Advertisement for Recruiting Study Subjects

Study Title: An Assessment on the Safety and Efficacy of High Intensity Focused Ultrasound (HIFU): Assessment of Safety and Efficacy for improvement of wrinkles on periorbital, perioral, and neck regions

1. Clinical Study Purpose

To corroboratively assess the safety and efficacy of High Intensity Focused Ultrasound (HIFU) technology for improvement of wrinkles around the eyes, mouth, and neck regions.

2. Clinical Study Method

A. Duration of Clinical Study : approximately 17 weeks (119 days)

B. No. of Hospital Visits : 6 ~ 7 / No. of Treatments : 3

(※ 6 Hospital Visits : If screening and first procedure are conducted on the same day.)

C. This study will be conducted in a single center and a total of 3 groups (periorbital, perioral, and neck) will be assigned for each subject by random selection

D. The subject will undergo vital signs, physical exams, and other assessments on visit.

(※ Subjects should expect that each visit including treatment will take approximately 2 hours and 30 minutes; 2 hours per visit that exclude treatments.)

3. Criteria of Participation

A. Healthy subjects at age range 30 – 65

B. Subjects who are interested in treatments for wrinkle reduction around the eyes, mouth, and neck

C. Subjects with visible wrinkles around the eyes, mouth, and neck based on clinical imaging

D. Subjects who understand and follow the instructions may participate in the entire duration of this clinical trial

4. Inclusion Criteria

For subjects who formally consent to participate in this clinical trial, which includes undergoing evaluation and treatments, a series of surveys and tests will be conducted to determine your eligibility as a study subject.

5. Expected Adverse Events

A. Hypersensitivity due to topical application of a local anesthetic (when the subject only uses Emla Cream)

B. During & Post Treatment: heat sensation, pain, stinging, erythema, edema, itching, ecchymosis,

erosion, hyperpigmentation, hypopigmentation, dysesthesia, numbness

C. Possibility of unexpected adverse events following the participation of clinical trial

6. Principal Investigator

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7. Sponsor

CLASSYS (Inc.) / 240, Teheran-ro, Gangnam-gu, Seoul, Rep. of Korea, (☎ : 070-5165-0024)

8. Contact

Please refer to the following contact information (https://www.alllivec.co.kr / ☎ : 1644-3685 [Call center]) for further inquiry.