



September 25, 2024

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

Re: K241860

Trade/Device Name: Diode Laser Hair Removal System

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: June 27, 2024

Received: June 27, 2024

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,

for **Yan Fu - S** Digitally signed by Yan Fu -
S
Date: 2024.09.25 22:50:20
-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

Submission Number (if known)

K241860

Device Name

Diode Laser Hair Removal System

Indications for Use (Describe)

The Diode Laser Hair Removal System 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.

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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The assigned 510(k) Number: K241860

510(k) Summary

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.

1. Date of Submission: 2024/06/27
2. Sponsor Identification

Beijing Winkonlaser Technology Limited.

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Diode Laser Hair Removal System
Common Name: Powered Laser Surgical Instrument
Model(s): DL1500

Regulatory Information

Classification Name: Powered Laser Surgical Instrument
Classification: II
Product Code: GEX

Regulation Number: 878.4810

Review Panel: General & Plastic Surgery

5. Identification of Predicate Device(s)

510(k) Number: K200525

Product Name: Medical Diode Laser Hair Removal System

Manufacturer: Weifang Mingliang Electronics CO., LTD.

6. Device Description:

808nm diode laser using selective light absorption, the Diode 808 laser is preferentially absorbed by the melanin of the hair. The light energy is taken up by the hair follicle and converted to heat energy, and minimal energy is transferred to the skin. This preferentially heats the hair and its DNA, while reducing oxygen organization around hair follicle – reducing the chance of hair regrowth. Special cooling technology is applied simultaneously during treatment to cool the skin and protect skin.

Diode Laser Hair Removal is the safest and fastest at the present. It adopts Gold standard 808nm semi-conductor laser, based on selective photothermolysis principle, through specific wavelength, penetrate epidermis into dermis, optical energy was absorbed and translated into heat energy with restraining hair follicle tissues, and produce photothermal effect. It takes laser energy in hair follicle with rich in melanin, surrounding tissues absorb less even no energy, reach to restrained melanin of hair follicles and remove hair. Meanwhile, don't hurt around tissues and virtually pain-free remove surplus hair; eventually, reach to permanent Hair Removal.

7. Indication For Use Statement:

The Diode Laser Hair Removal System 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

Tab 1 General Comparison

Item	Proposed Device	Predicate Device	Remark
Device Name	Diode Laser Hair Removal System	Diode Laser Hair Removal System	/
Classification Regulation	21 CFR 878.4810	21 CFR 878.4810	SAME
Classification Panel	General & Plastic Surgery	General & Plastic Surgery	SAME
Class	II	II	SAME
Product Code	GEX	GEX	SAME
Common Name	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument	SAME

Indication for use	The Diode Laser Hair Removal System 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 Medical Diode Laser Hair Removal System is used for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6, 9 and 12 months after the completion of a treatment regimen. Use on all skin types (Fitzpatrick I-VI), including tanned skin.	SAME
Prescription use or not	Prescription use	Prescription use	SAME

Tab 2 Performance Comparison

ITEM	Proposed Device	Predicate Device	Remark
Laser Type	Diode Laser	Diode Laser	SAME
Laser Classification	Class IV	Class IV	SAME
Laser Wavelength	808nm	808nm	SAME
Spot Size	12mm×12mm	1.44cm ² (1.2 x 1.2 cm)	SAME
Fluence	1-40J/cm ²	48J/cm ²	Different
Frequency	1-10Hz	1-10Hz	SAME
Pulse Duration	3-300ms	1-300ms	Different
Power Supply	100V- 240VAC /50Hz-60Hz	220/110 VAC/50Hz-60Hz	Different

Analysis:**Different - Fluence**

The proposed device has different Fluence from the predicate device.

For the difference on fluence between the predicate and proposed device(s), we can see that the proposed device has similar fluence with predicate device. The fluence between the proposed device and the predicate device only with minor difference. And we think this minor difference will not affect the effectiveness and safety. And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test, the safety and performance of the product can be ensured.

Different - Pulse Duration

The proposed device has different pulse duration from the predicate device.

For the difference on pulse duration between the predicate and proposed device(s), we can see that the pulse duration range of proposed device is within the range of the predicate device. The pulse duration

between the proposed device and the predicate device only with minor difference. And we think this minor difference will not affect the effectiveness and safety. And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test, IEC60825-1 test and performance test, the safety and performance of the product can be ensured.

Different - Power Supply

The power supply for the proposed device is different from the predicate device. However, electrical safety and EMC test has been conducted on the proposed device and the test result show that the device can work normally under this power supply. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Tab 3 Safety Comparison

Item	Proposed Device	Predicate Device	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: 2012 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. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device Diode Laser Hair Removal System (K200525).