February 24, 2026

Wingderm Electro-Optics Ltd.
℅ Mike Gu
RA Director
Suzhou Device Innovation Medical Consulting Co., Ltd
Room 1001, Building 19, No. 3188 Renming Road
Suzhou, Jiangsu 215000
China

Re: K252599
Trade/Device Name: Diode Laser Therapy Systems (WLA-02)
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: August 18, 2025
Received: August 18, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2026.02.24 15:25:31 -05'00'

Tanisha Hithe
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252599

Please provide the device trade name(s).

Diode Laser Therapy Systems (WLA-02)

Please provide your Indications for Use below.

The Diode Laser Therapy Systems is intended for use in dermatological procedures requiring coagulation.
Indications for Use:
Mixed Wavelength Handpiece (755 nm + 808 nm + 1064 nm):
·Temporary hair reduction (Hair-Removal function).
·Treatment of benign vascular and vascular-dependent lesions (Vascular-Lesion function).
Single Wavelength Handpieces (755 nm, 808 nm, or 1064 nm):
·Hair removal and permanent hair reduction in all skin types (Fitzpatrick skin types 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 completion of a treatment regimen.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary K252599

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

I. SUBMITTER

Submitter Name and Address:	Wingderm Electro-Optics Ltd. Building 6, No.97 Changping Road, Shahe Town, Changping District, 102206 Beijing, China Phone: +86 - 18513353536 Fax: +86-10-62910812
Primary Contact Person:	Mike Gu Regulatory Affairs Manager Suzhou Device Innovation Medical Consulting Co., Ltd. Phone: +86-139-1401-9083 Email: mike.gu@suzhoumedconsulting.com
Secondary Contact Person:	Juan Zhou Quality Manager Wingderm Electro-Optics Ltd. Phone: +86-10-6291-0812 Email: zhoujuan@wingderm.com
Date Prepared:	August 18, 2025

II. DEVICE

Device Name:	Diode Laser Therapy Systems
Model	WLA-02
Common or Usual Name	Diode Laser Therapy Systems

Classification Name	Powered Laser Surgical Instrument (21 CFR 878.4810)
Regulation Class	Class II
Product Code	GEX

III. PREDICATE DEVICES

Type	**510(k) #**	**Name**
Predicate device	K222064	The Alma Soprano Titanium
Predicate device	K251329	Diode laser device (RF3120-BI)
Predicate device	K172193	Modified Alma Lasers Soprano XL™ Family of Multi-Application & MultiTechnology Platforms [SopranoXL, SopranoXLi, SopranoICE and Soprano ICE Platinum] with Duo and Trio Diode Laser Modules., Soprano Duo and Trio Diode Laser Modules
Predicate device	K170179	Lightsheer Infinity
Predicate device	K191321	Primelase Excellence

IV. DEVICE DESCRIPTION

The Diode Laser Therapy Systems, Model WLA-02, is a medical device intended for dermatological procedures requiring coagulation. It includes mixed and single wavelength handpieces designed for temporary and permanent hair reduction, as well as the treatment of benign vascular lesions. The system delivers controlled laser energy to target melanin or vascular structures while integrated cooling helps protect surrounding skin tissue. The system comprises:

- **Main Console:** Includes power switch, handpiece holder, LCD touch screen, emergency shut-off, hand-grip grab bar, handpiece connector, access door, observation window, power input, inlet, air switch, gate interlock connector, foot switch connector, vent, drain, and cooling fans.

- **Treatment Handpiece:** Incorporates laser aperture, laser emission indicator, laser emission system, and handpiece display screen.
- **Foot Switch:** Activates laser emission.
- **Embedded Software:** Diode Laser Therapy Systems Control Software.

V. INDICATIONS FOR USE

The Diode Laser Therapy Systems is intended for use in dermatological procedures requiring coagulation.

Indications for Use:

Mixed Wavelength Handpiece (755 nm + 808 nm + 1064 nm):

- Temporary hair reduction (Hair-Removal function).
- Treatment of benign vascular and vascular-dependent lesions (Vascular-Lesion function).

Single Wavelength Handpieces (755 nm, 808 nm, or 1064 nm):

- Hair removal and permanent hair reduction in all skin types (Fitzpatrick skin types 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 completion of a treatment regimen.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

The Diode Laser Therapy Systems is substantially equivalent to the cleared predicate devices (K222064, K251329, K172193, K170179 and K191321).

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

Selective photothermolysis is the working principle of laser hair removal for both the subject and predicate devices. Melanin in the hair follicle selectively absorbs laser energy, whether through the Mixed Wavelength Handpiece (755+808+1064 nm combined) or Single Wavelength Handpieces (755 nm, 808 nm, or 1064 nm). This absorption rapidly raises the local temperature in the follicle, resulting in effective thermal damage to targeted structures while sparing surrounding tissue. The controlled pulse duration does not exceed the thermal relaxation time of the target, helping to confine the effect to hair follicles and minimize collateral tissue damage. Epidermal cooling provides additional protection for the

skin. For vascular lesion treatment, laser energy is also selectively absorbed by blood chromophores, coagulating targeted vessels while preserving adjacent tissues.

Comparison table of technological parameters of the Diode Laser Therapy Systems compared to those of the predicate devices is provided below.

Table 1 : The mixed wavelength handpiece hair removal function

Specification	Proposed device	Predicate device	Predicate device
Product Name	Diode Laser Therapy Systems (Mixed wavelength handpiece)	Soprano Titanium (Trio 2 cm^2 applicator)	Diode laser device (RF3120-BI) (Trio-Wavelength Handpiece)
K number	K252599	K222064	K251329
Manufacturer	Wingderm Electro-Optics Ltd.	Alma Lasers Inc.	RiSu Medical Technology Co., Ltd.
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Laser Medium	Diode	Diode	Diode
Wavelength	755&808&1064 nm	755&810&1064 nm	755&808&1064 nm
Fluence	0~8 [J/cm^2]	2~20 [J/cm^2]	2~8 [J/cm^2]
Frequency	1~10 [Hz]	up to 10 [Hz]	10 [Hz]
Pulse Width	5 to 200 [ms]	3.3 to 200 [ms]	3.3 to 200 [ms]
Spot Size	12*20 [mm^2]	2 [cm^2]	12*20 [mm^2]
Indications for Use	Temporary hair reduction	Temporary hair reduction	Temporary hair reduction

Table 2 : The mixed wavelength handpiece vascular lesion function

Specification	Proposed device	Predicate device	Predicate device
Product Name	Diode Laser Therapy Systems (Mixed wavelength handpiece)	Soprano Titanium (Trio 2 cm^2 applicator)	Diode laser device (RF3120-BI) (Trio-Wavelength Handpiece)
K number	K252599	K222064	K251329
Manufacturer	Wingderm Electro-Optics Ltd.	Alma Lasers Inc.	RiSu Medical Technology Co., Ltd.

Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Laser Medium	Diode	Diode	Diode
Wavelength	755&808&1064 nm	755&810&1064 nm	755&808&1064 nm
Fluence	0~80 [J/cm²]	2~120 [J/cm²]	2~60 [J/cm²]
Frequency	1~10 [Hz]	up to 10 [Hz]	1~10 [Hz]
Pulse Width	5 to 200 [ms]	3.3 to 200 [ms]	3.3 to 200 [ms]
Spot Size	12*20 [mm²]	2 [cm²]	12*20 [mm²]
Indications for Use	Benign vascular and vascular dependent lesions	Benign vascular and vascular dependent lesions	Benign vascular and vascular dependent lesions

Table 3 : The single wavelength handpieces

Specification	Proposed device	Predicate device	Predicate device	Predicate device	Predicate device
Product Name	Diode Laser Therapy Systems	Soprano Titanium	Soprano ICE Platinum	Lightsheer Infinity	Primelase Excellence
K number	K252599	K222064	K172193	K170179	K191321
Manufacturer	Wingderm Electro-Optics Ltd.	Alma Lasers Inc.	Alma Lasers Inc.	Lumenis Ltd.	High Technology Products SLU
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Laser Medium	Diode	Diode	Diode	Diode	Diode
Wavelength	755nm, 808nm, 1064 nm	755nm, 810nm	755nm, 810nm, 1064 nm	805nm, 1060nm	755nm, 810nm, 810-1060nm
Fluence	755nm, 808nm: 0~120 [J/cm²] 1064nm: 0~60 [J/cm²]	2~120 [J/cm²]	2~120 [J/cm²]	100 J/cm2	80 J/cm2
Frequency	1~10 Hz	0.5~3Hz(HR) 5~10Hz(SHR)	0.5~3Hz(HR) 5~10Hz(SHR)	Up to 3 Hz	UP TO 3 Hz (static) 5 – 10 Hz (dynamic)
Pulse Width	5~400 ms	810nm,755nm: 3.3~200ms;	810nm,755nm: 3.3~200ms; 1064nm: 3.3~280ms	5~400 ms	3~400 ms/ AUTO (3 ms)
Spot Size	12*20 [mm²]	810nm: 2 [cm²], 755nm: 1.5 [cm²]	810nm: 1.2 [cm²] and 2 [cm²], 755nm: 1.5 [cm²] 1064nm: 1 [cm²]	9x9, 27x9, 22x35 [mm²]	20x9, 30x9, 30x17 [mm²]

VII. **PERFORMANCE DATA**

The following performance data support the substantial equivalence determination for the Diode Laser Therapy Systems, Model WLA-02. All tests were conducted by accredited laboratories adhering to FDA-recognized standards and Good Laboratory Practices (GLP).

Biocompatibility Testing:

Evaluated per FDA's guidance "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process" (September 8, 2023) and ISO 10993-1:2018. The laser aperture, a tissue-contacting component for <24 hours, was tested for:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-23)

Results confirm the device is biocompatible and equivalent to predicate devices.

Electrical Safety and Electromagnetic Compatibility (EMC):

Tested per:

- IEC 60601-1:2005+AMD1:2012+AMD2:2020
- IEC 60601-1-2:2014+AMD1:2020 CSV
- IEC 60601-2-22:2019
- IEC TS 60601-4-2:2024
- IEC 60825-1:2014

The system complies with all applicable standards, ensuring safe operation and electromagnetic compatibility.

Software Verification and Validation:

Conducted per FDA's guidance *Content of Premarket Submissions for Device Software Functions* (June 14, 2023).

Based on the software architecture and risk controls—including manual activation, interlocks, and emission gating—the Diode Laser Therapy Systems Control Software qualifies for **Basic Documentation Level.**

Verification and validation confirmed reliable performance with no failures that could result in patient or operator harm.

Clinical Testing:

No clinical studies were required due to the technological similarity and identical intended use with the predicate devices, as supported by non-clinical testing and FDA guidance.

VIII. CONCLUSION

The Diode Laser Therapy Systems, Model WLA-02, has undergone comprehensive non-clinical testing to demonstrate substantial equivalence to the predicate devices (K222064, K251329, K172193, K170179 and K191321).

The device is as safe, as effective, and performs comparably to the predicates, with no new questions of safety or effectiveness raised by technological differences.