December 26, 2024

Shanghai Wonderful Opto-Electrics Tech.Co.,Ltd
Lily Zhou
Management Representative
2F, Building 11, Lane 1175, Tongpu Rd,
Shanghai, 200333
China

Re: K243037
Trade/Device Name: Diode Laser System model Dawn-S
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: July 22, 2024
Received: September 27, 2024

Dear Lily Zhou:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Shlomit Halachmi -S

Digitally signed by Shlomit Halachmi -S
Date: 2024.12.26 17:23:42 -05'00'

Shlomit Halachmi
For 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243037

Device Name
Diode Laser System model Dawn-S

Indications for Use *(Describe)*
The Diode Laser System model Dawn-S is indicated for incision, excision, ablation, vaporization, and coagulation of body soft tissues in surgical application.
The 980nm diode laser is generally indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue, including: general surgery, ENT (ear, nose, and throat) and oral surgery (otolaryngoloty), dental procedures, dermatology, plastic surgery, podiatry, urology, gastroenterology, and gynecology. The laser is further indicated for laser assisted lipolysis.

The 1470nm diode laser is indicated for use in surgical applications requiring the vaporization,incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, Endovascular, coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The laser is further indicated for laser assisted lipolysis.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K243037

Date Prepared: December 26, 2024

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 801.92

1. Submitter's Information

Name of Sponsor:	Shanghai Wonderful Opto-Electrics Tech. Co., Ltd.
Address:	2F, Building 11, Lane 1175, Tongpu Rd., Shanghai 200333, China
Contact Name:	Lily Zhou
Telephone No.:	0086-021-62642623
Fax No.:	0086-021-52827988
Email Address:	regulatory@wonderful-sh.com

2. Correspondent's Information

Company Name:	Shanghai Wonderful Opto-Electrics Tech. Co., Ltd.
Correspondent Name:	Lily Zhou
Telephone No.:	0086-021-62642623
Email Address:	regulatory@wonderful-sh.com

3. Trade Name, Common Name, Classification

Trade Name:	Diode Laser System
Common Name:	Powered Laser Surgical Instrument
Model:	Dawn-S
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Product Code:	GEX
Classification Panel:	General and Plastic Surgery
Device Class:	II
Classification Regulation:	21 CFR 878.4810

4. Identification of Predicate Device(s)

The identified predicates within this submission are as follows:

Predicate Devices:	510 (k) number: K212734 Trade name: Diode Laser Therapy Device Product code: GEX
	510(K) number:K240747 Device name: Medical Diode Laser Product code: GEX
	510 (k) number: K240644 Device name: Medical Diode Laser Product code: GEX

5. Description of the Device

The Diode Laser System model Dawn-S is intended for delivery of dual wavelength laser beam to soft tissue. The Diode Laser System model Dawn-S generates a 1470nm wavelength laser and 980nm wavelength laser.

The laser is controlled via a high-resolution color touch screen. The touch screen display includes a user interface allowing selection of CW and Pulse mode as well as duty cycle and frequency of operation, laser power level and Stand-by/Ready selection.

The laser system consists of an optical block with contains the laser diode, mirrors, lens, and aiming beam diode, an air cooling system, and the laser power system, as well as an external footswitch for laser activation.

6. Intended Use/Indication for Use

The Diode Laser System model Dawn-S is indicated for incision, excision, ablation, vaporization, and coagulation of body soft tissues in surgical application.

The 980 nm diode laser is generally indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue, including: general surgery, ENT (ear, nose, and throat) and oral surgery (otolaryngology), dental procedures, dermatology, plastic surgery, podiatry, urology, gastroenterology, and gynecology. The laser is further indicated for laser assisted lipolysis.

The 1470nm diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ ENT and Radiology, Oral Surgery and Dental procedures, Endovascular, coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The laser is further indicated for laser assisted lipolysis.

7. Technological Characteristics

The Diode Laser System model Dawn-S uses the same technology that is utilized in the predicate device. A comparison of technological characteristics is provided in the following table:

Item	Diode Laser System model Dawn-S	Predicate Device			Comparison
General Information					
Product Code	GEX	GEX	GEX	GEX	Identical
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Identical
Class	II	II	II	II	Identical
Product Name	Diode Laser System model Dawn-S	Diode laser therapy device	Medical Diode Laser	Medical Diode Laser	
510 (K) No.	K243037	K212734	K240747	K240644	
Models	Dawn-S	ST-AR	M2-GK	S1Pro	
Indications for Use	The Diode Laser System model Dawn-S is indicated for incision, excision, ablation, vaporization, and coagulation of body soft tissues in surgical application. The 980 nm diode laser is generally indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue, including: general surgery, ENT (ear, nose, and throat) and oral surgery (otolaryngology), dental procedures, dermatology, plastic surgery, podiatry, urology, gastroenterology, gynecology. The laser is further indicated for laser assisted lipolysis. The 1470 nm diode laser is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, Endovascular	The Diode laser therapy device is intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures. The device ' s 980 nm laser is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery(otolaryngology), dental procedures, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology. The device is further indicated for laser assisted lipolysis. The device's 1470nm laser is intended for delivery of laser light to soft tissue in non-contact mode during general surgery procedures, indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	The Medical Diode Laser (Model: M2-GK) is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The Medical Diode Laser (Model: M2-GK) is further indicated for laser assisted lipolysis.	The Medical Diode Laser(Model: S1Pro) is indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology, Thoracic Surgery, Plastic Surgery and Dermatology, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Oral Surgery and Dental procedures, Endovascular coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The Medical Diode Laser(Model: S1 Pro) is further indicated for laser assisted lipolysis.	Indications for use of the 980nm diode laser are the same as the indications of the 980nm laser in K212734. Indications for use of the 1470nm diode laser are identical to the indications for use of the 1470nm laser in K240747 and K240644.

	coagulation and endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The laser is further indicated for laser assisted lipolysis.				
Performance Information					
Wavelength	980nm, 1470nm	980nm, 1470nm	980nm, 1470nm	1470nm	Identical
Output Power	15W (980nm) 15W (1470nm)	16W/980nm±20%, 4.5W/1470nm±20%	30W-980nm 15W-1470nm	12W-1470nm	980nm power is similar to K212734, only 1W lower. 1470nm power is identical to K240747 and slightly higher than K240644
Aiming Beam	650nm, <5mW, adjustable	650 nm, red 0.5 mW, user controlled intensity	Red 650nm (<2mW)	Diode laser of 650 nm, power <2 mW, adjustable brightness.	Same wavelength, red light, the aiming beam of subjected and predicated devices are all classified as the lowest safety level, Class I.
Operation Mode	Continuous or Pulsed	Continuous or Pulsed	CW, Pulsed, Single Pulse	Continuous wave, single pulsed, pulsed	Identical
Pulse Duration	10-990ms	980nm 1% ~ 100%, 1470nm 2% ~100%, continuously adjustable energy	10ms-1s	10-990ms	Identical to K240644
Power Supply	100-240V, 50-60Hz	AC110V±11V, 60HZ	100-240V, 47-63 Hz	100-240VAC, 50-60Hz	Identical
User Interface	8” Color touch screen	Color touch screen	Color touch screen	Color touch screen	Identical
Laser Beam Delivery	Fiber	Sterile fiber, for single use	Fiber	Bare Fiber	Identical
Cooling System	Air cooled	Air cooled	Air cooled	Air cooled	Identical
Safety Information					
Non-clinical Safety testing	IEC 60601-1:2005+AMD 1:2012+AMD2:2020 ;IEC 60601-1-2 :2014+A1: 2020 ;IEC 60825-1: 2014;IEC 60601-2-22: 2019	Comply with IEC 60601-1:2005+A1:2012, IEC 60825-1:2014,IEC 60601-2 22:2007+A1:2012; IEC	IEC 60601-2-22:2007, IEC 60601-1:2005（Third Edition); IEC 60825-1:2007; EN	IEC 60601-1: 1988+AI:1991+A2:1995: IEC60601-1-2 IEC 60601-2-22:1995	Same standard as predicate devices, but comply with

		60601-1-2:2014	60601-1-2:2007	IEC 60825-1:2007	the latest version

8. Discussion of Non-clinical Testing

To verify the performance requirements of Diode Laser System model Dawn-S, the following tests were performed. It shows that the testing results do support substantial equivalence.

IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60825-1 Edition 2.0 2007-03
Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]

IEC 60601-2-22 Edition 3.1 2012-10
Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

9. Brief discussion of clinical tests

No human clinical data is need for Diode Laser System model Dawn-S

10. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Shanghai Wonderful Opto-Electrics Tech Co., Ltd. concludes that:

- The indications for use of Diode Laser System model Dawn-S are the same as those of the predicate devices.
- The technological characteristics are the same or similar to those of the predicate devices.
- Demonstrated by the safety and performance tests, Diode Laser System model Dawn-S is substantially equivalent to the predicate devices.