March 11, 2022

Resurgeonz LLC
Julie Lalonde
CEO
1550 Monte Carlo Court
Merritt Island, Florida 32952

Re: K213534
Trade/Device Name: PHantom Trilogy(TM)
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System For Aesthetic Use
878.5650
Regulatory Class: Class II
Product Code: OLI
Dated: January 20, 2022
Received: January 24, 2022

Dear Julie Lalonde:

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,

Purva Pandya
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)*
K213534

Device Name
Resurgeonz pHantom Trilogy(TM)

Indications for Use *(Describe)*
Resurgeonz pHantom Trilogy(TM) is indicated for use as a non-surgical, non-invasive aesthetic treatment for the temporary reduction of the circumference of waist, hips, thighs through the process of disrupting adipocyte cells, within the fat layer, for the release of fat and lipids from the targeted 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.

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510(k) SUMMARY

510(k) Summary of notification application K213534

Submitter Information	
Submitted By:	Resurgeonz
Address	1550 Monte Carlo Court Merritt Island, Florida 32952
Phone Number	321-222-5959
Fax Number	N/A
Establish Registration No.	622317
Are You a Small Business?	Yes – SBD22819
Name of Contact Person	Julie LaLonde
Contact Person Address	1550 Monte Carlo Court Merritt Island, Florida 32952
Contact Person Phone No.	407-233-6292
Contact Person email	Admin@resurgeonz.com
Date Prepared	November 29, 2020
Name of Medical Device	
Trade or proprietary name	pHantom Trilogy™
Common or usual name	Fat reducing Low Level Laser
Classification name	Fat reducing Low Level Laser system for aesthetic use
Classification panel	General & Plastic Surgery
Regulation	21 CFR 880.5440
Product Code(s)	OLI
Device Classification	II
Legally marketed device(s) to which equivalence is claimed	The Resurgeonz, pHantom Trilogy™ has the following similarities to the predicate device, IR Technology's invisa-RED ELITE (K192275) and Laser LipoLTD, Strawberry and Strawberry and Cream (K130341).

Reason for 510(k)	**New device offering to the non-invasive aesthetic enhancement market.**
Device Description	**The Resurgeonz pHantom Trilogy™ is a non-surgical, non-invasive, fat reducing low level laser system using a combination of Red and Infrared light spectrums to propagate laser frequencies of 660nm, 808nm and 980nm into a patient's dermal and adipose tissues for the reduction of the measured circumference of the patients waist, hips, and thighs. The device features an LCD touchscreen. Mode of operation is continuous. Allows individual patient session controls of: treatment time, energy, pulse and delay. Emergency safety cut off switch. Treatment applicators (multi diode paddles) connected to the device console can number 8,10, or 12. Paddles include built in air fan cooling. Combination of Coherent Frequencies of red and infrared: 26 diodes per big paddle, (13 red diodes at 660nm) and thirteen (13 infrared diodes) of the 13 infrared diodes, (6 diodes) are 808nm and (7 diodes) are 980nm. Two smaller paddles are available to swap out in place of two big paddles. The two smaller paddles only have 2 diodes each of red diodes at 660nm and are used for smaller hard to reach body areas. Power output or each diode is variable up to 72mW to per diode for all red and infrared diodes. The device does not have wireless and/or external wired communication. The device is powered by 120V, 60Hz. There is a side holder for paddles when not in use.**
Technological Characteristics	**For comparison of technological characteristics with the predicates please see the table below.**
Performance Data	**Resurgeonz pHantom TrilogyTM overall performance testing passed all specified test requirements of non-clinical (bench) tests conducted for determination of Substantial Equivalence (SE) results, and show of Substantial Equivalence (SE) with the predicate devices.**
Indication for Use	**Resurgeonz pHantom Trilogy™ is indicated for use as a non-surgical, non-invasive aesthetic treatment for the temporary reduction of the circumference of waist, hips, thighs through the process of disrupting adipocyte cells, within the fat layer, for the release of fat and lipids from the targeted cells.**
Manufacturing Site	**1550 Monte Carlo Court Merritt Island, FL 32952**
Environment for use	**Healthcare provider office, Medi-Spas, and Clinics.**

Single patient use	**No**
Sterilization process	**N/A - The Resurgeonz PHantom Trilogy™ is supplied a non-sterile device. Cleaning instructions are provided in the User Manual.**
Biocompatibility	**Meets acceptance criteria per ISO 10993: Parts 1, 5, and 10 requirements**
Conclusion on Substantial Equivalence	**The Resurgeonz pHantom Trilogy™ described and comparatively analyzed in this submission is determined to be Substantially Equivalent (SE) to the predicate device, for intended use, design, component and materials, operating principles, environment for use, performance, safety, effectiveness, product labeling and packaging, and is supported by the information provided in the 510(k) submission.**
Conclusions drawn from non-clinical and clinical data	**The Resurgeonz pHantom Trilogy™ meets the functional claims,and Intended Use as described in the product Labeling.**
Statement of Safety and Efficacy	**The safety and effectiveness are equivalent to the predicate device K192275 and predicate device K130341. The claim for Substantial Equivalence (SE) is supported by the information provided in the 510(k) submission.**

Characteristic	Subject Device Resurgeonz, LLC PHantom Trilogy™	Predicate Device (K192275) IR Technology invisa-RED ELITE ™	Predicate Device Strawberry/Strawberry & Cream (K130341)
Device Class	II	II	II
Regulation Number	21 CFR 878.5400	21 CFR 878.5400	21 CFR 878.5400
Product Code(s)	OLI	OLI	OLI
Intended Use	Resurgeonz pHantom Trilogy™ is indicated for use as a non-surgical, non-invasive aesthetic treatment for the temporary reduction of the circumference of waist, hips, thighs through the process of disrupting adipocyte cells within the fat layer for the release of fat and lipids from the targeted cells.	The invisa-RED ™ is indicated for use as a non-invasive aesthetic treatment for the temporary reduction of the circumference of waist, hips, thighs through the process of photobiomodulation affecting adipocyte cells within the adipose layer for the release of lipids from these cells.	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.
Technology	Laser lights in the visible red and infrared spectrums	Same	Laser lights in the visible red spectrum
Light Spectrum-Wavelength	Red light (Near Infrared) at 660nm and Infrared at 808nm and 980nm	Red light (Near Infrared) at 680nm and Infrared at 980nm	Red light (Near Infrared) 660 +/- 15nm
Light Waveform	Pulsed and Continuous	Same	Continuous

Laser Type	**Diode Laser**	**Same**	**Same**
Source Power	**120VAC / 60Hz**	**120-240VAC / 50-60Hz**	**100-240V, 50-60Hz**
Light Power Output	**72mW each for Laser Diodes 660nm, 808nm and 980 nm**	**200mW per diode each for Laser Diodes both 680nm and 980nm**	**40 mW +/- 15% for each laser diode 660 nm**
Number of Pads / Paddles	**6, 8, 10 or 12 Big Paddles (optional) (size 130 x 66mm)**	**6, 8, 10, or 12 Big Paddles (optional) (size 130 x 66mm)**	**4,6,8 or 10 Big paddles (optional) (size similar)**
Number of paddles/probes (size small)	**2 (optional) with two 660nm diodes used to replace 2 big paddles**	**NA**	**2 with one 660nm diode each, included with big paddles**
Number of diodes per big paddle	**26 total, 13 red diodes and 13 infrared diodes**	**Same**	**6 red diodes per paddle**
Number of diodes per small paddle	**2 total, 2 red diodes only 660NM**	**NA**	**Similar 1 red diode per small paddle 660NM**
Max number of Near Infrared diodes per system (red)	**156**	**Same**	**62**
Max number of Infrared diodes per system	**156**	**Same**	**NA**
Energy Delivery	**Machine mounted paddles**	**Same**	**NA**
Display	**TFT Color Touchscreen LCD**	**Same**	**same**
Console/Housing	**ABS Plastic**	**Same**	**similar**
Safety Features	**Emergency stop button/key switch**	**same**	**same**
Dust and Liquid ingression	**Rated IPXO**	**Not rated**	**Not rated**

Paddle Cooling	**Forced air cooled system**	**Same**	**NA**
Target Population	**18 years old and over**	**Same**	**Same**
Environment for use	**Healthcare provider office, MediSpas,and Clinics**	**Same**	**Same**
Time of treatment	**10-20 minutes**	**15-20 minutes**	**10-20 minutes**
Target body areas	**Waist, hips, thighs**	**Same**	**waist**
Biocompatibility	**Meets acceptance criteria per ISO 10993: Parts 1, 5, and 10 requirements**	**Same**	**similar**
Sterility	**Non sterile**	**Same**	**Same**
Environmental Conditions for Use	**Operating Temperature: 15.5°C ~ 26.6°C** **Operating Relative Humidity: ≤80%**	**Same**	**Same**
Labeling	**Product warnings and User Manual**	**Similar**	**Similar**
Big Pad Dimension	**130mm x 66mm**	**130mm x 66mm**	**152.4mm x 50.8mm**
Small Pad Dimension	**66mm x 45mm**	**N/A**	**57.15mm x 50.8mm**
Device Dimension	**Approximately 44” x 18” x 14”**	**Approximately 38.6” x 18.5” x 19.68” (98cm x 47cm x 50cm)**	**12” x 12” x 13”**
Device Weight	**Approximately 66.14 lbs**	**108 lbs**	**13 lbs**