December 9, 2022

Beijing Globalipl Development 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: K222916
Trade/Device Name: US 450 Diode Laser Equipment
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 26, 2022
Received: September 26, 2022

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 (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)*
K222916

Device Name
US 450 Diode Laser Equipment

Indications for Use *(Describe)*
The US 450 Diode Laser Equipment 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: K222916

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: 2022/12/8

2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: US 450 Diode Laser Equipment

Common Name: Powered Laser Surgical Instrument

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: K162659
Product Name: Diode Laser Hair Removal System (Model:M-DL100)
Manufacturer: Shandong Huamei Technology Co.,ltd.

6. Device Description:
US450 Diode Laser Equipment is a device which adopts the high-energy and continuous diode laser to realize the conversion of electricity, light and heat energy, and thus achieves disease treatment. Therefore, this is a laser therapeutic product that integrates laser technology, electronic technology, computer science and medical science.
Under the control of microprocessor, laser power supply can provide the adjustable constant current for the laser module, the high power laser diode in the laser module can transform the electric energy into the light, generate the continuous laser beam with a wavelength of 808nm. Semiconductor laser used for hair removal is mainly based on the principle of selective photothermal action, that is, a specific wavelength of laser can only be selectively absorbed by the target color base.
US450 Diode Laser Equipment consists of power supply system, microprocessor control system, operation display system, cooling system, treatment handle and safety alarm system.

7. Indication For Use Statement:
The US 450 Diode Laser Equipment 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 8-1 General Comparison

Item	Proposed Device	Predicate Device K162659	Remark
Device Name	US 450 Diode Laser Equipment	Diode Laser Hair Removal System (Model:M-DL100)	/
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 US 450 Diode Laser Equipment 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 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.	SAME
Prescription use or not	Prescription use	Prescription use	SAME
Configuration	Main Unit, Handpiece, Foot Control	Main Unit, Handpiece, Foot Control	SAME

Table 8-2 Performance Comparison

ITEM	Proposed Device	Predicate Device	Remark
Principle of Operation	Diode laser	Diode laser	SAME
Laser Type	Diode laser	Diode laser	SAME
Laser Classification	Class IV	Class IV	SAME
Laser Wavelength	808nm	808nm	SAME
Spot size	10×10 mm^2	1.44 cm^2	Different
Energy density	5~80J/cm^2 (continuously adjustable)	1-120J/cm^2	Different
Pulse frequency	0.5-3Hz	0.5-15Hz	Different
Pulse Duration	5~400ms	5-400ms	SAME

Power Supply	AC 110V 50/60Hz	AC 110V/60Hz	Different
Dimension	47 x 47 x 132cm	450mm× 550mm×380mm	Different
Weight	68 kg	52kg	Different

Analysis：

Different - Spot size

The proposed device has different spot size with the predicate device, which only relate to the treatment area size, will not affect the effectiveness and safety.

Different - Energy density

The proposed device has different Energy density from the predicate device.

Energy density of proposed device is within the predicate device. The greater the energy density, the more energy output, and the greater the risk. The maximum energy density that we can adjust is smaller than the predicate device. 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 of the product can be ensured.

In order to ensure the effectiveness of the product, we have established a reference device K221312, Diode Laser Hair Removal Device (Model:EVOLUTION MEDICAL). It is also a diode laser product which intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin. Its laser wavelength is also 808nm and its energy density is 1-77 J/cm^2. We have same intended use with reference device and the energy density of the proposed device is higher than the reference device. The energy output of the reference device is smaller than the proposed device and it can achieve the intended use effectively. We think the effectiveness of the proposed device also can be ensured.

Different - Pulse frequency

The proposed device has different Pulse frequency from the predicate device.

Frequency of proposed device is within the predicate device. 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.

Different - Dimension, Weight

The proposed device is different in dimension and weight from the predicate device. By complying with IEC 60601-1, the mechanical performance of the proposed device is determined to be accepted, therefore, this difference of dimension and weight have no effect the effectiveness and safety.

Table 8-3 Safety Comparison

ITEM	Proposed Device	Predicate Device	Remark
Electrical Safety	The proposed devices were tested to demonstrated to comply with IEC 60601-1	The predicate devices were tested to demonstrated to comply with IEC 60601-1	SAME
EMC	The proposed devices were tested to demonstrated to comply with IEC 60601-1-2	The predicate devices were tested to demonstrated to comply with IEC 60601-1-2	SAME
Patient Contact Material	Handle head: Aluminum Ophthalmic Lens: Aluminium oxide	Sapphire in handpiece	Different
Biocompatibility			
Cytotoxicity	No toxicity (ISO 10993-5)	No toxicity (ISO 10993-5)	SAME
Irritation	Applied sample did not induce irritation to skin. (ISO 10993-10)	Applied sample did not induce irritation to skin. (ISO 10993-10)	SAME
Sensitization	The test article showed no signification evidence of causing skin sensitization in the guinea pig .(ISO 10993-10)	The test article showed no signification evidence of causing skin sensitization in the guinea pig .(ISO 10993-10)	SAME

Discussion

The proposed device is different in Patient Contact Materials from the predicate device. But the predicate device and the proposed device has passed the ISO10993 series test. We believe that the difference will not affect the effectiveness and safety compared with the predicate device.

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 60601-1:2005, AMD1:2012 with US National Differences
- IEC 60601-1-2:2014, 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: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

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 (K162659).