safety profile and patient tolerance of treatment with the investigational devices, across both body areas (axillae and lower leg) and all skin tones.
Endpoints	Primary Endpoint The primary endpoint measured treatment effectiveness via quantitative hair counts (using automated software) at critical stages, aiming for at least a 30% hair count reduction. No control data were captured during this investigation. Secondary Endpoint Secondary efficacy measures were determined from subject-completed consumer questionnaires at pre-determined stages, asking for self-assessments of hair count reduction, hair re-growth characteristics, post-treatment skin texture, and overall satisfaction. The secondary safety endpoint was the possible occurrence of side effects or adverse events, which clinical staff evaluated for every subject at each treatment visit. The incidence of each effect was calculated as a percentage of subjects exhibiting it at any visit.

	Study Reference: CD3137
Methods and Results	**Methods** The statistical analysis was conducted on two defined female populations: the Full Analysis Sample (FAS), comprising of 34 participants, and the Sensitivity Analysis Group (SEN), comprising 28 participants. The six participants excluded from the SEN group were removed for various reasons, including issues with randomization, missed appointments, and one instance of receiving treatments too closely together. All analyses were carried out for both the FAS and SEN populations. The statistical analysis focused primarily on descriptive measures of the percentage change from the individual baseline average, calculated for each subject at every visit. Descriptive summaries, including the mean, standard deviation, median, minimum, maximum, and 95% confidence intervals, were calculated and presented, stratified by visit, device, and site. Effectiveness was measured by quantitative hair counts using bespoke automated software and assessed by independent assessors. Calculation: Percentage reduction was calculated as: $$\%\ \text{Reduction} = \frac{(\text{Baseline Count} - \text{Count at Review Point})}{\text{Baseline Count}} \times 100$$ **Results** A total of 36 female participants were initially enrolled in the study. Of these, 34 participants completed the study, while the remaining two either withdrew or were found to be unsuitable.

Study Reference: CD3137

Methods and Results

Table 1: Distribution of participants achieving up to 99% of hair reduction on legs in FAS population.

Visit	Device	Body Site	N	≥90% Reduction N (%)	≥100% Reduction N (%)
Week-12 Visit 16	Pure (no precision head)	Right Lower Leg	16	11 (68.8%)	2 (12.5%)
	Pure FIT (precision head)	Right Lower Leg	15	3 (20.0%)	2 (13.3%)
	Pure (no precision head)	Left Lower Leg	15	9 (60.0%)	2 (13.3%)
	Pure FIT (precision head)	Left Lower Leg	17	1 (5.9%)	0 (0.0%)
1 week post treatment Visit 17	Pure (no precision head)	Right Lower Leg	16	13 (81.2%)	4 (25.0%)
	Pure FIT (precision head)	Right Lower Leg	12	4 (33.3%)	2 (16.7%)
	Pure (no precision head)	Left Lower Leg	14	11 (78.6%)	5 (35.7%)
	Pure FIT (precision head)	Left Lower Leg	15	1 (6.7%)	1 (6.7%)

Table 2: Distribution of participants achieving up to 99% of hair reduction on legs in SEN population.

Visit	Device	Body Site	N	≥90% Reduction N (%)	≥100% Reduction N (%)
Week-12 Visit 16	Pure (no precision head)	Right Lower Leg	9	6 (66.7%)	2 (22.2%)
	Pure FIT (precision head)	Right Lower Leg	7	2 (28.6%)	1 (14.3%)
	Pure (no precision head)	Left Lower Leg	7	3 (42.9%)	0 (0.0%)
	Pure FIT (precision head)	Left Lower Leg	10	1 (10.0%)	0 (0.0%)
1 week post treatment Visit 17	Pure (no precision head)	Right Lower Leg	9	9 (100%)	3 (33.3%)
	Pure FIT (precision head)	Right Lower Leg	5	0 (0.0%)	0 (0.0%)
	Pure (no precision head)	Left Lower Leg	6	5 (83.3%)	3 (50.0%)
	Pure FIT (precision head)	Left Lower Leg	8	1 (12.5%)	1 (12.5%)

	Study Reference: CD3137
Methods and Results	Data from the Full Analysis Set population (Table 1) demonstrates significant hair reduction on the legs following the 12-week treatment period, with results sustained one-week post-treatment. Notably, the Pure device (without precision head) achieved ≥90% hair reduction for the majority of participants on both the right (68.8%) and left (60.0%) lower legs. Complete hair reduction (100%) was observed in 12.5% and 13.3% of participants for the right and left legs, respectively. These findings are further corroborated by the Sensitivity (SEN) population results (Table 2), which show fairly equivalent percentages at the highest reduction thresholds. While minor data collection issues were noted, the high level of consistency between the FAS and SEN populations justifies the use of these results for claim substantiation. Please note week-12 coincides with 12th IPL treatment- the readings are taken at the start of the session, before treatment is given and as such readings collected for week-12 are technically after 11 treatments. It is, however, worth noting that there were issues identified with the collected data and as such, the results should be interpreted with caution however, given that both SEN and FAS population have very similar results, it is deemed acceptable to use them for claim substantiation.
Conclusion	The clinical investigation confirms that both the Pure and Pure Fit devices effectively achieve significant hair reduction after 12-weeks of treatment. While the data shows that 100% hair reduction was achieved by a subset of participants (specifically those using the Pure device without the precision head), the decision was made to claim "up to 99% hair reduction" as up to 99% threshold accounts for the non-uniformity across different body sites and device configurations, ensuring that the evidence provided for **Claim 2** is robust and conservative. **The evidence collected is sufficient to substantiate claim 2.**

3.2.3 Claim 3

Visible results in just 2 weeks / Effective in just 2 weeks / See and feel the difference in just 2 weeks.

	Study Reference CD3191
Study Design	Single centre, randomized, controlled, non-blinded, prospective study. The aim of this study was to demonstrate the clinical efficacy, safety, and patient tolerance of the low-fluence, home-use, cooled intense pulsed light device (SmoothSkin Pure Ice and Pure Switch). • Allocation: Randomized, non-blinded • Endpoint classification: Efficacy and safety study • Intervention Model: Split body design with two treatment groups, both using different configurations of the SmoothSkin Pure device The study employed a split-body, randomized design where subjects were assigned sequentially to one of two groups (A or B). Group A received Pure Ice (cooled) treatment on the left side of the body and Pure Switch (non-cooled) treatment on the right side, while Group B received the reverse allocation. The investigation spanned 13-weeks, encompassing IPL treatment at week 6–9 followed post-intervention follow-up period at weeks 10–13.
Population	40 healthy participants enrolled <u>Inclusion Criteria (Main points)</u> • Females • Aged 18 to 55 inclusive • I-V skin tone • Natural brown or black hair in treatment areas- lower leg and axillae <u>Exclusion Criteria (Main points)</u> • Subjects with naturally white, grey, red, or blonde hair, for whom the device would be ineffective • Subjects with abnormally low hair count in the treatment areas – Although the investigation being a safety investigation – a minimum hair quantity is required • Subjects with infected, irritated, burnt, or cut skin at the treatment site • Subjects with any irritation, scars, birthmarks, or heavy presence of freckles at the treatment sites • Subjects with any tattoos or piercings at the treatment sites (axillae and back of the lower legs) • Subjects with a high BMI that affects the ability to capture and treat the proposed treatment area • Certain medications

	Study Reference CD3191
Objectives	Primary Objective The primary objective was to demonstrate the safety profile and subject tolerance of treatment with SmoothSkin Pure Ice and Pure Switch in the axillae and lower legs. Secondary Objective The secondary objectives were to determine if there were any changes in skin tone as a result of IPL treatment to the axillae and lower legs and to demonstrate the effectiveness of the investigational devices in reducing hair density.
Endpoints	Primary Endpoint The primary endpoint was a measure of safety: the possible occurrence of a moderate to severe side effect or adverse event, self-reported by subjects during the investigation via subject diaries. The occurrence of erythema was assessed at each treatment visit. An indicator of moderate to severe pain/discomfort, a Visual Analogue Scale, was recorded by subjects after each treatment. Secondary Endpoint The secondary endpoint for measuring changes in skin tone was comparisons of STS and ColorMeter values throughout the investigation at both treatment sites for each subject. The endpoint for measuring efficacy was the % hair reduction at the end of treatment and the end of follow-up from baseline

Study Reference CD3191

Methods and Results

Methods

The statistical analysis was conducted on two defined populations to ensure the reliability and robustness of the study findings. Full Analysis Set (FAS) consisted of 40 subjects. This population included all randomized participants who received at least one treatment with the investigational device and had valid post-baseline data available for analysis. Sensitivity Analysis Set (SEN) consisted of 39 subjects. This population is a subset of the FAS that excludes any participants with protocol deviations or notes-to-file (NTFs) identified as having the potential to impact data integrity or reliability. Positive values signify hair reduction.

"The Visible results" were defined as achieving a reduction in hair count of at least 30%.
SD - Standard deviation, CI – Confidence Intervals

Calculation of Percentage Change at the 2-week assessment (Visit 7), the percentage reduction in hair count was derived for each participant using the formula below. Please note - the readings were always taken at the start of the visit before any treatment was given, so at the 3rd treatment visit, only 2 treatments would have been administered prior to the readings.

$$\text{Percent Change} = \left(\frac{\text{Visit 7 Value} - \text{Baseline Average}}{\text{Baseline Average}} \right) \times 100$$

Results

Table 1: Mean Percentage Hair Reduction by Treatment Site (2 Weeks) in Full Analysis Set.

Body Site	Device	N	Mean % Change	SD	Median	Range (Min, Max)	95% CI (Lower, Upper)
Right Axilla	Pure Ice	19	34.9%	25.06	32.9	(-34.4, 82.7)	(22.8, 47.0)
	Pure Switch	21	21.8%	19.76	21.9	(-16.9, 68.7)	(12.8, 30.8)
Left Axilla	Pure Ice	21	34.1%	16.79	32.4	(-1.4, 66.8)	(26.5, 41.7)
	Pure Switch	19	21.4%	28.07	20.7	(-42.1, 64.5)	(7.8, 34.9)
Left Lower Leg	Pure Ice	21	46.1%	33.20	55.2	(-16.1, 95.5)	(31.0, 61.2)
	Pure Switch	19	36.4%	38.46	46.6	(-88.6, 80.6)	(17.8, 54.9)
Right Lower Leg	Pure Ice	19	48.9%	25.03	54.3	(-14.9, 86.1)	(36.8, 60.9)
	Pure Switch	21	40.9%	21.64	44.8	(-2.4, 78.4)	(31.1, 50.8)

Study Reference CD3191

Methods and Results

Table 2. Mean Percentage Hair Reduction by Treatment Site (2-Weeks) in Sensitivity Analysis Set.

Body Site	Device	N	Mean % Change	SD	Median	Range (Min, Max)	95% CI (Lower, Upper)
Right Axilla	Pure Ice	16	35.4%	26.31	32.9	(-34.4, 82.7)	(21.4, 49.4)
	Pure Switch	20	23.1%	19.44	23.6	(-16.9, 68.7)	(14.0, 32.2)
Left Axilla	Pure Ice	20	33.7%	17.17	32.1	(-1.4, 66.8)	(25.7, 41.7)
	Pure Switch	17	24.0%	26.98	20.8	(-42.1, 64.5)	(10.1, 37.8)
Left Lower Leg	Pure Ice	19	47.5%	34.10	59.3	(-16.1, 95.5)	(31.1, 64.0)
	Pure Switch	16	34.6%	40.26	46.6	(-88.6, 80.6)	(13.2, 56.1)
Right Lower Leg	Pure Ice	16	51.7%	24.96	57.8	(-14.9, 86.1)	(38.4, 65.0)
	Pure Switch	18	41.4%	22..57	44.8	(-2.4, 78.4)	(30.2, 52.6)

Table 3. Distribution of participants achieving visible results.

Device	Body Site	% of Users with Visible Results (FAS)		% of Users with Visible Results (SEN)	
		Right Side	Left Side	Right Side	Left Side
Pure Ice	Axilla	57.1%	57.9%	55.0%	62.5%
	Lower Leg	66.7%	78.9%	68.4%	87.5%
Pure Switch	Axilla	23.8%	26.3%	25.0%	29.4%
	Lower Leg	71.4%	73.7%	75.0%	77.8%

The Pure Ice (cooled) device demonstrated effectiveness across all body sites. In the Full Analysis Set (FAS) the device achieved a mean hair reduction of 34.1% to 34.9% in the axillae and 46.1% to 48.9% on the lower legs.

The Pure Switch (non-cooled) device showed varying results by body site. While it achieved a mean reduction of 36.4% to 40.9% on the lower legs, it showed a mean reduction of 21.4% to 21.8% in the axillae.

	Study Reference CD3191
Conclusion	Clinical data from the CD3191 investigation substantiates the claim that the device is effective in just 2-weeks. This is based on objective hair count analysis. Effectiveness was defined as achieving a mean hair count reduction of at least 30% after two weekly treatments (Visit 7). Results from both the Full Analysis Set and the stricter Sensitivity Analysis Set confirm that the Pure Ice device consistently met and exceeded this threshold across all body sites tested. Specifically, the Pure Ice device achieved a mean reduction of 33.7% to 35.4% on the axillae and 46.1% to 51.7% on the lower legs within the 2-week period (after two treatments). Furthermore, the Pure Switch device also demonstrated effectiveness in just 2 weeks on the lower legs, showing mean reductions ranging from 34.6% to 41.4% across both analysis populations. These findings demonstrate that significant, visible hair reduction is achievable early in the treatment regimen. Responder analysis confirms that "visible results" were achieved by the majority of participants after just two weeks. Specifically, 55.0%–62.5% of Pure Ice users saw results on underarms, while 66.7%–87.5% achieved results on lower legs. Similarly, 71.4%–77.8% of Pure Switch users saw visible results on their legs. These metrics demonstrate that significant hair reduction is attainable for the vast majority of users early in the regimen. **In summary, the entirety of the clinical evidence presented above is deemed robust and sufficient to substantiate the clinical and performance claim 3.**

3.2.4 Claim 4

Proven to deliver up to 95% of hair reduction after just 2 treatments/weeks/ Up to 95% hair reduction after just 2 weeks/treatment / See significant results in just 2 weeks/treatment with up to 95% hair reduction.

*When tested on legs

	Study Reference CD3191
Study Design	Single centre, randomized, controlled, non-blinded, prospective study. The aim of this study was to demonstrate the clinical efficacy, safety, and patient tolerance of the low-fluence, home-use, cooled intense pulsed light device (SmoothSkin Pure Ice and Pure Switch). • Allocation: Randomized, non-blinded • Endpoint classification: Efficacy and safety study • Intervention Model: Split body design with two treatment groups, both using different configurations of the SmoothSkin Pure device The study employed a split-body, randomized design where subjects were assigned sequentially to one of two groups (A or B). Group A received Pure Ice (cooled) treatment on the left side of the body and Pure Switch (non-cooled) treatment on the right side, while Group B received the reverse allocation. The investigation spanned 13-weeks, encompassing IPL treatment at week 6–9 followed post-intervention follow-up period at weeks 10–13.
Population	40 healthy participants enrolled <u>Inclusion Criteria (Main points)</u> • Females • Aged 18 to 55 inclusive • I-V skin tone • Natural brown or black hair in treatment areas- lower leg and axillae <u>Exclusion Criteria (Main points)</u> • Subjects with naturally white, grey, red, or blonde hair, for whom the device would be ineffective • Subjects with abnormally low hair count in the treatment areas – Although the investigation being a safety investigation – a minimum hair quantity is required • Subjects with infected, irritated, burnt, or cut skin at the treatment site • Subjects with any irritation, scars, birthmarks, or heavy presence of freckles at the treatment sites • Subjects with any tattoos or piercings at the treatment sites (axillae and back of the lower legs) • Subjects with a high BMI that affects the ability to capture and treat the proposed treatment area • Certain medications

	Study Reference CD3191
Objectives	Primary Objective The primary objective was to demonstrate the safety profile and subject tolerance of treatment with SmoothSkin Pure Ice and Pure Switch in the axillae and lower legs. Secondary Objective The secondary objectives were to determine if there were any changes in skin tone as a result of IPL treatment to the axillae and lower legs and to demonstrate the effectiveness of the investigational devices in reducing hair density.
Endpoints	Primary Endpoint The primary endpoint was a measure of safety: the possible occurrence of a moderate to severe side effect or adverse event, self-reported by subjects during the investigation via subject diaries. The occurrence of erythema was assessed at each treatment visit. An indicator of moderate to severe pain/discomfort, a VAS (Visual Analogue Scale), was recorded by subjects after each treatment. Secondary Endpoint The secondary endpoint for measuring changes in skin tone was comparisons of STS and ColorMeter values throughout the investigation at both treatment sites for each subject. The endpoint for measuring efficacy was the % hair reduction at the end of treatment and the end of follow-up from baseline

Study Reference CD3191

Methods and Results

Methods

Please see claim 3 substantiations for Methods description. The results have been generated at the same time through the same methodology.

Results

Table 1. Statistical substantiation of up to 95% hair reduction when tested on legs.

			Mean % Reduction		Maximum % Reduction Observed
Device	**Treatment Area**	**N**	**Right Side**	**Left Side**	
Pure Ice	Lower Leg	40	46.1%	48.9%	95.5% - Substantiates 'up to 95% claim'
	Axilla	40	34.1%	34.9%	82.7%
Pure Switch	Lower Leg	40	36.4%	40.9%	88.6%
	Axilla	40	21.4%	21.8%	68.7%

The claim "Up to 95% hair reduction" is directly supported by the 95.5% reduction achieved by a single subject (Screening Number 3449) on the lower leg using the Pure Ice device. This result is based on the entire sample (FAS) analysis. Table with the raw data for this participant is located in the appendix associated with this study - Appendix C- Study CD3191.

Conclusion

In summary, the entirety of the clinical evidence presented above is deemed robust and sufficient to substantiate the clinical and performance claim 4. Furthermore, the analysis of individual subject data specifically substantiates high-performance capability, with results demonstrating that the device can achieve up to 95.5% hair reduction on the lower leg after just two treatments.

3.2.5 Claim (Subjective) 5

*Painless and gentle. 97.5% of users found the treatment gentle to their skin. Get professional results with the ease of shaving—92.5% of users felt the treatment was as pain-free as shaving. 95% of users found the treatment on their armpits gentler to the skin than shaving.**

*Pure Ice only

	Study Reference CD3191
Study Design	Single centre, randomized, controlled, non-blinded, prospective study. The aim of this study was to demonstrate the clinical efficacy, safety, and patient tolerance of the low-fluence, home-use, cooled intense pulsed light device (SmoothSkin Pure Ice and Pure Switch). • Allocation: Randomized, non-blinded • Endpoint classification: Efficacy and safety study • Intervention Model: Split body design with two treatment groups, both using different configurations of the SmoothSkin Pure device The study employed a split-body, randomized design where subjects were assigned sequentially to one of two groups (A or B). Group A received Pure Ice (cooled) treatment on the left side of the body and Pure Switch (non-cooled) treatment on the right side, while Group B received the reverse allocation. The investigation spanned 13-weeks, encompassing IPL treatment at week 6–9 followed post-intervention follow-up period at weeks 10–13.

	Study Reference CD3191
Population	40 healthy participants enrolled Inclusion Criteria (Main points) • Females • Aged 18 to 55 inclusive • I-V skin tone • Natural brown or black hair in treatment areas- lower leg and axillae Exclusion Criteria (Main points) • Subjects with naturally white, grey, red, or blonde hair, for whom the device would be ineffective • Subjects with abnormally low hair count in the treatment areas – Although the investigation being a safety investigation – a minimum hair quantity is required • Subjects with infected, irritated, burnt, or cut skin at the treatment site • Subjects with any irritation, scars, birthmarks, or heavy presence of freckles at the treatment sites • Subjects with any tattoos or piercings at the treatment sites (axillae and back of the lower legs) • Subjects with a high BMI that affects the ability to capture and treat the proposed treatment area • Certain medications
Objectives	Primary Objective The primary objective was to demonstrate the safety profile and subject tolerance of treatment with SmoothSkin Pure Ice and Pure Switch in the axillae and lower legs. Secondary Objective The secondary objectives were to determine if there were any changes in skin tone as a result of IPL treatment to the axillae and lower legs and to demonstrate the effectiveness of the investigational devices in reducing hair density.

Study Reference CD3191

Endpoints

Primary Endpoint

The primary endpoint was a measure of safety: the possible occurrence of a moderate to severe side effect or adverse event, self-reported by subjects during the investigation via subject diaries. The occurrence of erythema was assessed at each treatment visit. An indicator of moderate to severe pain/discomfort, a VAS (Visual Analogue Scale), was recorded by subjects after each treatment.

Secondary Endpoint

The secondary endpoint for measuring changes in skin tone was comparisons of STS and ColorMeter values throughout the investigation at both treatment sites for each subject. The endpoint for measuring efficacy was the % hair reduction at the end of treatment and the end of follow-up from baseline.

Methods and Results

Methods

Please see claim 3 substantiations for Methods description. The results have been generated at the same time through the same methodology.

Results

Table 1. Summary of the three pre-specified Consumer Questionnaire items at Visit 8.

			Top 2 box	
Marketing Claim Category	**Survey Question**	**Treatment Area**	**FAS Result (N=40)**	**SEN Result (N=37-39) ***
Gentle to Skin	Q10: "Gentler to skin than shaving"	Lower Legs	97.5%	97.1%
Comfort / Gentleness	Q10: "Gentler to skin than shaving"	Axillae	95.0%	94.6%
Painless Treatment	Q7: "Treatment was painless"	Axillae	92.5%	94.6%
Pain-Free vs. Shaving	Q9: "As pain-free as shaving"	Axillae	92.5%	94.6%
Pain-Free vs. Shaving	Q9: "As pain-free as shaving"	Lower Legs	90.0%	91.4%

Note : The SEN population size varies by question due to exclusions associated with specific protocol deviations. Based on top 2 box scores, across all metrics, ≥90% of participants consistently rated the device as comparable to shaving in terms of being pain-free, regardless of the body site treated.

	Study Reference CD3191
Conclusion	User feedback collected at Visit 8 demonstrates exceptionally high tolerability and satisfaction with the SmoothSkin Pure Ice device across both analysis populations. The data indicates robust consistency between the Full Analysis Set (FAS) and the stricter Sensitivity Analysis Set (SEN). **In summary, the entirety of the clinical evidence presented above is deemed robust and sufficient to substantiate the clinical and performance claim 5.**

4. Summary and Conclusion

The claims listed in Section 2 are substantiated by results from three independent randomized controlled trials summarized above. The studies demonstrate statistically and clinically significant hair reduction, coupled with confirmed long-term efficacy and high user comfort and tolerance. We deem these results to be reliable, highly relevant, and appropriate to support the performance, safety, and experiential claims being made for the device.

5. Appendices

Please note, the tables and figures presented below have been sourced from their respective final study reports/ protocols. They are the exact, unedited representation of the source clinical data to ensure and provide integrity. For this reason, the tables and figures may not follow the same formatting.

Appendix A – Study CD3028

Assessment Type	S	Pre-Tx	Tx	Post-Tx	F/UP	AR
Informed consent	X					
Demographics & medical history	X					
Inclusion/exclusion criteria	X	X				
Review of medication	X	X			X	X
Treatment			X			
AE/ADE assessment				X	[V14]	
Completion of VAS				X		
Photograph	[V1]	[V2,V6,V14]			[V16,V18,V20]	
Completion of questionnaire		[V2,V6]			[V14,V20]	

KEY:

S	Screening	[V1]
Pre-Tx	Immediately pre-treatment	[V2 – V13]
Tx	Treatment	[V2 – V13]
Post-Tx	Immediately post-treatment	[V2 – V13]
F/Up	Follow-up visits	[V14, V16, V18 & V20]
AR	Additional reviews (pre-shave appointments)	[V15, V17 & V19]

Figure 1. Study Schedule. In depth schedule of events for each visit and each task carried out.

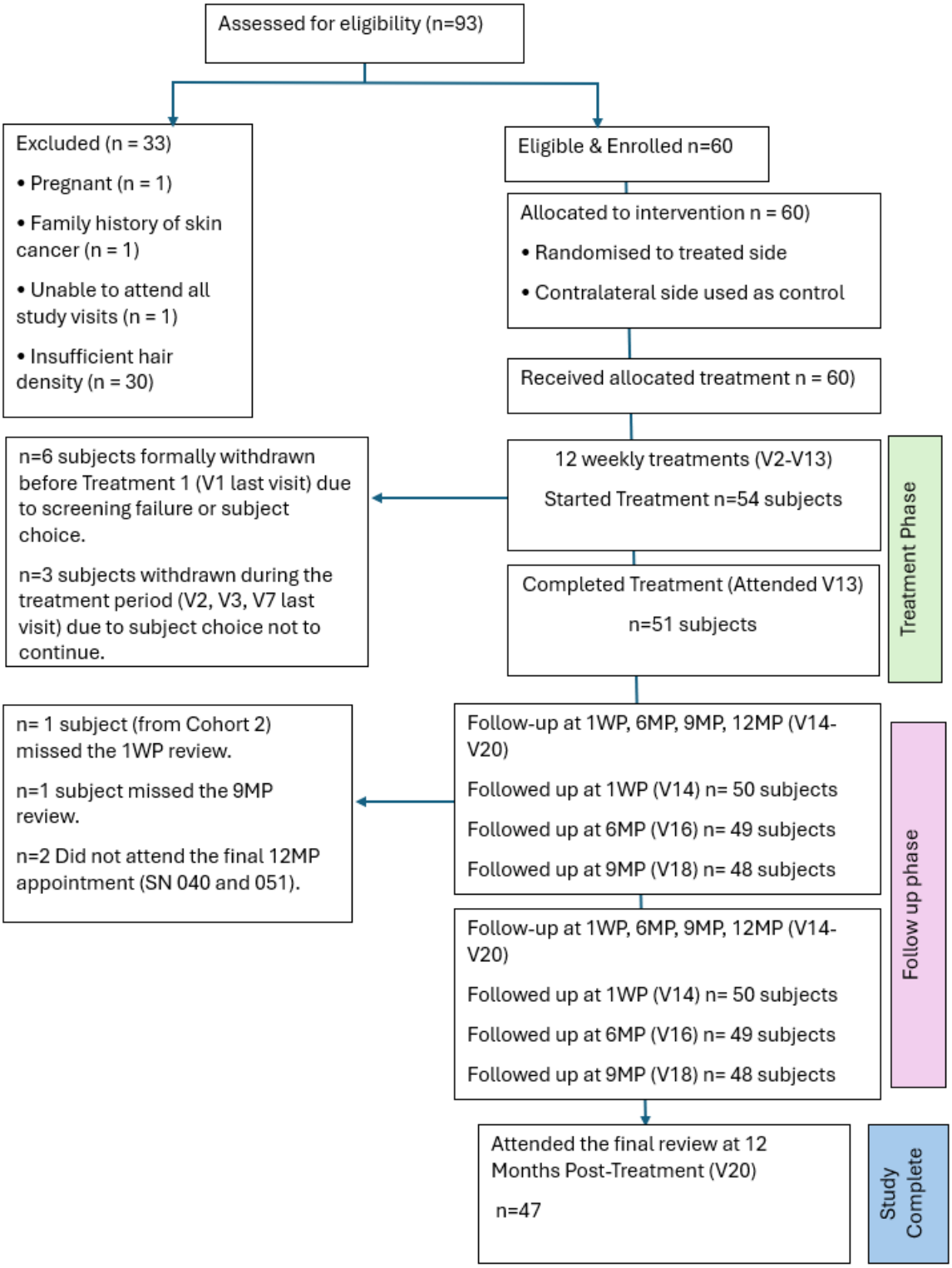

Figure 2. Participant flow through the study CD3028

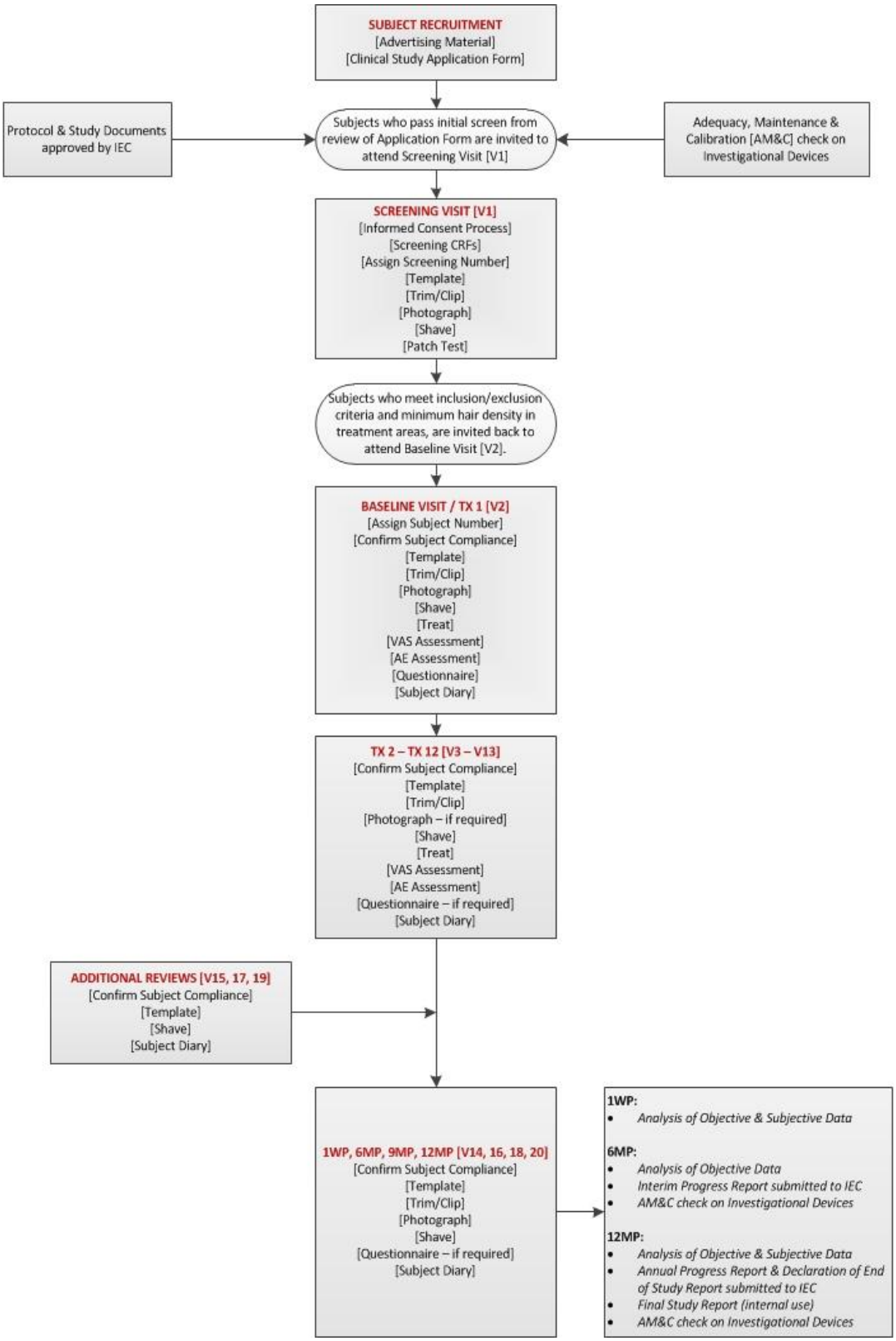

Figure 3. Key stages of the investigation

Appendix B – Study CD3137

				Assessments				
Week No	Visit No	Phase	Appointment Type	ipulse STS	RGB / M & E	VAS	Erythema	AE/ADEs
W1	V1	Screening / Baseline	Screening	✓	✓	PT	PT	PT
W2	V2		Baseline 1		✓			
W3	V3		Baseline 2		✓			
W4	V4		Baseline 3		✓			
W5	V5	Treatment Phase	Baseline 4 / Treatment 1		✓	✓	✓	✓
W6	V6		Treatment 2		✓	✓	✓	✓
W7	V7		Treatment 3		✓	✓	✓	✓
W8	V8		Treatment 4		✓	✓	✓	✓
W9	V9		Treatment 5		✓	✓	✓	✓
W10	V10		Treatment 6	✓	✓	✓	✓	✓
W11	V11		Treatment 7		✓	✓	✓	✓
W12	V12		Treatment 8		✓	✓	✓	✓
W13	V13		Treatment 9		✓	✓	✓	✓
W14	V14		Treatment 10		✓	✓	✓	✓
W15	V15		Treatment 11		✓	✓	✓	✓
W16	V16		Treatment 12		✓	✓	✓	✓
W17	V17	Review / Follow-up Phase	1 Week Post		✓			
W18								
W19	V18		Pre-shave		✓			
W20	V19		1 Month Post	✓	✓			

Figure 4. Study Schedule. Schedule of events for each visit and each task carried out.

Impulse STS- Impulse skin tone sensor reading

RGB/M&E - DSM III COLORMETER, RGB, MELANIN & ERYTHEMA measures

VAS- Measurement of discomfort

AE/ADE- Adverse events

PT- Post Treatment

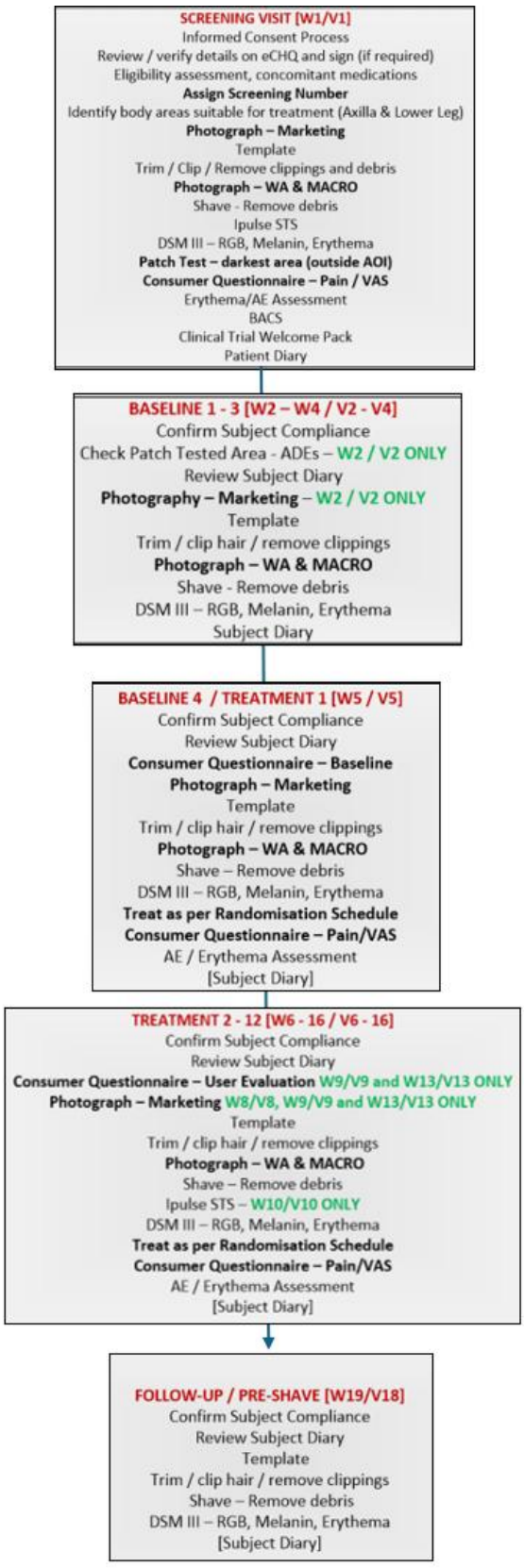

Figure 5. Key stages of the investigation

Visit Number	Visit	Body Site (N)	Body Site	Device	>=10	>=20	>=30	>=40	>=50	>=60	>=70	>=80	>=90	>=100
16	TX12	1	Right Axilla	Pure (no precision head)	16 (94.1%)	15 (88.2%)	15 (88.2%)	15 (88.2%)	15 (88.2%)	15 (88.2%)	15 (88.2%)	11 (64.7%)	8 (47.1%)	0 (0.0%)
16	TX12	1	Right Axilla	Pure FIT (precision head)	10 (76.9%)	8 (61.5%)	7 (53.8%)	6 (46.2%)	5 (38.5%)	5 (38.5%)	2 (15.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
16	TX12	2	Left Axilla	Pure (no precision head)	14 (100.0%)	14 (100.0%)	14 (100.0%)	13 (92.9%)	13 (92.9%)	12 (85.7%)	11 (78.6%)	8 (57.1%)	7 (50.0%)	0 (0.0%)
16	TX12	2	Left Axilla	Pure FIT (precision head)	12 (75.0%)	8 (50.0%)	7 (43.8%)	4 (25.0%)	2 (12.5%)	2 (12.5%)	1 (6.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
16	TX12	3	Right Lower Leg	Pure (no precision head)	15 (93.8%)	15 (93.8%)	15 (93.8%)	15 (93.8%)	14 (87.5%)	14 (87.5%)	13 (81.2%)	13 (81.2%)	11 (68.8%)	2 (12.5%)
16	TX12	3	Right Lower Leg	Pure FIT (precision head)	10 (66.7%)	9 (60.0%)	9 (60.0%)	9 (60.0%)	9 (60.0%)	8 (53.3%)	7 (46.7%)	4 (26.7%)	3 (20.0%)	2 (13.3%)
16	TX12	4	Left Lower Leg	Pure (no precision head)	14 (93.3%)	14 (93.3%)	14 (93.3%)	14 (93.3%)	14 (93.3%)	13 (86.7%)	13 (86.7%)	11 (73.3%)	9 (60.0%)	2 (13.3%)
16	TX12	4	Left Lower Leg	Pure FIT (precision head)	14 (82.4%)	13 (76.5%)	13 (76.5%)	11 (64.7%)	11 (64.7%)	8 (47.1%)	5 (29.4%)	3 (17.6%)	1 (5.9%)	0 (0.0%)
17	1WP	1	Right Axilla	Pure (no precision head)	15 (93.8%)	15 (93.8%)	15 (93.8%)	14 (87.5%)	14 (87.5%)	13 (81.2%)	11 (68.8%)	9 (56.2%)	6 (37.5%)	0 (0.0%)
17	1WP	1	Right Axilla	Pure FIT (precision head)	11 (91.7%)	10 (83.3%)	9 (75.0%)	6 (50.0%)	4 (33.3%)	4 (33.3%)	3 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
17	1WP	2	Left Axilla	Pure (no precision head)	15 (100.0%)	15 (100.0%)	14 (93.3%)	13 (86.7%)	11 (73.3%)	10 (66.7%)	10 (66.7%)	8 (53.3%)	6 (40.0%)	0 (0.0%)
17	1WP	2	Left Axilla	Pure FIT (precision head)	12 (75.0%)	12 (75.0%)	8 (50.0%)	5 (31.2%)	2 (12.5%)	1 (6.2%)	1 (6.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
17	1WP	3	Right Lower Leg	Pure (no precision head)	15 (93.8%)	15 (93.8%)	15 (93.8%)	15 (93.8%)	15 (93.8%)	14 (87.5%)	14 (87.5%)	13 (81.2%)	13 (81.2%)	4 (25.0%)
17	1WP	3	Right Lower Leg	Pure FIT (precision head)	11 (91.7%)	11 (91.7%)	10 (83.3%)	10 (83.3%)	10 (83.3%)	8 (66.7%)	7 (58.3%)	6 (50.0%)	4 (33.3%)	2 (16.7%)
17	1WP	4	Left Lower Leg	Pure (no precision head)	12 (85.7%)	12 (85.7%)	12 (85.7%)	11 (78.6%)	11 (78.6%)	11 (78.6%)	11 (78.6%)	11 (78.6%)	11 (78.6%)	5 (35.7%)
17	1WP	4	Left Lower Leg	Pure FIT (precision head)	14 (93.3%)	12 (80.0%)	10 (66.7%)	9 (60.0%)	9 (60.0%)	7 (46.7%)	6 (40.0%)	4 (26.7%)	1 (6.7%)	1 (6.7%)

Figure 6. Distribution of Subjects by Hair Reduction Threshold (≥10% to 100%, in 10% increments) by Visit, Device and Body Site for Visit 16 and 17 for FAS population

Visit Number	Visit	Body Site (N)	Body Site	Device	>=10	>=20	>=30	>=40	>=50	>=60	>=70	>=80	>=90	>=100
16	TX12	1	Right Axilla	Pure (no precision head)	10 (100.0%)	10 (100.0%)	10 (100.0%)	10 (100.0%)	10 (100.0%)	10 (100.0%)	10 (100.0%)	6 (60.0%)	4 (40.0%)	0 (0.0%)
16	TX12	1	Right Axilla	Pure FIT (precision head)	4 (80.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
16	TX12	2	Left Axilla	Pure (no precision head)	6 (100.0%)	6 (100.0%)	6 (100.0%)	5 (83.3%)	5 (83.3%)	5 (83.3%)	4 (66.7%)	3 (50.0%)	3 (50.0%)	0 (0.0%)
16	TX12	2	Left Axilla	Pure FIT (precision head)	8 (88.9%)	5 (55.6%)	5 (55.6%)	2 (22.2%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
16	TX12	3	Right Lower Leg	Pure (no precision head)	9 (100.0%)	9 (100.0%)	9 (100.0%)	9 (100.0%)	8 (88.9%)	8 (88.9%)	7 (77.8%)	7 (77.8%)	6 (66.7%)	2 (22.2%)
16	TX12	3	Right Lower Leg	Pure FIT (precision head)	4 (57.1%)	4 (57.1%)	4 (57.1%)	4 (57.1%)	4 (57.1%)	4 (57.1%)	3 (42.9%)	2 (28.6%)	2 (28.6%)	1 (14.3%)
16	TX12	4	Left Lower Leg	Pure (no precision head)	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)	5 (71.4%)	3 (42.9%)	0 (0.0%)
16	TX12	4	Left Lower Leg	Pure FIT (precision head)	9 (90.0%)	9 (90.0%)	9 (90.0%)	8 (80.0%)	8 (80.0%)	6 (60.0%)	4 (40.0%)	3 (30.0%)	1 (10.0%)	0 (0.0%)
17	1WP	1	Right Axilla	Pure (no precision head)	9 (100.0%)	9 (100.0%)	9 (100.0%)	9 (100.0%)	9 (100.0%)	8 (88.9%)	7 (77.8%)	5 (55.6%)	2 (22.2%)	0 (0.0%)
17	1WP	1	Right Axilla	Pure FIT (precision head)	4 (100.0%)	3 (75.0%)	3 (75.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
17	1WP	2	Left Axilla	Pure (no precision head)	7 (100.0%)	7 (100.0%)	6 (85.7%)	5 (71.4%)	5 (71.4%)	5 (71.4%)	5 (71.4%)	3 (42.9%)	2 (28.6%)	0 (0.0%)
17	1WP	2	Left Axilla	Pure FIT (precision head)	8 (88.9%)	8 (88.9%)	6 (66.7%)	4 (44.4%)	2 (22.2%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
17	1WP	3	Right Lower Leg	Pure (no precision head)	9 (100.0%)	9 (100.0%)	9 (100.0%)	9 (100.0%)	9 (100.0%)	9 (100.0%)	9 (100.0%)	9 (100.0%)	9 (100.0%)	3 (33.3%)
17	1WP	3	Right Lower Leg	Pure FIT (precision head)	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	3 (60.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)
17	1WP	4	Left Lower Leg	Pure (no precision head)	6 (100.0%)	6 (100.0%)	6 (100.0%)	5 (83.3%)	5 (83.3%)	5 (83.3%)	5 (83.3%)	5 (83.3%)	5 (83.3%)	3 (50.0%)
17	1WP	4	Left Lower Leg	Pure FIT (precision head)	8 (100.0%)	8 (100.0%)	6 (75.0%)	5 (62.5%)	5 (62.5%)	4 (50.0%)	4 (50.0%)	3 (37.5%)	1 (12.5%)	1 (12.5%)

Figure 7. Distribution of Subjects by Hair Reduction Threshold (≥10% to 100%, in 10% increments) by Visit, Device and Body Site for Visit 16 and 17 for SEN population.

Appendix C – Study CD3191

Table 1. Schedule of Events													
Visit Description	**Pre-Screening**	**Screening**	**Baseline**	**Baseline**	**Baseline (Pre-Treatment)**	**Treatment 1**	**Treatment 2**	**Treatment 3**	**End of Treatment (Treatment 4)**	**Review/Follow-up**	**Review/Follow-up**	**Review/Follow-up**	**Final Review/Follow-up**
Visit	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 5**	**Week 6**	**Week 7**	**Week 8**	**Week 9**	**Week 10**	**Week 11**	**Week 12**	**Week 13**
Pre-screen consent	X												
Informed consent		X											
Patch test STS hybrid		X											
Photo	X	X	X	X	X	X	X	X	X	X	X	X	X
STS & DSM	X	X	X	X	X	X	X	X	X	X	X	X	X
VAS		X				X	X	X	X				
Subject Dairy		X	X	X	X		X	X	X	X	X	X	X
IPL Treatment						X	X	X	X				
Consumer questionnaire						X			X				
Ae Form		X	X	X	X	X	X	X	X	X	X	X	X
Record medications or change in medications		X	X	X	X	X	X	X	X	X	X	X	X
eCHQ	X												

Figure 8. Study Schedule.

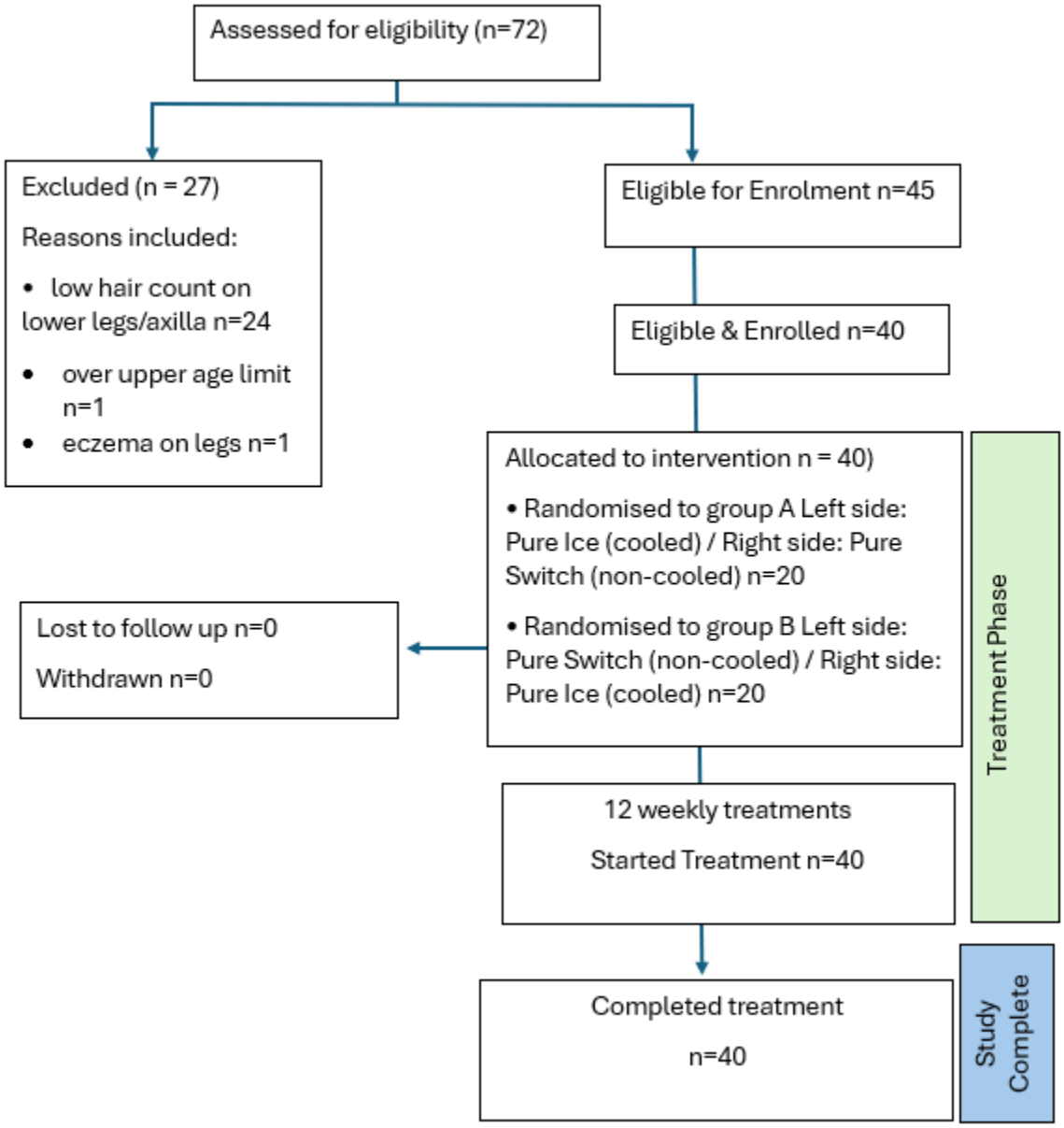

Figure 9. Participant flow through the study CD3191.

Body Site (N)	Body Site	Device	Variable	N	Mean	SD	Median	Minimum	Maximum	Lower CI	Upper CI
1	Right Axilla	Pure Ice	Total Hair Count Change from Baseline Average Value	19	99.7	77.95	120.5	-86.0	218.2	62.1	137.3
1	Right Axilla	Pure Switch	Total Hair Count Change from Baseline Average Value	21	69.0	86.79	42.1	-109.2	247.5	29.5	108.5
2	Left Axilla	Pure Ice	Total Hair Count Change from Baseline Average Value	21	120.2	79.14	105.0	-1.5	324.0	84.2	156.3
2	Left Axilla	Pure Switch	Total Hair Count Change from Baseline Average Value	19	69.0	81.07	59.9	-54.5	229.5	29.9	108.0
3	Left Lower Leg	Pure Ice	Total Hair Count Change from Baseline Average Value	21	29.2	30.51	22.5	-27.2	92.2	15.3	43.1
3	Left Lower Leg	Pure Switch	Total Hair Count Change from Baseline Average Value	19	30.3	30.22	25.1	-27.2	82.0	15.8	44.9
4	Right Lower Leg	Pure Ice	Total Hair Count Change from Baseline Average Value	19	39.8	30.84	36.9	-6.5	110.8	25.0	54.7
4	Right Lower Leg	Pure Switch	Total Hair Count Change from Baseline Average Value	21	28.9	22.21	23.2	-2.0	70.7	18.8	39.0
1	Right Axilla	Pure Ice	Total Hair Count Percentage Change from Baseline Average Value	19	34.9	25.06	32.9	-34.4	82.7	22.8	47.0
1	Right Axilla	Pure Switch	Total Hair Count Percentage Change from Baseline Average Value	21	21.8	19.76	21.9	-16.9	68.7	12.8	30.8
2	Left Axilla	Pure Ice	Total Hair Count Percentage Change from Baseline Average Value	21	34.1	16.79	32.4	-1.4	66.8	26.5	41.7
2	Left Axilla	Pure Switch	Total Hair Count Percentage Change from Baseline Average Value	19	21.4	28.07	20.7	-42.1	64.5	7.8	34.9
3	Left Lower Leg	Pure Ice	Total Hair Count Percentage Change from Baseline Average Value	21	46.1	33.20	55.2	-16.1	95.5	31.0	61.2
3	Left Lower Leg	Pure Switch	Total Hair Count Percentage Change from Baseline Average Value	19	36.4	38.46	46.6	-88.6	80.6	17.8	54.9
4	Right Lower Leg	Pure Ice	Total Hair Count Percentage Change from Baseline Average Value	19	48.9	25.03	54.3	-14.9	86.1	36.8	60.9
4	Right Lower Leg	Pure Switch	Total Hair Count Percentage Change from Baseline Average Value	21	40.9	21.64	44.8	-2.4	78.4	31.1	50.8

Figure 10. Summary Statistics of Hair Count (Absolute and Percent) Change from Baseline Average at Visit 7, by Device and Body Site for FAS.

Body Site (N)	Body Site	Device	>=10	>=20	>=30	>=40	>=50	>=60	>=70	>=80	>=90	>=100
1	Right Axilla	Pure Ice	16 (84.2%)	14 (73.7%)	11 (57.9%)	7 (36.8%)	3 (15.8%)	2 (10.5%)	1 (5.3%)	1 (5.3%)	0 (0.0%)	0 (0.0%)
1	Right Axilla	Pure Switch	13 (61.9%)	11 (52.4%)	5 (23.8%)	4 (19.0%)	1 (4.8%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
2	Left Axilla	Pure Ice	17 (81.0%)	16 (76.2%)	12 (57.1%)	7 (33.3%)	4 (19.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
2	Left Axilla	Pure Switch	12 (63.2%)	9 (47.4%)	5 (26.3%)	4 (21.1%)	2 (10.5%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3	Left Lower Leg	Pure Ice	16 (76.2%)	15 (71.4%)	14 (66.7%)	14 (66.7%)	14 (66.7%)	9 (42.9%)	5 (23.8%)	3 (14.3%)	1 (4.8%)	0 (0.0%)
3	Left Lower Leg	Pure Switch	16 (84.2%)	14 (73.7%)	14 (73.7%)	11 (57.9%)	6 (31.6%)	4 (21.1%)	1 (5.3%)	1 (5.3%)	0 (0.0%)	0 (0.0%)
4	Right Lower Leg	Pure Ice	17 (89.5%)	16 (84.2%)	15 (78.9%)	11 (57.9%)	10 (52.6%)	7 (36.8%)	2 (10.5%)	2 (10.5%)	0 (0.0%)	0 (0.0%)
4	Right Lower Leg	Pure Switch	17 (81.0%)	17 (81.0%)	15 (71.4%)	12 (57.1%)	6 (28.6%)	3 (14.3%)	2 (9.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Figure. 11 Distribution of Subjects by Hair Reduction Threshold (≥10% to 100%, in 10% increments) at Visit 7, by Device and Body Site for FAS.

Device	Body Site	Question Label	Strongly Disagree	Somewhat Disagree	Somewhat Agree	Strongly Agree	Top 2 Box
Pure Ice	Axilla	Q7: Treatment Axilla was painless	0 (0.0%)	3 (7.5%)	1 (2.5%)	36 (90.0%)	37 (92.5%)
Pure Ice	Axilla	Q9: As pain-free as shaving	0 (0.0%)	3 (7.5%)	1 (2.5%)	36 (90.0%)	37 (92.5%)
Pure Ice	Lower Leg	Q9: As pain-free as shaving	1 (2.5%)	3 (7.5%)	1 (2.5%)	35 (87.5%)	36 (90.0%)
Pure Ice	Axilla	Q10: Gentler to skin than shaving	0 (0.0%)	2 (5.0%)	5 (12.5%)	33 (82.5%)	38 (95.0%)
Pure Ice	Lower Leg	Q10: Gentler to skin than shaving	0 (0.0%)	1 (2.5%)	5 (12.5%)	34 (85.0%)	39 (97.5%)

Figure 12. Summary of the 3 pre-specified Consumer Questionnaire items at Visit 8 by Device and Body Site for FAS.

Screening Number	Randomisation Group	Device	Body Site (N)	Body Site	Baseline Hair Count Average	Visit 7 Hair Count	Change from Baseline	% Reduction from Baseline	Visible Results (at least 30% reduction)
3,422	A	Pure Ice	3	Left Lower Leg	42.5	20	22.5	52.9	Y
3,423	A	Pure Ice	3	Left Lower Leg	168.8	196	-27.2	-16.1	N
3,425	A	Pure Ice	3	Left Lower Leg	30.5	8	22.5	73.8	Y
3,426	A	Pure Ice	3	Left Lower Leg	60.8	56	4.8	7.8	N
3,430	A	Pure Ice	3	Left Lower Leg	41.8	17	24.8	59.3	Y
3,436	A	Pure Ice	3	Left Lower Leg	89.5	91	-1.5	-1.7	N
3,439	A	Pure Ice	3	Left Lower Leg	133.5	53	80.5	60.3	Y
3,446	A	Pure Ice	3	Left Lower Leg	51.5	25	26.5	51.5	Y
3,449	A	Pure Ice	3	Left Lower Leg	22.0	1	21.0	95.5	Y

Figure 13. Subject-Level Hair Count Data and Percentage Change from Baseline Average at Visit 7, by Body Site, and Device with focus on Screening Number 3449 (FAS population).

Body Site (N)	Body Site	Device	Variable	N	Mean	SD	Median	Minimum	Maximum	Lower CI	Upper CI
1	Right Axilla	Pure Ice	Total Hair Count Change from Baseline Average Value	16	98.1	80.31	120.5	-86.0	218.2	55.3	140.9
1	Right Axilla	Pure Switch	Total Hair Count Change from Baseline Average Value	20	73.2	87.08	44.0	-109.2	247.5	32.4	113.9
2	Left Axilla	Pure Ice	Total Hair Count Change from Baseline Average Value	20	118.4	81.01	103.9	-1.5	324.0	80.5	156.3
2	Left Axilla	Pure Switch	Total Hair Count Change from Baseline Average Value	17	76.8	77.46	60.0	-54.5	229.5	36.9	116.6
3	Left Lower Leg	Pure Ice	Total Hair Count Change from Baseline Average Value	19	30.5	31.75	22.5	-27.2	92.2	15.2	45.8
3	Left Lower Leg	Pure Switch	Total Hair Count Change from Baseline Average Value	16	33.0	31.12	29.1	-27.2	82.0	16.4	49.5
4	Right Lower Leg	Pure Ice	Total Hair Count Change from Baseline Average Value	16	44.0	30.19	40.6	-6.5	110.8	27.9	60.0
4	Right Lower Leg	Pure Switch	Total Hair Count Change from Baseline Average Value	18	28.1	22.97	21.1	-2.0	70.7	16.6	39.5
1	Right Axilla	Pure Ice	Total Hair Count Percentage Change from Baseline Average Value	16	35.4	26.31	32.9	-34.4	82.7	21.4	49.4
1	Right Axilla	Pure Switch	Total Hair Count Percentage Change from Baseline Average Value	20	23.1	19.44	23.6	-16.9	68.7	14.0	32.2
2	Left Axilla	Pure Ice	Total Hair Count Percentage Change from Baseline Average Value	20	33.7	17.17	32.1	-1.4	66.8	25.7	41.7
2	Left Axilla	Pure Switch	Total Hair Count Percentage Change from Baseline Average Value	17	24.0	26.98	20.8	-42.1	64.5	10.1	37.8
3	Left Lower Leg	Pure Ice	Total Hair Count Percentage Change from Baseline Average Value	19	47.5	34.10	59.3	-16.1	95.5	31.1	64.0
3	Left Lower Leg	Pure Switch	Total Hair Count Percentage Change from Baseline Average Value	16	34.6	40.26	46.6	-88.6	80.6	13.2	56.1
4	Right Lower Leg	Pure Ice	Total Hair Count Percentage Change from Baseline Average Value	16	51.7	24.96	57.8	-14.9	86.1	38.4	65.0
4	Right Lower Leg	Pure Switch	Total Hair Count Percentage Change from Baseline Average Value	18	41.4	22.57	44.8	-2.4	78.4	30.2	52.6

Figure 14. Summary Statistics of Hair Count (Absolute and Percent) Change from Baseline Average at Visit 7, by Device and Body Site for SEN.

Body Site (N)	Body Site	Device	>=10	>=20	>=30	>=40	>=50	>=60	>=70	>=80	>=90	>=100
1	Right Axilla	Pure Ice	14 (87.5%)	13 (81.2%)	10 (62.5%)	6 (37.5%)	3 (18.8%)	2 (12.5%)	1 (6.2%)	1 (6.2%)	0 (0.0%)	0 (0.0%)
1	Right Axilla	Pure Switch	13 (65.0%)	11 (55.0%)	5 (25.0%)	4 (20.0%)	1 (5.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
2	Left Axilla	Pure Ice	16 (80.0%)	15 (75.0%)	11 (55.0%)	6 (30.0%)	4 (20.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
2	Left Axilla	Pure Switch	12 (70.6%)	9 (52.9%)	5 (29.4%)	4 (23.5%)	2 (11.8%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3	Left Lower Leg	Pure Ice	14 (73.7%)	14 (73.7%)	13 (68.4%)	13 (68.4%)	13 (68.4%)	9 (47.4%)	5 (26.3%)	3 (15.8%)	1 (5.3%)	0 (0.0%)
3	Left Lower Leg	Pure Switch	14 (87.5%)	12 (75.0%)	12 (75.0%)	10 (62.5%)	5 (31.2%)	3 (18.8%)	1 (6.2%)	1 (6.2%)	0 (0.0%)	0 (0.0%)
4	Right Lower Leg	Pure Ice	15 (93.8%)	15 (93.8%)	14 (87.5%)	11 (68.8%)	10 (62.5%)	7 (43.8%)	2 (12.5%)	2 (12.5%)	0 (0.0%)	0 (0.0%)
4	Right Lower Leg	Pure Switch	15 (83.3%)	15 (83.3%)	14 (77.8%)	11 (61.1%)	6 (33.3%)	3 (16.7%)	2 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Figure 15. Distribution of Subjects by Hair Reduction Threshold (≥10% to 100%, in 10% increments) at Visit 7, by Device and Body Site for SEN.

Device	Body Site	Question Label	Strongly Disagree	Somewhat Disagree	Somewhat Agree	Strongly Agree	Top 2 Box
Pure Ice	Axilla	Q7: Treatment Axilla was painless	0 (0.0%)	2 (5.4%)	1 (2.7%)	34 (91.9%)	35 (94.6%)
Pure Ice	Axilla	Q9: As pain-free as shaving	0 (0.0%)	2 (5.4%)	1 (2.7%)	34 (91.9%)	35 (94.6%)
Pure Ice	Lower Leg	Q9: As pain-free as shaving	0 (0.0%)	3 (8.6%)	1 (2.9%)	31 (88.6%)	32 (91.4%)
Pure Ice	Axilla	Q10: Gentler to skin than shaving	0 (0.0%)	2 (5.4%)	4 (10.8%)	31 (83.8%)	35 (94.6%)
Pure Ice	Lower Leg	Q10: Gentler to skin than shaving	0 (0.0%)	1 (2.9%)	4 (11.4%)	30 (85.7%)	34 (97.1%)

Figure 16. Summary of the 3 pre-specified Consumer Questionnaire items at Visit 8 by Device and Body Site for SEN.

Appendix D – Inclusion / Exclusion criteria

Study Code	CD3028	CD3137	CD3191
Inclusion Criteria	Healthy female subjects Subjects aged between 18 and 45 years Subjects who are skin tones I – V in the proposed treatment area(s) Subjects who have signed the 'Subject Informed Consent Signature Form' (F20073) after the nature of the study has been fully explained (Subject Information Form, F20074) Subjects who have sufficient unwanted body hair in the proposed treatment area(s); a minimum hair density at screening of 10 hairs per cm2 for the axilla, 7 hairs per cm2 for both the bikini area and lower leg Subjects who have naturally dark terminal hair (light brown to black) in the treatment area(s) Subjects who are willing to have the proposed assessment area(s) shaved and treated in accordance with the randomisation schedule Subjects who are willing to attend all study assessments and follow-up appointments Subjects who are able to understand the study, and are willing to co-operate with the study procedures and restrictions Subjects who are non-smokers (or have not smoked for at least 2 years) Subjects who are surgically sterilized or are prepared to take necessary precautions to prevent becoming pregnant during the entire study duration, i.e. using medically acceptable forms of birth control that are not contraindicated (oral contraceptives, IUD, contraceptive implant, barrier methods with spermicide) or abstinence.	Healthy female subjects Subjects aged between 18 and 55 years. Subjects who are skin tones I – V at the proposed treatment areas (skin tone 1.0 – 5.5 with ipulse STS). Subjects who have signed the 'Patient Informed Consent Signature Form' after the nature of the study has been fully explained (Patient Information Form). Subjects who have sufficient unwanted hair in the proposed treatment areas: 15 hairs/cm^2 for the underarm, 4 hairs per cm^2 for the lower leg. Subjects who have naturally dark terminal hair (light brown to black) in the treatment areas. Subjects who are willing to have the proposed assessment areas shaved and treated in accordance with the randomisation schedule. Female subjects who are surgically sterilized or are prepared to take necessary precautions to prevent becoming pregnant during the entire study duration, i.e., using medically acceptable forms of birth control that are not contraindicated (oral contraceptives, IUD, contraceptive implant, barrier methods with spermicide) or abstinence. Female subjects, who have been on the contraceptive pill for at least 6 months prior to the start of the study, are eligible provided they are prepared to continue such medication throughout the study duration. ADDITIONAL CRITERIA Subjects who are willing to attend all study assessments and follow-up appointments. Subjects who can understand the study and are willing to co-operate with the study procedures and restrictions. PERMITTED DISORDERS Subjects with a mild form of Irritable Bowel Disease. Subjects with localised eczema to non-treatment areas. Subjects with a history of glandular fever. Subjects with a history of mumps. Subjects with history of diet induced gout to non-treatment areas (must confirm the triggers). PERMITTED MEDICATIONS Antihistamines provided not being taken for long periods of time (as and when required) as could dampen down well-known associated side effects of IPL treatment; pruritis and itchiness.	Healthy female subjects Subjects of all skin tones, I-V Subjects aged between 18 and 55 years Subjects who have signed the 'Patient Informed Consent Signature Form' after the nature of the investigation has been fully explained (Patient Information Form) Subjects who have sufficient hair in the proposed treatment areas: 1 hair/cm^2 for the underarms and lower legs Subjects who have naturally dark terminal hair (light brown to black) in the treatment areas Subjects willing to take necessary precautions during the investigation to prevent pregnancy (different forms of birth control) Subjects who can independently read and understand the investigation information leaflet and are willing to co-operate with the investigation procedures and restrictions

Study Code	CD3028	CD3137	CD3191
Exclusion Criteria	• Females who are pregnant, lactating or who have given birth within the previous 3 months or, if of childbearing potential, are not taking adequate contraceptive precautions. • Subjects with naturally white, grey, red or blonde hair, for whom the device would be ineffective. Subjects with abnormally low hair count in the centre of the treatment area(s) compared with published data and the minimum hair density specified in the inclusion criteria. • Subjects who have participated in any clinical study during the previous 30 days of initiation of this study. Subjects with a history of alcohol, substance or drug abuse in the previous 12 months. • Subjects with any significant concurrent illness. Subjects with a history of heart disease; angina, heart pacemaker, taking anti-coagulant medication including the use of aspirin. • Subjects with insulin-dependent diabetes (owing to possible poor wound healing). Subjects that have undergone surgery in the past 3 months. Subjects with any active or significant history of skin disorders at the treatment area(s) e.g. hypo pigmentation (vitiligo). • Subjects with any inflammatory skin condition (eczema, psoriasis, herpes simplex/complex). Subjects with a history (or family history) of skin cancer, skin tumours or any other malignant disease. Subjects with keloid scarring. • Subjects with any irritation, tattoos, piercings, scars, birthmarks, or heavy presence of freckles at the treatment site(s). • Subjects with a history of epilepsy, migraines or seizures triggered by light. Subjects with photosensitivity or taking medication known to cause photosensitivity. • Subjects takings NSAIDs two weeks before and two weeks after treatment. Subjects with an allergy likely to interfere with the study • Use of laser, IPL or other skin treatment device or chemical peels within 3 months of the initial treatment • Botox within 4 months of the initial treatment • Collagen, fat injections or other methods of skin augmentation (enhancement with injected or implanted material) in treated area(s) within 6 months of the initial treatment Subjects who have used any of the following hair removal procedures at the proposed treatment area(s): • Electrolysis, waxing, threading, plucking or mechanical epilators in the past 3 months • Chemical depilatories or bleaching (hair lightening) chemicals within 6 months of initiation of this study Subjects with tanned skin	GENERAL & TREATMENT SITE CONDITIONS -Subjects with naturally white, grey, red, or blonde hair, for whom the device would be ineffective. Subjects with abnormally low hair count in the treatment areas. - Subjects who have participated in any hair removal clinical study in the 18 months prior to initiation of this study (this is due to the length of the hair growth cycle for lower leg). -Subjects with infected, irritated, burnt, or cut skin at the treatment area. Subjects with any irritation, scars, birthmarks, or heavy presence of freckles at the treatment site. HORMONAL -Females who are pregnant, lactating or who have given birth within the previous 3 months or, if of childbearing potential, are not taking adequate contraceptive precautions. --Females who are taking a Cyproterone Acetate contraceptive product. PSYCHIATRIC - Subjects with psychological disease in the last 5 years (anxiety, depression, post-natal depression). GASTROINTESTINA - Subjects with GI complaints (coeliac, crohn's, ulcerative colitis) due to the impact on metabolism and hair growth. - Subjects with moderate to severe Irritable Bowel Syndrome. CARDIOVASCULAR -Subjects with a history of heart disease; angina, arrhythmias, heart pacemaker. -Subjects with an implantable metal device in the treatment area - Subjects with insulin-dependent diabetes (owing to possible poor wound healing). BLOOD & LYMPHATIC -Subjects with blood clotting disorders or taking medication to thin the blood. - Subjects with anaemia controlled by iron tablets (due to the impact on hair growth). -Subjects taking anti-coagulant medication including the use of aspirin.	GENERAL & TREATMENT SITE CONDITIONS Subjects with naturally white, grey, red, or blonde hair, for whom the device would be ineffective • Subjects with abnormally low hair count in the treatment areas – Although the investigation being a safety investigation – a minimum hair quantity is required. • Subjects with infected, irritated, burnt, or cut skin at the treatment sites • Subjects with any irritation, scars, birthmarks, or heavy presence of freckles at the treatment sites • Subjects with any tattoos or piercings at the treatment sites (axilla and back of the lower legs) • Subjects with a high BMI that affects the ability to capture and treat the proposed treatment areas GASTROINTESTINAL • Subjects with GI complaints (coeliac, Crohn's, ulcerative colitis) due to the impact on metabolism and hair growth • Subjects with moderate to severe irritable bowel syndrome Cardiovascular • Subjects with a history of heart disease; angina, arrhythmias, heart pacemaker • Subjects with irregular heart beats • Subjects with an implantable metal device in the treatment area. Blood & Lymphatics • Subjects with blood clotting disorders or taking medication to thin the blood • Subjects with a history of anaemia or anaemia controlled by iron tablets (As anaemia can have different medical reasons, the risk of complications is too high) • Subjects taking anti-coagulant medication including the use of aspirin NERVOUS SYSTEM • Subjects with a history of epilepsy, migraines or seizures triggered by light ENDICRONOLOGY/HORMONAL • Subjects with insulin-dependent diabetes (owing to possible poor wound healing)

Study Code	CD3028	CD3137	CD3191
	(active tan) through sun exposure or tanning bed use, or has used self-tan in the previous 30 days of initiation of this study. • . Current or previous use of any topical or systemic medication likely to interfere with the study in the last 3 months. Including, but not limited to: • Medication for which sunlight is a contraindication • St John's Wort or Feverfew (herbal remedies) • Oral isotretinoin Roaccutane or Retin A for the treatment of acne or other dermatological conditions. • Any topical medication (e.g. hydrocortisone) being used at treatment sites.	NERVOUS SYSTEM - Subjects with a history of epilepsy, migraines or seizures triggered by light. DERMATOLOGICAL / SUBCUTANEOUS TISSUE & INFECTIONS - Subjects with any active or significant history of skin disorders at the treatment area e.g., hypo pigmentation (vitiligo). - Subjects with any inflammatory skin condition in or around the treatment area (eczema, psoriasis, herpes simplex/complex). Psoriasis is a systemic disease. - Subjects with active mumps. –Subjects with active or history of shingles. -Subjects with a history (or family history) of skin cancer, skin tumours or any other malignant disease. - Subjects with keloid scarring. -Subjects with any systemic disease that could affect the skin status. -Subjects with connective tissue disease (hyper mobility). -Subjects with active or history of hives. Subjects with an allergy likely to interfere with the study. - Subjects with tanned skin (active tan) through sun exposure or tanning bed use or has used self-tan in the previous 7 days of initiation of this study. MEDICATIONS -Subjects takings NSAIDs two weeks before treatment (will reduce VAS scores). -Current or previous use of any topical or systemic medication likely to interfere with the study in the last 3 months. Including, but not limited to: -Medication for which sunlight is a contraindication. - St John's Wort or Feverfew (herbal remedies). - Oral isotretinoin - Roaccutane or Retin A for the treatment of acne or other dermatological conditions. - Any medication (prescribed or herbal for menopause). - Any products with Hypercin. Any topical medication (e.g., hydrocortisone) being used at treatment site. Subjects with photosensitivity or	• Females who are pregnant, lactating or who have given birth within the previous 3 months or, if of childbearing potential, are not taking adequate contraceptive precautions. DERMATOLOGICAL / SUBCUTANEOUS TISSUE & INFECTIONS • Subjects with any active or significant history of skin disorders at the treatment area e.g., hypo pigmentation (vitiligo) • Subjects with any inflammatory skin condition in or around the treatment area (active eczema, psoriasis, herpes simplex/complex). Psoriasis is a systemic disease • Subjects with active mumps • Subjects with active shingles • Subjects with a history (or family history) of skin cancer, skin tumours or any other malignant disease • Subjects with keloid scarring in treatment areas • Subjects with any systemic disease that could affect the skin status Subjects with connective tissue disease (hyper mobility) • Subjects with active urticaria • Subjects with active or history of hives or rashes • Subjects with an allergy likely to interfere with the investigation • Subjects with viral exanthemata as it includes: measles, rubella, varicella, erythema infectious, mild viral illnesses and infectious mononucleosis MEDICATIONS • Subjects' takings NSAIDs two weeks before treatment (will reduce VAS scores) • Current or previous use of any topical or systemic medication likely to interfere with the investigation in the last 3 months. Including, but not limited to: • Medication for which sunlight is a contraindication • St John's Wort or Feverfew (herbal remedies) • Oral isotretinoin - Roaccutane or Retin A for the treatment of acne or other dermatological conditions • Any products with Hypericin

Study Code	CD3028	CD3137	CD3191
		taking medication known to cause photosensitivity (commonly reported side effects). SURGICAL & MEDICAL PROCEDURES -Subjects that have undergone surgery in the past 3 months. -Subjects who have had any of the following cosmetic procedures at the proposed treatment area: o Use of LASER, IPL, electrolysis, or other skin treatment device within 18 months of the initial treatment. o Use of chemical peels within 3 months of the initial treatment. o Botox within 3 months of the initial treatment. o Collagen, fat injections or other methods of skin augmentation (enhancement with injected or implanted material) in treated area within 3 months of the initial treatment. o Subjects who have used any of the following hair removal procedures at the proposed treatment area: o Waxing, threading, plucking or mechanical epilators in the past 3 months. o Chemical depilatories or bleaching (hair lightening) chemicals within 3 months of initiation of this study. EXTERNAL FACTORS - Subjects with a history of alcohol, substance, or drug abuse in the previous 12 months. - Subjects with any tattoo or piercings at the treatment site . -Subjects considered a heavy smoker 1-2 packs/day for past 10 years (affects peripheral circulation and may impact on hair growth). - Subjects considered a light to moderate smoker 1 pack/day for past 5 years. COVID-19 Subjects with COVID-19 symptoms or who has tested positive for COVID-19.	• Any topical medication (e.g., hydrocortisone) being used at treatment sites • Subjects with photosensitivity or taking medication known to cause photosensitivity (commonly reported side effects) SURGICAL & MEDICAL PROCEDURES • Subjects that have undergone surgery in the past 3 months • Subjects who have had any of the following cosmetic procedures at the proposed treatment area: o Use of LASER, IPL, electrolysis, or other skin treatment device in treatment areas within 18 months of the initial treatment, UNLESS hair re-growth is substantial enough to meet inclusion criteria o Use of chemical peels in treatment areas within 3 months of the initial treatment. o Botox in treatment areas within 3 months of the initial treatment o Collagen, fat injections or other methods of skin augmentation (enhancement with injected or implanted material) in treatment areas within 3 months of the initial treatment • Subjects who have used any of the following hair removal procedures at the proposed treatment area: o Waxing, threading, plucking or mechanical epilators in the past 3 months UNLESS hair re-growth is substantial enough to meet inclusion criteria o Chemical depilatories or bleaching (hair lightening) chemicals within 3 months of initiation of this investigation • Subjects with COVID-19 symptoms, who also test Positive for COVID-19