June 6, 2023

Triangel Rsd Limited
% Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room608,No.738,Shangcheng Rd.,Pudong
Shanghai, Shanghai 200120
China

Re: K212734
Trade/Device Name: Diode laser therapy device
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: April 28, 2023
Received: May 1, 2023

Dear Boyle Wang:

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,

Jianting Wang -S

Jianting Wang
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212734

Device Name
Diode laser therapy device

Indications for Use *(Describe)*
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 980nm 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

510(k) number: K212734
This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

1.0 Submitter's information

Name: TRIANGEL RSD LIMITED
Address: Center Building 4, C Unit 324, #3088, Lekai North Street, Power Valley Technology, Baoding City, Heibei, China
Phone Number: 86-18931273229
Contact: Zhao Fengdan
Email: triangelrsd@triangelaser.com
Date of Preparation: Jun.02, 2023

Prior submissions
This is the first submission, there is no prior submission.

Designated Submission Correspondent
Mr. Boyle Wang
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No. 738 Shangcheng Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device information

Trade name: Diode laser therapy device
Common name: Powered Laser Surgical Instrument
Regulation name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Model(s): ST-AR.

3.0 Classification

Production code: GEX
Regulation number: 21 CFR 878.4810
Classification: Class II
Panel: General & Plastic Surgery

4.0 Predicate device information

510(k) Number: K081015
Product Name: Ceralas Diode 980nm Laser System
Manufacturer: Biolitec, Inc.

510(k) Number: K073063
Product Name: 15W Ceralas Diode 1470nm Laser System
Manufacturer: Biolitec, Inc.

5.0 Indication for Use Statement

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 980nm 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.

6.0 Device description

The diode laser generates a 980nm wavelength laser to act on a target tissue to achieve resection, hemostasis, ablation, and coagulation of the target tissue.
The diode laser generates a 1470 nm wavelength laser that acts on the water molecules of the target tissue to achieve the function of treatment of reflux of the saphenous veins associated with varicose veins and varicosities.
The Diode laser therapy device has following characteristics:

- Dual wavelengths
- Temperature monitoring system

7.0 Non-Clinical Test Conclusion

Table 1 - Product Technical Specification

Item	Technical specification
Wavelength	980nm±5nm, 1470nm±5nm
Max Power	16W/980nm±20%, 4.5W/1470nm±20%, 0.5mw/650nm
Security Level	Class IV type B
Laser Output Mode	Continuous, Pulse, Single.
Pulse Width	0.05ms-1s (stepping 0.05, 0.1ms)
Cooling	Air Cooling
Size	38×46.5×22.5cm
Net Weight	8KG
Fuse	Ø5×25, 2A
Laser Output Power	16W/980nm±10%, 4.5W/1470nm±10%

	0.05mw/650nm
Fiber Diameter	Φ400
Aiming beam	650 nm, red 0.5 mW, user controlled intensity
Treatment mode	Continuous, Pulse , Single.

Table 2 - Biocompatibility testing for components contacting patients

Item	Proposed Device	Result
Cytotoxicity	Under the conditions of the study, the device is noncytotoxic.	Pass
Irritation	Under the conditions of the study, the device is nonirritating.	Pass
Sensitization	Under the conditions of the study, the device is nonsensitizing	Pass
Aucte systemic toxicity,	Under the conditions of the study, the device does show aucte systemic toxicity	Pass
Pyrogen test	Under the conditions of the study, the device does show pyrogen	Pass
In vitro hemolytic test	Under the conditions of the study, the device does show In vitro hemolytic risk	Pass

8.0 Clinical Test Conclusion

No clinical study implemented for the Diode laser therapy device.

9.0 Technological Characteristic Comparison Table

Table 3- General Comparison

Item	Proposed device	Predicated device		Remark
Product Code	GEX	GEX	GEX	Identical
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Identical
Class	II	II	II	Identical
Product name	Diode laser therapy device	Ceralas Diode 980nm Laser System	15W Ceralas Diode 1470nm Laser System	-
510(k) No.	K212734	K081015	K073063	-
Models	ST-AR	D15	D1470	-
Intended use	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 980nm 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 Ceralas D 980 is intended for delivery of laser light to soft tissue in the contact or noncontact mode during surgical procedures, including via endoscopes, introducers, or catheters. The Ceralas D 980 is generally indicated for incision, excision, vaporization, ablation, hemostasis, or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery, and cardiothoracic surgery, and	-	* Gap 1

		ophthalmology. This Ceralas D 980 is specifically 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 Ceralas D1470 is a diode laser that is intended for delivery of laser light to soft tissue in non-contact mode during general surgery procedures. The device is indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.	Same
Patient Population	Adult	Adult	Adult	Same

* Gap analysis:

Gap 1: The proposed device does not use with the endoscope, the indication of Arthroscopy, Cardiothoracic Surgery, Pulmonary Surgery, Neurosurgery, treatment of reflux of the saphenous veins associated with varicose veins and varicosities, which the predicate device applies does not apply to the proposed device, less indication will not bring additional risks to the proposed device.

Gap 2: The proposed device defines specific contraindication which does not bring additional clinical risk for the product use.

Table 4- Performance Comparison

Item	**Proposed Device**	**Predicate Device**		**Remark**
	Diode laser therapy device	Ceralas Diode 980nm Laser System	15W Ceralas Diode 1470nm Laser System	
	K212734	K081015	K073063	

Wavelength	980nm±5nm,1470nm±10nm	980 nm	1470 nm	Same
Output Power max.	16W/980nm±20%, 4.5W/1470nm±20%	15 Watt	15 Watt	* Gap 2
Aiming beam	650 nm, red 0.5 mW, user controlled intensity	635 nm, red 4 mW, user controlled intensity	635 nm, red 4 mW, user controlled intensity	* Gap 3
Treatment mode	Continuous or Pulsed	Continuous or Pulsed	Continuous or Pulsed	Same
Power supply	AC110V±11V, 60HZ	110/220 V	110/220 V	* Gap 4
Interval	980nm 1% ~ 100%, 1470nm 2% ~100%, continuously adjustable energy	980nm 1% ~ 100%, continuously adjustable energy	1470nm 2% ~100%, continuously adjustable energy	Same
Cooling system	Air cooled	Air cooled	Air cooled	Same
Fiber (applied part)	Sterile, for single use	Single use or repeated use	Single use or repeated use	* Gap 5

* Gap analysis:

Gap 2, the 980nm max power of the proposed device is close to the predicate device, which does not create additional risk to the product use. For 1470nm max power of the proposed device is different to the predicate device, we collect clinical survey data, and clinical literature which can support the efficacy of the 4.5W is effective to realize its intended performance, the lower 4.5W can not create additional clinical risks compared to predicate device.

Gap 3, the aiming beam of the two device are close, which difference does not create additional risks to the product clinical use.

Gap 4, the power supply range of the proposed device is included in the predicate device.

Gap 5, the fiber (applied part) of the proposed device is for single use, sterile, which will not create addtional risks compared to the equivalence device.

Table 5- Safety Comparison

Item	Proposed Device	Predicate Device	Remark

	Diode laser therapy device	Ceralas Diode 980nm Laser System	15W Ceralas Diode 1470nm Laser System	
	K212734	K081015	K073063	
Materials contacting user	Fiber	Fiber	Fiber	Same
Biocompatibility of materials contacting user	Cytotoxicity, Comply with ISO 10993-5; Irritation, Sensitization, comply with ISO 10993-10; Aucte systemic toxicity, Pyrogen test comply with ISO 10993-11; In vitro hemolytic test comply with ISO 10993-4.	Cytotoxicity, Comply with ISO 10993-5; Irritation, Sensitization, comply with ISO 10993-10	Cytotoxicity, Comply with ISO 10993-5; Irritation, Sensitization, comply with ISO 10993-10	Gap 6
Electric safety	Comply with IEC 60601-1:2005+A1:2012, IEC 60825-1:2014, IEC 60601-2-22:2007+A1:2012	Comply with IEC 60601-1, IEC 60825-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60825-1, IEC 60601-2-22	Same
EMC	Comply with IEC 60601-1-2:2014	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same

* Gap analysis:

Gap 6: the proposed device implement more biocompatibility study for the device, which does not create additional risks for product use

10.0 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Diode laser therapy device is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K081015, K073063.