September 3, 2025

Beijing Superlaser Technology Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.
FangShan District
Beijing, Beijing 102401
China

Re: K251457
Trade/Device Name: Diode laser therapy device (VADER)
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 29, 2025
Received: August 29, 2025

Dear Ray 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 (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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2025.09.03 14:08:51 -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

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.	K251457 ?

Please provide the device trade name(s). ?

Diode laser therapy device (VADER)

Please provide your Indications for Use below. ?

Diode laser therapy device (Model:VADER) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.
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.

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: K251457

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: ————————————

1. Date of Preparation:2025/04/28

2. Sponsor Identification

Beijing Superlaser Technology Co., Ltd

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Diode laser therapy device
Common Name: Powered Laser Surgical Instrument
Model(s): VADER

Regulatory Information:
Classification Name: Powered Laser Surgical Instrument
Classification: II;
Product Code: GEX;
Regulation Number: 21 CFR 878.4810；
Review Panel: General & Plastic Surgery;

5. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K210168
Product Name: Diode Laser Therapy Systems
Manufacturer: BEIJING KES BIOLOGY TECHNOLOGY CO., LTD.

Reference Device-1
510(k) Number: K241498
Product Name: Diode laser Treatment System
Manufacturer:HEBEI KEYLASER SCI-TECH Co.,Ltd

Reference Device-2
510(k) Number: K210663
Product Name: Dermatological Diode Laser Systems
Manufacturer:Beijing HuaCheng Taike Technology Co., Ltd.

Reference Device-3
510(k) Number: K142845
Product Name: SILKPRO Laser Hair Removal System
Manufacturer:Wuhan Lotuxs Technology Co., Ltd.

6. Device Description:

Diode laser therapy device is a surgical device, which is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI);

The Diode laser therapy device utilize a semiconductor diode with invisible infrared radiation as a laser source to emit 808nm wavelength laser which is absorbed by melanin. The laser power is delivered to the treatment area via laser handle. The emission laser is activated by foot-switch or

handle button.

The laser light targets on melanin and treat selectively in a precise way. Melanin could absorb the energy from the laser, which would result in temperature rapid increase, to destroy germinal cell and does not damage epidermis and the surrounding normal tissue. After laser exposure, the debris of these cells is removed from the body by phagocytic cells.

The Diode laser therapy device has a Treatment Handpiece and 2 removable Treatment of the head. The Treatment of the head can be mounted by means of magnetic attraction.

7. Indication For Use Statement:

The Diode laser therapy device (Model:VADER) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.
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.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	**Proposed Device**	**Predicate Device K210168**	**Reference Device K241498**	**Reference Device K210663**	**Reference Device K142845**	**Remark**
Device Name	Diode laser therapy device	Diode Laser Therapy Systems	Diode laser Treatment System	Dermatological Diode Laser Systems	SILKPRO Laser Hair Removal System	/
Classification Panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	SAME
Product Code	GEX	GEX	GEX	GEX	GEX	SAME
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	II	II	II	II	II	SAME
Indication for Use	The Diode laser therapy device (Model:VADER) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. 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.	The Diode Laser Therapy Systems are intended for hair removal permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. 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.	The Diode laser Treatment System (Model: K18) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. 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.	The Dermatological Diode Laser Systems(Model:CM01D/CM02D) is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-Vl), including tanned skin. 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.	SILKPRO is an over-thecounter device intended for adjunctive use shaving for hair removal sustained with periodic treatments.SILKPRO is also intended for pemmanent reduction in hair regrowth defined as a long-term,stable reduction in hair counts following a treatment regime.	SAME

Table 2 Performance Comparison

Item	**Proposed Device**		**Predicate Device K210168**	**Reference Device K241498**	**Reference Device K210663**	**Reference Device K142845**	**Remark**
Laser Type	Diode Laser		Diode Laser	Diode Laser	Diode Laser	Diode Laser	SAME
Laser Classification	Class IV		Class IV	Class IV	Class IV	Class IV	SAME
Laser Wavelength	808 nm		808 nm	808 nm	808 nm	810 nm	SAME
Spot Size	12×12mm	12×20mm	12 mm×12 mm =1.44 cm²	12mm × 24mm	10*30mm	9mm ×9 mm （0.81cm²）	Analysis 1
Fluence	1-125 J/cm²	1-75 J/cm²	10-125 J/cm2	1-70J/cm2	5-100J/cm2	5-25J/cm2	Analysis 3
Frequency	1-10 Hz	1-10 Hz	1-10 Hz	1-10 Hz	1-10Hz	/	Analysis 4
Pulse Duration	10-400 ms	10-400 ms	10-400 ms	3-320ms	15-400ms	/	SAME
Configuration	Main Unit		Main Unit	Main Unit	Main Unit	/	SAME
	Handpiece		Handpiece	Handpiece	Handpiece	/	SAME
	Foot Control		Foot Control	Foot Control	Foot Control	/	SAME
Power Supply	AC 110V/60Hz		99V-121V, 50/60Hz 1400VA	AC 110V, 50Hz/60Hz	AC 110V/60Hz	AC100~240，50/60Hz	Analysis 2
Dimension	436 x 318 x 271mm		450×430×1000mm	460×370×1150mm	65cm*65cm*123cm	/	
Weight	24kg		52kg	52kg	75KG	/	

Analysis：

Analysis 1:

The proposed device is different in Spot Size from the predicate, Spot size only affects the area of treatment, not affect the therapeutic effect. Therefore, this difference will not affect the safety and effectiveness.

Analysis 2:

The proposed device is different in Dimension and Weight from the predicate device. However, the dimension and weight difference are just in physical specification and this difference will not raise any issues in safety and effectiveness. By complying with IEC 60601-1, the mechanical performance of the proposed device is determined to be accepted. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Analysis 3

The proposed device is different in fluence from the predicate device, the difference is very slight.Fluence of the proposed device is within the range of the predicate and reference devices.And theproposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test ,IEC60825-1 test, the safety and performance of the product can be ensured. So the proposed device is determined to be as safe, as effective, and performs as well as the legally marketed predicate devices.

Analysis 4

The proposed device is different in Frequency from the predicate device, the frequency is the number oftimes light is emitted in a second.The Frequency of the proposed device is within the range of the predicate device.And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test,IEC60601-2-22 test ,IEC60825-1 test, the safety and performance of the product can be ensured.Therefore, this difference will not affect the safety and effectiveness.

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Table 3 Safety Comparison

Item	**Proposed Device**	**Predicate Device K210168**	**Remark**
EMC, Electrical and Laser Safety			
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22	Comply with IEC 60601-1, IEC 60601-2-22	SAME
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SAME
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	SAME
Patient Contact Materials and Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	SAME
Sensitization	No evidence of sensitization	No evidence of sensitization	SAME
Irritation	No evidence of irritation	No evidence of irritation	SAME

9. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1 Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.1 2020-09, Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Tests
- 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
- ISO 10993-5: 2009 Biological Evaluation of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10 Fourth edition 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23 First edition 2021-01, Biological evaluation of medical devices - Part 23: Tests for irritation

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Substantially Equivalent (SE) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device (K210168).