April 3, 2020

Beijing Lead Beauty S & T Co., Ltd
% Diana Hong
General Manager
Mid-Link Consultinf Co., Ltd
P.O Box 120-119
Shanghai, 200120 CN

Re: K192735
Trade/Device Name: Diode Laser Hair Removal Machine
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: February 24, 2020
Received: March 5, 2020

Dear Diana Hong:

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,

Jessica Mavadia-Shukla, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Diode Laser Hair Removal Machine

Indications for Use *(Describe)*
The Diode Laser Hair Removal Machine is intended for hair removal permanent hair reduction on all skin types (Fitzpatrick skin type IVI), 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.

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Exhibit #4 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K192735

1. Date of Preparation: 02/07/2020

2. Sponsor Identification

Beijing Lead Beauty S & T Co., Ltd.
202, No.5 workshop, No.1 caida 3rd Road Nancai Shunyi District, Beijing, China

Establishment Registration Number: Not registered

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Diode Laser Hair Removal Machine
Common Name: Laser Hair Removal instrument
Model: QDTM-01

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

Intended Use Statement:

The Diode Laser Hair Removal Machine is intended for hair removal permanent hair reduction on all skin types (Fitzpatrick skin type IVI), 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.

Device Description

The proposed device, Diode Laser Hair Removal Machine, is a surgical device. It utilizes a semiconductor diode as a laser source (808nm). The laser power is delivered to the treatment area via a laser handpiece. The emission laser is activated by a footswitch.

The treatment can be applied on different Fitzpatrick skin type, including I (White), II (White with pigment), III (Yellow), IV (Yellow with pigment), V (Brown) and VI (Black); in addition, the treatment can also be applied to different parts of the body.

5. Identification of Predicate Device

510(k) Number: K180353
Product Name: Diode laser hair removal device
Manufacturer: Zhengzhou PZ Laser Slim Technology Co., Ltd.

6. 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.

Biocompatibility testing

The biocompatibility evaluation for the Diode Laser Hair Removal Machine was conducted in accordance with the guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The biocompatible testing including cytotoxicity, Sensitization and Irritation are conducted according to the following standards:

- ISO 10993-1: 2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- 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

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on Diode Laser Hair Removal Machine. The device complies with the following standards

- IEC 60601-1: 2005+CORR.1:2006+CORR.2:2007+AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60825-1:2007 Safety of laser products - Part 1: Equipment classification and requirements.

Particular Performance testing

Performance testing was conducted on the device according to the following standard:

- IEC 60601-2-22:2007+A1: 2012 Medical electrical equipment - Part 2-22: Particular requirements for the safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

Software Verification and Validation Testing

The software for this device was considered as a "major" level of concern. Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Accuracy Testing

The accuracy test was conducted to verify that the energy output and spot size of the proposed laser system do not deviate the tolerance of the setting value of energy output or the fixed value of spot size.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device K180353	Remark
Product Code	GEX	GEX	SE
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	SE
Intended Use	The Diode Laser Hair Removal Machine is intended for hair removal permanent hair reduction on all skin types (Fitzpatrick skin type IVI), 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 device 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.	SE
Configuration	Main Unit	Main Unit	SE
	Hand piece	Hand piece	SE
	Foot Control	Foot Control	SE
Laser Type	Diode Laser	Diode Laser	SE
Laser Classification	Class IV	Class IV	SE
Laser Wavelength	808nm	808 nm	SE
Spot Size	12×20mm=2.4cm^2	1.44 cm^2	Analysis 1
Power Density	0.96~70J/cm^2	1-100J/ cm^2	Analysis 2
Output	20.8-208.3W/cm^2	14-360W/cm2	Analysis 3
Frequency	1-10Hz	1-20 Hz	Analysis 4
Pulse Duration	50 ~ 400ms	10~400ms	Analysis 5
Power Supply	AC110V-240V/50-60Hz	AC 110V-230V/50-60Hz 2000VA	SE
Dimension	460×425×1120mm	560×380×1180mm	Analysis 6
Weight	52Kg	60Kg	
Patient contact material			
Hand peice	photoconductive crystals	Sapphire	Analysis 7

Handpiece Shell	ABS	Unknown	
Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	SE
Sensitization	No evidence of Sensitization	No evidence of sensitization	SE
Irritation	No evidence of Irritation	No evidence of irritation	SE
Electrical Safety	Comply with IEC 60601-1 IEC 60601-2-22, IEC 60825	Comply with IEC 60601-1 IEC 60601-2-22, IEC 60825	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE

Analysis 1-Spot Size

The spot size of the proposed device is larger than the spot size of the predicate device. Fluency (energy density) is a key factor in laser therapy. The fluency of the proposed device is not much different from the fluency of the predicate device. Therefore, the difference on spot size is considered would not raise any issues in safety and effectiveness. Thus, the proposed device is determined to be substantially equivalency with predicate device.

Analysis 2-Fluence

The fluence for the proposed device is different from predicate device. However, this difference is very slight and electrical safety and EMC test has been conducted on the proposed device and the test result can comply with related standards requirement. Therefore, this difference will not affect substantially equivalence between proposed device and equivalent device.

Analysis 3-Irradiance

The irradiance for the proposed device is different from predicate device. However, the irradiance range for the proposed device can be covered in the range of predicate device. Therefore, this difference will not affect substantially equivalence between proposed device and equivalent device.

Analysis 4-Frequency

The frequency for the proposed device is different from predicate device. However, the frequency range for the proposed device can be covered in the range of predicate device. Therefore, this difference will not affect substantially equivalence between proposed device and equivalent device.

Analysis 5- Pulse Duration

The pulse duration for the proposed device is different from predicate device. However, the pulse duration range for the proposed device can be covered in the range of predicate device. Therefore, this difference will not affect substantially equivalence between proposed device and equivalent device.

Analysis 6-Dimension and weight

The dimension and weight for the proposed device is different from predicate device. However, the dimension and weight difference is just in physical specification and this difference will not raise any issues in safety and effectiveness. Thus, the proposed device is determined to be substantially equivalency with predicate device.

Analysis 7-Patient Contact Material

The patient contact material for the proposed device is different from predicate device. However, biocompatibility test has been conducted on the proposed device and the test result can meet the requirements of ISO 10993 series standard. Therefore, this difference will not affect substantially equivalence between proposed device and equivalent device.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.