May 10, 2021

Beijing Kes Biology Technology CO., LTD.
℅ Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K210168
Trade/Device Name: Diode Laser Therapy Systems
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: March 30, 2021
Received: April 2, 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); 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)*

K210168

Device Name
Diode Laser Therapy Systems

Indications for Use *(Describe)*

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.

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: K210168

1. Date of Preparation: 3/30/2021

2. Sponsor Identification

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
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4. Identification of Proposed Device

Trade Name: Diode Laser Therapy Systems
Common Name: Powered Laser Surgical Instrument

Regulatory Information

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

Indication for use:
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.

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 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, such as arm, chest, leg, underarm etc.

5. Identification of Predicate Device

510(k) Number: K180353
Product Name: Diode laser hair removal device

6. Identification of Reference Device

Reference Device 1
510K Number: K182924
Trade Name: Diode Laser Treatment System

Manufacturer: Weifang KM Electronics Co., Ltd.

Reference Device 2
510K Number: K193426
Trade Name: Elite iQ™
Manufacturer: Cynosure, LLC

Note: The Elite iQ™ including two models, 755nm and 1064nm. The 755nm of Elite iQ™ was selected as reference device.

7. 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:

- 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

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K180353	Reference Device 1 K182924	Reference Device 2 K193426
Product Code	GEX	GEX	GEX	GEX
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Class	II	II	II	II
Indication for Use	The Diode Laser Therapy Systems are 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.	The Diode Laser Treatment 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 Elite iQ Laser System is indicated for stable long-term or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing when measured at 6, 9 or 12 months after the completion of a treatment regime. It is used for skin types (Fitzpatrick I-VI) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles.
Configuration	Main Unit	Main Unit	Main Unit	Main Unit
	Handpiece	Handpiece	Handpiece	Handpiece
	Foot Control	Foot Control	/	Foot Control and Finger Control
Laser Type	Diode Laser	Diode Laser	Diode Laser	Alexandrite
Laser	Class IV	Class IV	Class IV	Unknown

Classification				
Laser Wavelength	808 nm	808 nm	808nm	755nm
Spot Size	12 mm×12 mm=1.44 cm^2	1.44 cm^2	1.44 cm^2	2.5mm, 5mm, 7mm, 10mm, 12mm, 15mm, 18mm, 20mm, 22mm, & 24mm
Fluence	10-125 J/cm^2	1-100 J/ cm^2	2-120 J/ cm^2	Up to 600J/ cm^2
Frequency	1-10 Hz	1-20 Hz	1-10Hz	0.5~10Hz
Pulse Duration	10-400 ms	10-400 ms	10-300ms	0.5~300ms
Power Supply	99V-121V, 50/60Hz 1400VA	AC 110V-230V/50-60Hz 2000VA	100-240V AC, 50/60Hz	208V~240V/50~60Hz 5500VA
Dimension	450×430×1000mm	560×380×1180mm	600×420×380mm 600×420×350mm 600×420×400mm 550×420×300mm	Unknown
Weight	52kg	60 Kg	35Kg	Unknown
Patient Contacting Material	Aluminum alloy, ABS	Sapphire in handpiece	Sapphire in handpiece and handpiece tip (stainless steel)	316 Stainless Steel
Biocompatibility				
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Comply with ISO 10993-1	Comply with ISO 10993-1
Sensitization	No evidence of Sensitization	No evidence of Sensitization		
Irritation	No evidence of Irritation	No evidence of Irritation		
Electrical Safety and EMC				
Electrical Safety	Comply with IEC 60601-1 IEC 60601-2-22	Comply with IEC 60601-1 IEC 60601-2-22	Comply with IEC 60601-1 IEC 60601-1-22	Comply with IEC 60601-1 IEC 60601-1-22

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

10. Substantially Equivalent (SE) Conclusion

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