November 10, 2021

BEIJING UNT Technology Co., Ltd
℅ Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K212978
Trade/Device Name: Diode laser therapy 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: August 28, 2021
Received: September 17, 2021

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 and Part 809); 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,

Purva Pandya
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)*
K212978

Device Name
Diode laser therapy system

Indications for Use *(Describe)*
The Diode laser therapy 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.

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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: K212978

1. Date of Preparation: 10/27/2021

2. Sponsor Identification

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jinlei Tang (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Diode laser therapy system
Common Name: Powered Laser Surgical Instrument
Model: Alpha

Regulatory Information

Classification Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Classification: II;
Product Code: GEX;
Regulation Number: 21 CFR 878.4810
Review Panel: General & Plastic Surgery;

Indications for use:
The Diode laser therapy 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.

Device Description:

The proposed device, Diode laser therapy system, 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 handle. The emission laser is activated by handle and footswitch linkage.

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).

5. Identification of Predicate Device

510K Number: K210168
Trade Name: Diode Laser Therapy Systems
Manufacturer: Beijing Kes Biology 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

same or similar to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5:2009 Biological Evaluation of Medical Device, Part 5-Tests for Vitro Cytotoxicity.
- ISO 10993-10: 2010 Biological Evaluation of Medical Device, Part 10-Test for irritation and skin sensitization.
- ANSI/AAMI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/（R）2012 Medical electrical equipment - Part1: General requirements for basic safety and essential performance
- 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.
- IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements.
- 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

Software Validation & Verification Testing

Software verification & 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.” The software for this device was considered as a “Moderate” level of concern, since a failure or latent flaw in the software could directly result in erroneous diagnosis or a delay in delivery of appropriate medical care, which could result in minor injury.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Technological Comparison

Table 1. Comparison of Technology Characteristics

Item	Proposed Device K212978	Predicate Device K210168	Remark
Product Code	GEX	GEX	Same
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	Same
Class	II	II	Same
Indications for Use	The Diode laser therapy 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 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.	Same
Configuration	Main Unit	Main Unit	Same
	Handle	Handpiece	Same
	Foot Control	Foot Control	Same
Laser Type	Diode Laser	Diode Laser	Same
Laser Classification	Class IV	Class IV	Same
Laser Wavelength	808 nm	808 nm	Same
Spot Size	1.2 cm×2.4 cm=2.88 cm^2	12 mm×12 mm=1.44 cm^2	Different
Fluence	10-120 J/cm^2	10-125 J/cm^2	Different
Frequency	1-10 Hz	1-10 Hz	Same
Pulse Duration	10-300 ms	10-400 ms	Different
Power Supply	AC 100~230V/50/60Hz 2000VA	99V-121V, 50/60Hz 1400VA	Different
Dimension	430×500×1030mm	450×430×1000mm	Different
Weight	65kg	52kg	
Patient contact material	Aluminum alloy, Sapphire	Aluminum alloy, ABS	Different
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Sensitization	No evidence of Sensitization	No evidence of Sensitization	
Irritation	No evidence of Irritation	No evidence of Irritation	
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1	Same

	IEC 60601-2-22 IEC 60825-1	IEC 60601-2-22 IEC 60825-1	
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same

Different - Spot Size

The spot size for the proposed device is different from the predicate device. However, non-clinical tests about the spot size have been conducted on the proposed device and the results show that the proposed device meets the requirements. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Different - Fluence

The fluence for the proposed device is different from the predicate device. However, the fluence of the proposed device is within the range of that of the predicate device, which can justify that the difference in the parameter of fluence will not raise new safety issues of the proposed device. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Different - Pulse Duration

The pulse duration for the proposed device is different from the 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 safety and effectiveness of the proposed device.

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 and Weight

The dimension and weight for the proposed device is different 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. Therefore, this difference will not affect safety and effectiveness of the proposed device.

Different - Patient contact material

The patient contact material for the proposed device is different from the 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 safety and effectiveness of the proposed device.

9. Conclusion

Based on the comparison and analysis above, the proposed device is as safe, as effective, and perform as well as the legally marketed predicate device.