

Safety and Effectiveness Evaluation of the High-intensity Focused Ultrasound Device for Lifting Lax Submental and Neck Tissue

NCT07229430

Status	RECRUITING
Phase	Not Applicable
Sponsor	CLASSYS Inc.
Enrollment	273 participants

Key Eligibility Criteria

Inclusion (6)

- Male or female subjects aged 30 to 65 years, inclusive, at the time of informed consent.
- Subjects presenting with mild to moderate submental and/or neck skin laxity, as determined by the investigator.
- Subjects in good general health with stable body weight ($\pm 5\%$) for at least 6 months prior to screening.
- Subjects willing to avoid other aesthetic or dermatologic procedures (surgical or non-surgical) to the treatment area during the study period.
- Subjects able to understand and sign informed consent and comply with all study visits and procedures.

... and 1 more (see full listing online)

Exclusion (10)

- Prior facelift, neck lift, liposuction, or contouring surgery involving the lower face, submental, or neck areas.
- Receipt of any energy-based aesthetic treatment (e.g., HIFU, radiofrequency, laser) or injectable aesthetic treatment (e.g., botulinum toxin, dermal filler, collagen stimulator) to the treatment area within 6 months prior to baseline.
- Presence of any implanted electronic medical device, such as a pacemaker, defibrillator, or neurostimulator.
- Active skin infection, wound, cystic acne, inflammation, or severe scarring within or near the treatment area.
- History of keloid formation or abnormal wound healing.

... and 5 more (see full listing online)

Locations (5 total)

Rebecca Fitzgerald, MD, Inc., Los Angeles, California, United States
Dermatology, Laser & Vein Specialists of the Carolinas, Charlotte, North Carolina, United States
Wilmington Dermatology Center, Wilmington, North Carolina, United States

... and 2 more locations