October 27, 2026

Risu Medical Technology Co., Ltd.
% Owen He
Consulant
Microkn Medical Technology Service (Shanghai) Co., Ltd.
Rm. 901, Huafa Center, 889 Pinglu Rd., Jing 'An District
Shanghai, Shanghai 200040
China

Re: K262349
Trade/Device Name: Diode laser device (DT25-BI, DT212-BI, DT213-BI, DT214-BI, DT215-BI)
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: September 28, 2026
Received: September 28, 2026

Dear Owen He:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@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: 2026.10.27 16:14:36 -04'00'

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

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)*
K262349

Device Name
Diode laser device(DT25-BI, DT212-BI, DT213-BI, DT214-BI, DT215-BI)

Indications for Use *(Describe)*
The Diode laser device 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 Diode laser device is further indicated for laser assisted lipolysis.
Diode Laser in low level laser therapy:
Temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.

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
K262349

1. Contact information

1.1. Applicant

Applicant Name: Risu Medical Technology Co., Ltd.

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Email: yangfuyan@risumed.com

Date prepared: Oct. 27. 2026

1.2. Consultant

Company: Microkn Medical Technology Service (Shanghai) Co.,Ltd.

Address: Room 901, No. 889, Pinglu Road, Jing'an District, Shanghai (Shanghai Jing'an HUAFA Center)

Contact Person: Mr. Owen He

Telephone: +86 13524136210

Email: fda@microkn.com

2. Device information

- Trade Name: Diode laser device
- Model(s): DT25-BI, DT212-BI, DT213-BI, DT214-BI, DT215-BI
- Classification: II
- Product Code: GEX
- Regulation Number: 21 CFR 878.4810

3. Indications for Use

The Diode laser device 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 Diode laser device is further indicated for laser assisted lipolysis.

Diode Laser in low level laser therapy:

Temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood

circulation and/or temporary relaxation of muscles.

4. Legally Marketed Predicate Device

✧ Predicate Device 1

- Trade/Device Name: Medical Diode Laser (M2-GK)
- 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
- 510k number: K240747

✧ Predicate Device 2

- Trade/Device Name: SkyPulse
- 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
- 510k number: K193656

✧ Reference Device

- Trade/Device Name: D-Laser Blue, D-Laser 16
- 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
- 510k number: K210367

5. Description of the device

This medical device utilizes a Diode Laser to achieve therapeutic functions and can output continuous or pulsed infrared laser with nominal wavelengths of 980 nm and 1470 nm. The device is equipped with a 650 nm red indicator semiconductor tube for positioning and marking the laser irradiation area. The product consists of a main unit, power cord, foot switch, and protective glasses. The power cord connects the main unit to the mains power supply, providing the necessary electrical energy for operation. The main unit contains a power supply device, a control device, and a Diode Laser light source. The power supply device distributes electrical energy to each component. The control device (including a 10.4-inch touch display screen and a control board) sends control signals to the control board by adjusting user interface parameters, thereby controlling and adjusting the laser output energy and frequency. The Diode Laser light source is responsible for emitting the laser, and its emission on/off is controlled by the foot switch. The protective glasses are used to protect the operator's eyes during operation.

6. Non-Clinical Test

6.1 Safety and Performance test

The proposed device has been tested according to the following standards for basic safety, laser safety, and essential performance:

IEC 60601-1:2005+A1:2012+A2:2020 – Medical electrical equipment – Part 1:

General requirements for basic safety and essential performance

IEC 60825-1:2014 – Safety of laser products – Part 1: Equipment classification and requirements

IEC 60601-2-22:2019 – Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

The safety and performance of the device meet the applicable requirements of the above standards.

6.2 EMC test

The proposed device has been tested according to the following electromagnetic compatibility standards:

IEC 60601-1-2:2014+A1:2020 – Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

IEC TR 60601-4-2:2016 – Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

The EMC properties of the device meet the applicable requirements

6.3 Bench test

The proposed device has been tested according to the following items:

Appearance Requirements, Laser Wavelength, Laser Terminal Output Power, Laser Output Power Instability, Reproducibility of Laser Output Power, Laser Pulse Width, Laser Pulse Interval, Aiming Beam, Software Functions

6.4 Software test

Software verification and validation testing were conducted and documentation was

provided as recommended by FDA's Guidance for Industry and FDA Staff, “Content of Premarket Submissions for Device Software Function”.

The recommended Documentation Level for software of this device was considered as a “Basic Documentation Level " and the documentation was provided accordingly

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

The Diode laser device has been carefully compared to the legally marketed predicate devices with General comparison (Table 1: vs. K240747 for 980nm and 1470nm wavelengths), and General comparison (Table 2: vs. K193656 and K210367 for 650nm wavelength).

Table 1 General comparison

Item	**Proposed Device (K262349)**	**Predicated device 1 (K240747)**	**Remark**
Product Code	GEX	GEX	SE
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SE
Class	II	II	SE
Indication for use	The Diode laser device 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,	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,	SE

	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 Diode laser device is further indicated for laser assisted lipolysis.	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.	
Use of Device	Rx only	Rx only	SE
Laser Type	Diode laser	Diode laser	SE
Laser Classification	Class IV	Class IV	SE
Configuration	Main Unit	Main Unit	SE
	Foot Control	Foot Control	
Wavelength	980nm 1470nm	980nm 1470nm	SE
Max Power	980nm-30W	980nm-30W	SE

	1470nm-15W	1470nm-15W	
Operation Mode	CW, QCW	CW, single pulse, repeat pulse	Note1
Pulse Duration	10ms – 1s	10 ms – 1s	SE
Repetition Rate	0.5 to 50 Hz	0.5 to 50 Hz	SE
Aiming Beam	650nm, ＜2mW	Red 650nm (<2mW)	SE
Cooling Method	TEC + Air Cooling	Air cooling	Note 2
Delivery System	Optical Fiber Output	Fiber delivery	SE
User Interface	LCD capacitive touch screen	Color LCD touch screen	SE
Microprocess or Control	Yes	Yes	SE
Power Supply	AC100-240V, 50/60Hz, 500VA	100-240VAC, 50/60Hz, 4A-2A	Note 3
Dimensions &Weight	343×230×318 mm (L×W×H); 10kg	29cm (L) x 25cm (W) x13cm (H) ≤8 Kg.	Note 4

Table 2 General comparison

Item	Proposed Device (K262349) 650nm Low level laser therapy	Predicated device 2 (K193656) 670nm Low level laser therapy	Reference Device (K210367) 650nm Low level laser therapy	Remark
Indication for use	Temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.	Temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.	Temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, and for the temporary increase in local blood circulation and/or temporary relaxation of muscles.	SE
Energy source	Solid state diode	Solid state diode	Solid state diode	SE
Wavelength	650nm	670 nm	650	Note 5
Power range	0.1 – 0.2W	0.1-4 W	25mW-200 mW; CW	Note 6
Pulse width	10ms-1s; CW	10ms-10s; CW	/	Note 7
Repetition rate	0.5 to 50 Hz	up to 100 Hz	1 Hz - 20kHz	Note 8

Delivery system	Optical Fiber Output	Fiber delivery	Optical Fiber Output	SE
User interface	Touch screen control	Touch screen control	Touch screen control	SE

Note 1:

The subject device offers CW and QCW (understood as repeat mode, substantial equivalent to repeat pulse mode of the predicate device), while the predicate device offers CW, single pulse, and repeat pulse modes. Both devices provide CW mode and pulsed modes for soft tissue surgical applications. The difference in pulse mode terminology does not affect the safety or performance of the devices.

Note 2:

The subject device uses TEC (Thermoelectric Cooling) combined with air cooling, while the predicate device uses air cooling only. TEC provides more efficient and stable thermal management for the laser diode, enhancing device reliability and longevity. This difference does not affect clinical performance or safety.

Note 3:

The subject device specifies input power of 500VA, while the predicate device specifies 4A-2A at 100-240VAC. Both are equivalent and compatible with standard mains supply (100-240VAC, 50/60Hz). The difference in specification format does not affect safety or performance.

Note 4:

The subject device has dimensions of 343×230×318mm and weighs 10kg, while the predicate device measures 29×25×13cm and weighs ≤8kg. The differences in size and weight are due to design choices (larger touchscreen, enhanced TEC cooling system, dual-wavelength integration) and do not affect clinical safety or performance for the intended use.

Note 5:

The subject device's 650nm wavelength and the reference device's 650nm wavelength are the same.

Note 6:

The subject device's 0.1-0.2W power range for 650nm falls within the predicate's 0.1-4W range. For

LLLT applications, both devices utilize the same low-power output levels (0.1-0.2W) to achieve temporary relief of minor muscle and joint pain, stiffness, arthritis pain, muscle spasm, and temporary increase in local blood circulation. The predicate's higher maximum power (4W) is not relevant to the LLLT indication being compared.

Note 7:

The subject device's pulse width, 10ms–1s (CW available), is within the range of the pulse width of the predicate device, 10ms–10s (CW available).

Note 8:

The subject device repetition rate, 0.5 to 50 Hz, is within the range of the predicate's repetition rate (up to 100Hz).

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined tobe Substantially Equivalent (SE) to the predicate devices.