IR Technology LLC
% Thomas Namynanik
Special Projects Consultant
Vidantis Technologies, Inc
300 Lismore Terrace
Woodstock, Georgia 30189

August 19, 2020

Re: K192275
Trade/Device Name: invisa-RED ELITE
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
Regulatory Class: Class II
Product Code: OLI
Dated: August 22, 2019
Received: August 22, 2019

Dear Thomas Namynanik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin Kejing Chen
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192275

Device Name
InvisaRED™ Technology ELITE

Indications for Use *(Describe)*
The InvisaRED™ Technology ELITE is indicated for use as a non-invasive dermatological aesthetic treatment for the temporary reduction of the circumference of waist, hips, and thighs through the process of photobiomodulation, affecting adipocyte cells within the adipose layer for the release of lipids from these cells.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

The assigned 510(k) Number: K199275

1. Date of Submission:

2. Sponsor

IR Technology LLC 2707 Hampton TRL Woodstock GA 30189

Contact Person: Name: Stephen Reardon
Title: Manager
E-mail: Stephen Reardon info@invisaredtech.com
Phone number: (888) 221-7119

3. Submission Correspondent

Thomas A Namynanik
FDA Compliance Consultant
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Acworth GA Suite 107
30102
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Email: andyn@invisaredtech.com

4. Proposed Device Identification

Proposed Device Name: invisa-RED™ Technology Elite
Common/Usual Name: Fat Reducing Low Level Laser Classification: Class II
Product Code: OLI
Regulation Number: 21 CFR 878.5400
Review Panel: Division of Surgical Devices

5. Predicate Device Identification

Primary Predicate:

510(k) Number: K130341
Product Name: Strawberry, Strawberry & Cream
Manufacturer: LASER LIPO LIMITED

Secondary Predicates**:**

510(k) Number: K123237
Product Name: Zerona 2.0 Laser
Manufacturer: ERCHONIA CORPORATION

510(k) Number: K143741
Product Name: Lipofina Laser System
Manufacturer: YOLO Medical Inc.

510(k) Number: K160880
Product Name: Photonica Professional
Manufacturer: WARD PHOTONICS LLC

6. Device Description

Device console:

- Electrical Power: 110v
- Cooling: Air Cooled
- Operation: LCD touch screen
- Allows Control of Individual Patient Session Protocol (Time, Energy, Pulse, Delay)
- Integrated Device Power-On Self Test
- Emergency Safety cut off switch
- Treatment applicators (multi diode paddles) connected to the device console can number 8,10, or 12
- Paddle Cooling: Air cooled
- Dual Coherent Frequencies: Thirteen (13) 680nm and thirteen (13) 980nm laser diodes on each paddle
- Concurrent Laser Diode Mode of Operation: pulsed or continuous output
- Power output: Variable up to 200mw per diode for both 680nm and 980nm wavelengths

What is invisa-RED™ Technology?

- A patented technology that uses laser diodes to propagate dual coherent laser frequencies of 980nm and 680nm into a patients dermal and adipose tissues for the reduction of the measured circumference of the patients waist, hips, and thighs.

How it works

- The invisa-RED Elite laser diode paddles are secured to the exposed body area of the patient as prescribed for their treatment.
- A patients specific protocol settings for power, pulse, delay and session length are set as prescribed.
- The invisa-RED Elite's laser-diodes of 680nm and 980nm are energized and the dermal and adipose tissues absorb photonic energy experiencing the effects of Photobiomodulation.
- Note: The laser-diode paddle faces are designed with a surrounding raised lip in order to create an offset and air gap to prevent direct contact between the paddle surface and the patients skin.

Detail Science

- Photobiomodulation is defined as the utilization of non-ionizing electromagnetic energy to trigger photochemical changes within cellular structures which absorb photonic energy. The invisa-RED Elite uses concurrent Red and Near Infrared Laser Light for this purpose.
- Lipolysis is the metabolic process through which body fats are released into the interstitial space surrounding the cell, thereby reducing the size of the fat cells. It usually occurs in adipocytes cells which are specialized for the storage of fat.
- The invisa-RED Elite device induces lipolysis through Photobiomodulation in adipocyte cells releasing fat and creating the desired aesthetic of a reduced circumference of the treated body area.

Reference Articles:

Proposed Mechanisms of Photobiomodulation or Low-Level Light Therapy *NCBI*
Lucas Freitas and Michael R Hamblin

The Nuts and Bolts of Low-level Laser (light) Therapy. *Ann Biomed Eng. 2012 Feb;40(2):516-33. doi: 10.1007/s10439-011-0454-7. Epub 2011 Nov 2. PMID: 22045511; PMCID: PMC3288797.*
Chung H, Dai T, Sharma SK, Huang YY, Carroll JD, Hamblin MR.

Efficacy of low-level laser therapy for body contouring and spot fat reduction.
Caruso-Davis MK1, Guillot TS, Podichetty VK, Mashtalir N, Dhurandhar NV, Dubuisson O, Yu Y, Greenway FL.

7. Intended Use

The invisa-RED™ Technology Elite is indicated for use as a non-invasive aesthetic treatment for the temporary reduction of the circumference of waist, hips, and thighs through the process of photobiomodulation affecting adipocyte cells within the adipose layer for the release of lipids from these cells.

8. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate devices. The test results demonstrated that the proposed device complies with the following:

(a) IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance - Standards: IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012
(b) IEC 60601-2-22 Medical electrical equipment Part 2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment - Standards: IEC 60601-2-22:2019 for use in conjunction with IEC 60601-1:2005, AMD1:2012
(c) IEC 60601-1:2005 + AMD 1:2012 US NATIONAL DIFFERENCES Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
(d) IEC 60825-1 Safety of Laser Products Part 1: Equipment Classification and Requirements - Standards: IEC 60825-1:2014 Ed. 3.0 and IEC 60825-1:2007 Ed. 2.0
(e) IEC 60601-1-2:2014
(f) Bio-compatibility Testing - In Vitro Cytotoxicity Test of Diode laser paddle

9. Randomized Double Blind Clinical Study

At the request of CDRH, IR Technology LLC conducted a randomized double blind study with a randomization ratio of 1:1.

The trial was undertaken with subjects comprised of 35 female subjects and 5 male subjects.

A null and alternative hypotheses was adopted for the primary trial endpoint "Change in Measured Body Circumference" as follows:

H0 : μτ = μc vs Ha : μτ ≠ μc where **μτ** and **μc** represent the change in measured body circumference of subjects treated by the invisa-Red Technology and the change in measured body circumference of subjects treated by the sham or placebo device.

Using an intent-to treat population, M=20 Imputations, an estimated mean difference of 6.880 inches greater loss was observed when comparing the totals of the measured areas of the subjects who underwent therapy using the invisa-RED Elite than with the placebo device. This with a 95% confidence interval from 3.715 inches to 10.046 inches and a two tailed P value < 0.001.

Based on the analysis performed the alternative hypothesis (**Ha**) for the superiority trial is affirmed for the primary endpoint (change in measured body circumference) as stated below:

Ha : μτ ≠ μc where **μτ** and **μc** represent the change in measured body circumference of the trial subjects treated with the invisa-Red Technology and the change in measured body circumference of those treated with the sham device.

During the trial no adverse effects or complications as a result of the treatments were reported or observed for any trial subjects. Subsequent to the trial there have been no reports of subjects experiencing any adverse effects or complications.

Conclusion:
A conclusion therefore may be drawn that there is an interventional superiority of the invisa-RED Elite over the sham (placebo) device when employed for aesthetic therapy and that the invisa-RED Elite when used as directed is both clinically safe and effective when used to reduce the measured circumferences of a subjects waist, hips, and thighs.

10. Technological Characteristics Comparison

The predicate devices cited below employ differing wavelengths of laser light. The invisa-RED ELITE™ employs both Red and NIR laser light simultaneously at 680nm and 980nm, which is unique in the marketplace. Therefore in order to address questions of efficacy and safety raised by any technological difference we have included data from a clinical trial which has shown the invisa-RED ELITE™ to be both safe and effective when used as prescribed.

Substantial Equivalence Comparison

ITEM	Proposed Device invisa-RED™ Technology ELITE	Predicate Device Zerona 2.0 Laser (K 123237)	Predicate Device Strawberry/Strawberry & Cream (K 130341)
Product Code	OLI	OLI	OLI
Regulation Number	21 CFR 878.5400	21 CFR 878.5400	21 CFR 878.5400
Class	II	II	II
Intended Use	The invisa-RED™ Technology ELITE is indicated for use as a non-invasive aesthetic treatment for the temporary reduction of the circumference of waist, hips, and thighs through the process of photobiomodulation affecting adipocyte cells within the adipose layer for the release of lipids from these cells. .	The Zerona 2.0 Laser is indicated for use as a non-invasive dermatological aesthetic treatment as an adjunct for individuals intending to undergo liposuction procedures for the reduction of circumference of hips, waist and thighs. .	The Strawberry/Strawberry & Cream is indicated for use as a non-invasive aesthetic treatment for the temporary reduction in waist circumference by the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells.

ITEM	Proposed Device invisa-RED™ Technology	Predicate Device Zerona 2.0 Laser (K 123237)	Predicate Device Strawberry/Strawberry & Cream (K 130341)
Enclosure	Plastic	Same	Same
Wavelength	680nm, 980nm	Green 532	660 +/- 15 nm
Waveform	Pulsed or continuous	Pulsed	Pulsed
Display	LCD	Same	Same
Power Supply	100-240 v ac 50-60 Hz	AC	100-240 v ac 50-60 Hz
Energy Source	200mw per diode	6 diodes, each collected then line dispersed and rotated	Laser Diode from 660nm
Energy Delivery	Machine mounted probe	Same	Same
Paddles	6/8/10/12 pads are optional	4-10	4/6/8/10
Pad Size	130X66mm	Similar	15.0 x 4.5 cm
Safety Features	Emergency Stop button – Key Switch	Similar	Same
Cooling Requirements	Air cooled	Same	Same
Locations for Use	Hospital, healthcare provider office, MediSpas	Same	Same

Substantial Equivalence Comparison Con't

ITEM	Proposed Device invisa-RED™ Technology ELITE	Predicate Device Lipofina Laser System (K 143741)	Predicate Device Photonica Professional (K 160880)
Product Code	OLI	OLI	OLI
Regulation Number	21 CFR 878.5400	21 CFR 878.5400	21 CFR 878.5400
Class	II	II	II
Intended Use	The invisa-RED™ Technology ELITE is indicated for use as a non-invasive aesthetic treatment for the temporary reduction of the circumference of waist, hips, and thighs through the process of photobiomodulation affecting adipocyte cells within the adipose layer for the release of lipids from these cells.	The Lipofina Laser System is indicated for non-invasive aesthetic treatment for the temporary reduction of circumference of hips. .	The Photonica Professional is indicated for use as a non-invasive aesthetic treatment for the temporary reduction of hips, waist and thighs.
Enclosure	Plastic	Same	Same
Wavelength	680nm, 980nm	658 (central)	635 +/- 2 nm
Waveform	Pulsed or continuous	Pulsed	Pulsed
Display	LCD	Same	Same
Power Supply	100-240 v ac 50-60 Hz	100-240 v ac 50-60 Hz	100-240 v ac 50-60 Hz
Energy Source	200mW each for Laser Diodes both 680nm and 980nm	35mW/diode	Laser Diode from 105mW/cm2
Energy Delivery	Machine mounted paddle	Same	Same
Paddles	6/8/10/12 pads are optional	12	Similar
Pad Size	130X66mm	Similar	Similar
Safety Features	Emergency Stop button – Key Switch	Similar	Same
Cooling Requirements	Air cooled	Same	Same
Locations for Use	Hospital, healthcare provider office, MediSpas	Same	Same

11. Substantially Equivalent Conclusion

Based on both clinical trial results and comparative analysis of the intended use, design, energy used or delivered, materials, performance, safety, effectiveness, labeling, biocompatibility, and standards, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.