

K192275 invisa-RED ELITEAug 19, 2020
363 days to decisionK192275 · Product code: **OLI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k192275/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fat Reducing Low Level Laser (OLI)
Date received	Aug 22, 2019
Decision date	Aug 19, 2020
Days to decision	363 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	IR Technology, LLC
Location	Woodstock, GA, US
Contact	Thomas A. Namynanik
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Vidantis Technologies, Inc.
Contact	Thomas A. Namynanik

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT03811093**Comparing the Efficacy of a Dual-Frequency LLLT Device With a Sham Device as a Therapy for Adipose Tissue Loss**

Status	Completed
Enrollment	39 patients (actual)
Study sites	1 site
Condition studied	Obesity; Body Weight; Fat Burn; Cellulite; Abdominal Fat; Adipose Tissue Atrophy
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Double blind
Completion date	Feb 9, 2019
Sponsor	IR Technology, LLC (Industry)

Primary outcome**Change in Body Fat Percentage**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03811093