Clinical Investigation of Safety and Efficacy of the Emerald IPL Device for Hair Reduction for the Extension of its Intended Use to Face and to Skin Type V population

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Protocol Synopsis

Study Title & ID	Title: "Clinical Investigation of Safety and Efficacy of the Emerald IPL Device for Hair Reduction for the Extension of its Intended Use to Face and to Skin Type V population." ID: PC-BEA-Emerald ST-V and Face-2019-10560
Project Name/ Acronym	Emerald ST-V and Face
Investigational Device	Emerald BRI956
Study Objectives	<u>Primary Objectives:</u> • Evaluate the safety of the Emerald IPL device on removal of unwanted hair on face, axillae, bikini area and legs over the course of the hair removal treatment with the IPL device and during the one year follow up period. • Evaluate the efficacy of the Emerald IPL device on short-term hair reduction on face, axillae, bikini area and legs, 1 month after the last treatment (12th treatment). • Evaluate the efficacy of the Emerald IPL device on short-term hair reduction on face, axillae, bikini area and legs, 3 months after the last treatment (12th treatment). <u>Secondary Objectives:</u> • Evaluate the efficacy of the Emerald IPL device on removal of unwanted hair after the Initial Treatment period, at 8 weeks after baseline (2 weeks after the 4th treatment) and at 10 weeks after baseline (4 weeks after the 4th treatment). • Assess the subjective satisfaction with the treatment results of the Emerald IPL device for removal of unwanted hair in each body area, up until 3 months after the last treatment (12th treatment). • Assess the acceptance of the Emerald IPL device for removal of unwanted hair in each body area. Evaluate the time course of hair reduction to baseline achieved by the Emerald IPL device for each body area during the Intensive Treatment period <u>Exploratory Objective</u>: • Assess the percentage of body areas for which the device setting indicated by the STS device is the same as the device setting based on the result of Test Flash or is the same as the device setting recommended by skin tone self-assessment. • Evaluate the long-term hair reduction at 6, 9 and 12 months after completion of the 12 treatments with the Emerald IPL device. • Assess the long-term subjective satisfaction with the treatment results of the Emerald IPL device for removal of unwanted hair in each body area, 6, 9 and 12 months after the last treatment

Study Endpoints	Primary Efficacy Endpoints: Primary efficacy endpoints are the proportion of body areas with greater than or equal to 30% hair reduction 1 and 3 months post last hair removal treatment compared to the baseline. Secondary Endpoints: • Proportion of body areas with successful hair reduction (greater than or equal to 30% relative to baseline) at 8 weeks post-baseline (2 weeks after the 4th treatment) per body area. • Proportion of body areas with successful hair reduction (greater than or equal to 30% relative to baseline) at 10 weeks post-baseline (4 weeks after the 4th treatment) per body area • Percent reduction of hair counts relative to baseline as the result of all bi-weekly treatments per body area • Percent of top-two category answers in assessment of subjective satisfaction with the treatment results up until 3 months post last hair removal in all body areas. • Percent of top-two category answers in assessment of acceptance of the treatment in all body areas Exploratory Endpoints: • Percent of subjects with the same device setting when based on comfort (Test Flash) and on setting indication. • Percent reduction of hair counts relative to baseline at 6, 9 and 12 months post final treatment (12 treatments) per body area. • Percent of top-two category answers in assessment of subjective satisfaction with the treatment results at 6, 9 and 12 months post final treatment (12 treatments) in all body areas
Subject Population	It is planned to enroll healthy female subjects of Fitzpatrick Skin Type ST I up to and including V and age 18 – 65 for hair removal treatment in qualified areas bilaterally on body and face. Eligible subjects will be enrolled into one of the following groups. : Skin Types I–IV – Face group: Enrollment of approximately 58 subjects of Fitzpatrick skin types I, II, III, and IV, with a melanin index ≤ 375 (and a minimum of 10 hairs in the qualifying treatment areas bilateral on face (upper lip). All four skin types have to be represented. Approximately 46 eligible subjects are expected to complete the 3 months post treatment visit. . Skin Type V – All Body Area group: Enrollment of 26 subjects with Fitzpatrick skin type V (ST V), with a melanin index ≤ 553 in each qualifying treatment area bilateral on face (upper lip), axilla, bikini line, and leg.

	A minimum of 24 hairs is required in the qualifying treatment areas bilateral on axilla, bikini line and leg. A minimum of 10 hairs is required in the qualifying treatment areas bilateral on face (upper lip). Approximately 21 eligible subjects are expected to complete the 3 months post treatment visit. **Inclusion Criteria:** 1. Be willing to provide informed consent 2. Are healthy female subjects, in age of 18-65 years 3. Have natural body hair color that is dark blonde, brown or black in the designated treatment areas 3.1. Subjects of ST I-IV – Face group: 3.1.1 Have Fitzpatrick Skin Type I, II, III, or IV 3.1.2 Measure melanin value ≤ 375 in the qualifying treatment areas bilateral on upper lip (face) 3.1.3. Have a minimum of 10 hairs in the 1 cm x 2 cm qualifying treatment areas bilateral on upper lip (face), by visual inspection 3.2. Subjects of ST V – All Body Area group: 3.2.1. Have Fitzpatrick Skin Type V 3.2.2. Measure melanin value ≤ 553 in the qualifying treatment areas bilateral on upper lip (face), axilla, bikini line, and leg 3.2.3. Have a minimum of 10 hairs in the 1 cm x 2 cm qualifying treatment areas bilateral on upper lip (face), by visual inspection 3.2.4. Have a minimum of 24 hairs in each of the 2 cm x 4 cm qualifying treatment areas bilateral on axilla, bikini line, and leg, by visual inspection 4. Be either post-menopausal or surgically sterilized, or using a medically acceptable form of birth control (e.g., oral contraceptives, IUD, contraceptive implant, barrier methods with spermicide or abstinence, etc.). 5. Be willing to participate in all study visits 6. Be willing to refrain from deliberate exposure to strong sun, products or procedures that would cause the skin to become darker in the designated treatment areas during the treatment phase 7. Be willing to refrain from the use hair growth inhibitors/accelerators during the course of the study 8. Be willing to refrain from waxing, depilating or epilating of the upper lip, axilla, bikini line and leg areas 9. Be willing to refrain from using aspirin or NSAIDs (e.g. acetaminophen, ibuprofen, etc.) within 5 days prior to and 5 days after treatment(s) **Exclusion Criteria:**

	1. Have natural body hair color that is white, light blond, or red in the designated treatment areas 1.1. Subjects of ST I to IV – Face group: 1.1.1. Have Fitzpatrick Skin Type V or VI 1.1.2. Measure melanin value higher than 375 in the qualifying treatment areas bilateral on upper lip 1.1.3. Have fewer than 2 qualifying treatment areas on bilateral on upper lip (face) 1.2. Subjects of ST V – All Body Area group: 1.2.1. Have Fitzpatrick Skin Type I, II, III, IV, or VI 1.2.2. Measure melanin value higher than 553 in any of the qualifying treatment areas in axilla, bikini line, on legs, or face (upper lip) 1.2.3. Have fewer than 4 qualifying treatment areas in axilla, bikini line, on legs, or face (upper lip) 2. Have a malignant or pre-malignant pigment in the areas to be treated 3. Have scarring or infection in the areas to be treated 4. Have a known history of photosensitivity or use of medication known to induce photosensitivity 5. Are currently pregnant or lactating or planning to become pregnant in the period of the study, per subject report 6. Are currently on a daily dose of aspirin or NSAIDs (e.g. acetaminophen, ibuprofen, etc.) or have taken aspirin and/or NSAIDs within 5 days prior to treatment that would reduce or increase the sensation of pain 7. Are not willing to abstain from the use of products or light exposure that would induce tanning in the treatment areas during the IPL treatment period (first 10 months) 8. Have a history of immunosuppressive disease (including HIV infection or AIDS) 9. Are on a anticoagulative medication or have a thromboembolic condition 10. Have taken any form of isotretinoin (such as Accutane or Roaccutane etc.) in the last six months 11. Have an active implantable device such as a pacemaker, neurostimulator or internal defibrillator 12. Have used waxing or other methods of root hair removal, or photo-epilation within 6 months prior to treatment in the areas to be treated 13. Have been exposed to strong sunlight or an artificial tanning machine within 4 weeks of enrolment in the areas to be treated 14. Have a tattoo(s), warts, moles, benign skin lesions, dark pigmented areas, permanent make-up etc. in the in the areas to be treated. 15. Have eczema, psoriasis, lesions, open wounds or any skin affliction in the in the areas to be treated 16. Have a history of keloid scar formation 17. Have a history of herpes outbreaks in the in the areas to be treated 18. Have a history of photosensitive epilepsy

	19. Have a condition related to hormonal changes like polycystic ovarian syndrome (PCOS) or taking drugs leading to hormonal changes resulting in excessive hair growth like hirsutism or idiopathic hirsutism 20. Have diabetes, or metabolic disease that affects hair growth 21. Taking immunosuppressive medication(s) 22. Have a disease related to photosensitivity, such as polymorphic light eruption (PMLE), solar urticaria, porphyria etc. 23. Have a history of skin cancer, including past basal cell carcinoma and/or squamous cell carcinoma in any of the areas to be treated 24. Have a history of any radiation therapy in any of the areas to be treated 25. Have history of radiation therapy in non-treatment areas within 5 years 26. Have a history of chemotherapy 27. Have used hair growth inhibitors and/or accelerators within 6 months preceding enrolment 28. Have had laser or electrolysis treatment for the removal of hair in the areas to be treated within the last year 29. Have natural body hair colors of white, grey, light to mid-blond, or red in the areas to be treated 30. Have bleaching of their body hair in the areas to be treated 6 months prior to study enrolment 31. Have shaved the areas to be treated within 7 days prior to study enrolment 32. Participating in other clinical studies prior to, or concurrently with this study, that could be deemed to interfere with full and complete participation in this study – as determined by the site Investigator. .
Study Design	Prospective, multi-center, single-arm, single blinded (Philips hair counter) study in healthy women of Fitzpatrick skin types I up to and including V (ST I-V). Safety and efficacy of hair removal with the Emerald IPL-device will be investigated for treatment in face of subjects with ST I – V and for treatment in axilla, bikini area, and legs of subjects with ST V. In-clinic, the study subjects will undergo twelve IPL-treatments bilaterally at the qualified areas (face and / or axilla, bikini line, and legs) with the Emerald IPL device applied by a device operator. Hair re-growth will be evaluated for the face separately, and evaluated combined for the axilla, bikini line and legs After the 4 bi-weekly treatments, one follow-up visit will be organized two weeks after the 4th treatment. After the completion of the full treatment cycle (12 treatments), subjects will be followed for 1 and 3 months (short-term follow-up) and for 6, 9 and 12 months (long-term follow up) (see Amendment 3 – Summary of changes)
Test Groups	Two groups will undergo treatment with the Investigational Device on different body areas: Face group including subjects with Skin Types I –IV (ST I-IV) for face treatment only. All Body Area group including subjects with Skin Type V (ST V) for treatment of face, axillae, bikini, or legs.

Lengths of study	The total duration of this study is estimated to be approximately 30 months. After successful screening at the study center, a study subject is enrolled for 22 months in total to accommodate 18 study visits at the clinical study center (see Amendment 3 – Summary of changes).
Clinical and Safety Procedures/ Evaluations	Screening visit: • Informed Consent • Medical History & Demographics • Subjective assessment of Skin type/tone • Determination Fitzpatrick Skin Type Scale • Measurement Melanin Index • Enrolment (Inclusion/Exclusion criteria) • Selection of Treatment/Photograph Area • Determination of Device Setting (Test Flash Applications) • Evaluation of Skin Reactions after Test Flash • Setting indication assessment (IPL family device) Treatment visits: • Safety Monitoring, Adverse Events, Concomitant Medications since last visit • Compliance to study rules • Marking of Treatment Areas • Trim Hairs in Treatment Areas • Digital Photographs at Treatment Areas • Shave and Clean Treatment Areas • Apply IPL device to Treatment Areas [Treatment] • Assessment of subject's discomfort using 5-point pain grade scale • Self-Assessment Questionnaires • Assessment of post-treatment skin reactions – Safety Monitoring Follow-up Visits: • Safety Monitoring, Adverse Events, Concomitant Medications since last visit • to study rules • Marking of Treatment Areas • Digital Photographs at Treatment Areas • Self-Assessment Questionnaires
Study Visit(s) Summary & Duration	After the screening visit, 18 study visits are planned within 22 months consisting of bi-weekly treatment visits, one follow-up visit two weeks after the 4th treatment, 8 monthly treatment visits starting four weeks after the 4th treatment, and 5 follow-up visits 1, 3, 6, 9, and 12 months after last, 12th treatment (see Amendment 3 – Summary of changes).
Nature and extent of the burden	• Before the start of the treatment period, as part of the Screening visit, each test subject will undergo the Test Flash procedure to define eligibility of each treatment area and the device setting (energy output) for each area. Test flashes will be applied close to the potential treatment areas of face, axilla, bikini area, and leg. The duration of the Screening visit is approximately 60 min or less for subjects in the Face group,

	and 120min or less for subjects in the All Body Area group. Test subjects will observe possible skin reactions in the tested areas for at least 24 hours and report those in the Post-treatment Self-Assessment diary. • Each Treatment visit will occupy approximately 30 min for subjects in the Face group and approximately 90 min for subjects in the All Body Area group. • Each Follow-up visit will occupy approximately 30min for subjects in the Face group and approximately 60min for subjects in the All Body Area group. • During visits, subjects will be asked between minimum three and maximum six questions concerning protocol compliance between the visits, about subject's sensations during and after the IPL-treatments, and about the subject's personal impression of the IPL-results. • At each visit between week 1 through week 10, and at all Follow-up visits, all treated areas will be photographed.
Potential Risks	According to previous studies conducted, it has been noted that IPL hair removal devices may cause skin reactions that are typically mild and temporary. Among them, the most frequently reported skin reactions are transient erythema. Other infrequently observed skin reactions are warm sensation, pigmentation changes, or itchiness in the treated area. The risk that these skin reactions last longer than 24 hours is expected to be low. On rare occasions burns and blisters have been observed. These complications are predominantly caused by user error such as incorrect device settings, or user error such as failure to avoid excessive sun exposure after treatment. Therefore, in order to reduce further risk of complications, the prevailing recommendation is to avoid excessive sun exposure and to use SPF50 crème after the treatment. In very rare occasions, paradoxical hair growth can occur. In previous clinical studies with the Emerald IPL device, paradoxical hair growth was not observed.
Potential Benefits	The anticipating benefits for study participants include bilateral removal of unwanted hair in the face (full upper lip) and both axilla.