Wingderm Electro-Optics Ltd.
℅ Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Service Co., Ltd
8-9th Floor, R&D Building, No.26 Qinglan Street
Panyu District
Guangzhou, 510006 CN

July 31, 2019

Re: K191611
Trade/Device Name: Diode Laser Therapy Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 14, 2019
Received: June 17, 2019

Dear Mike Gu:

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,

Neil R.P. Ogden
Assistant Director, THT4A4
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)*
K191611

Device Name
Diode Laser Therapy Systems

Indications for Use *(Describe)*
The Diode Laser Therapy Systems are intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI).
Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

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

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

Wingderm Electro-Optics Ltd.

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Secondary Contact Person:	Juan Zhou Quality Manager Wingderm Electro-Optics Ltd. Tel: 86-010-62910812
Date Prepared:	June 13, 2019

II. DEVICE

Name of Device:	Diode Laser Therapy Systems, Model WLA-01
Common or Usual Name:	Diode Laser Therapy Systems
Classification Names:	Powered Laser Surgical Instrument (21 CFR 878.4810)
Regulation Class:	II
Product Code:	GEX

III. PREDICATE DEVICE

Predicate device	Diode Laser Therapy Systems: K152898
Reference device	GME LinScan System: K141063

These predicates have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Diode Laser Therapy Systems has one model WLA-01, which mainly consist of the main console, treatment hand piece and a foot switch. The treat hand piece consist of the laser aperture, laser emission indicator, laser emission and hand piece display screen. The main console consist of power switch, hand piece holder, LCD touch screen, emergency shut off, hand-grip grab bar, connector hand piece, access door, observation Window, power input, inlet, air switch, gate interlock connector, foot switch connector, vent, drain and fans. The device has an embedded software named Diode Laser Therapy Systems Control Software.

The principle of laser hair removal is selective photothermolysis, 808nm wavelength effectively penetrates deep into and absorbed by the target chromophore. The adequate pulse duration, energy density and epidermal cooling ensure an adequate thermal damage to the target tissue without damaging the surrounding tissue to achieve effective hair removal.

The laser window of the hand piece will contact the skin directly and the laser output will contact the skin through the window. The Diode Laser Therapy System is suitable for use in healthcare facility/hospital. Only trained personnel who have been trained in the use of laser products and clinical training should be able to use this product for treatment.

V. INDICATION FOR USE

The Diode Laser Therapy Systems are intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI).

Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Diode Laser Therapy Systems are substantially equivalent to the cleared predicate device (K152898) and the reference device (K141063).

The Diode Laser Therapy Systems have same indications for use, patient population and material with the predicates.

Selective photothermolysis is the principle of laser hair removal for both the subject and predicate devices. Melanin selectively absorbs laser energy with wavelength of 808nm, and immediately forms local high temperature. When the temperature in hair follicles rises to some certain degree, thermal expansion occurs in hair follicle. Fractures melanin cells are pushed out of hair pores by steam. Meanwhile, dermal papilla nutrient vessels are damaged because of hemoglobin solidification. Under above dual functions, effective hair removal will be achieved and hair regeneration will be prevented. Treatment time for each pulse is no longer than target tissue s thermal relaxation time, which enables that photothermy effect limits in target tissues and prevent thermal energy damaging surrounding tissues. Epidermal cooling is also designed for the protection of surrounding tissues.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Use the same Class IV Diode Laser as the laser source.
- Use the same 808nm laser wavelength as selective absorption wavelength.
- Use the same energy density
- Use the same pulse width
- Use the same frequency
- Use the same cooling system
- Footswitch or Laser Emission button can control the system.
- Use of a touch Screen Control Panel to display.
- Hand piece is cleaned between patients.
- Anatomical Sites include axilla, facial, bikini, upper limb and lower limb.
- The proposed device is similar with the predicate in Spot Size.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Diode Laser Therapy Systems was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’” May 1, 1995, and International Standard ISO 10993-1 “Biological Evaluation

of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The laser aperture is considered tissue contacting for a duration of less than 24 hours.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Diode Laser Therapy Systems, consisting of the main console, treatment hand piece and foot switch. The system complies with the ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text), IEC 60601-2-22 Edition 3.1 2012-10 and IEC 60825-1: 2014 standards for safety and the IEC 60601-1-2:2014 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure of latent design flaw could directly result in minor injury to the patient or operator.

Clinical Testing

Based on the similarities of the device specifications, intended use, indications for use between the Diode Laser Therapy Systems and its predicate devices, no clinical studies were needed to support this 510(k) Premarket Notification.

VIII. CONCLUSION

The Diode Laser Therapy Systems and its application comply with standards as detailed in section 9, 11 and 17 of this premarket notification. Non-clinical tests determined that the Diode Laser Therapy Systems to be as safe, as effective and performance is substantially equivalent to the predicates.