May 27, 2020

Weifang Mingliang Electronics CO., LTD
℅ Mr. Ray Wang
Beijing Believe-Med Technology Service Co., Ltd.
Rm. 912, Building#15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K200525
Trade/Device Name: Medical 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: February 28, 2020
Received: March 2, 2020

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,

Colin Kejing Chen
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)*

K200525

Device Name
Medical Diode Laser Hair Removal System

Indications for Use *(Describe)*

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.

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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Tab #7 510(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.

The assigned 510(k) Number: K200525

1. Date of Preparation

   04/23/2020

2. Sponsor

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3. Submission Correspondent

Mr. Ray Wang

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510(k) Summary

4. Identification of Proposed Device

Trade Name: Medical Diode Laser Hair Removal System

Common Name: Powered Laser Surgical Instrument

Model(s): V16

Regulatory Information:

Classification Name: Powered Laser Surgical Instrument

Classification: II;

Product Code: GEX;

Regulation Number: 21 CFR 878.4810;

Review Panel: General& Plastic Surgery;

Intended Use:

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.

5. Device Description

Laser parameters and other system features are controlled from the control panel on the console, which provides an interface to the system's micro-controller through an LCD touch-screen.

In the handpiece of the machine, the light emitted by each discharge at 808nm.

6. Identification of Predicate Device

Primary Predicate Device

510(k) Number: K181019

Product Name: Diode Laser System

Manufacturer: Guangzhou Huafei Tongda Technology Co., Ltd.

Secondary Predicate Device

510(k) Number: K153718

Product Name: Spirit Hair Removal laser Family

Manufacturer: ACTIVE OPTICAL SYSTEMS , LTD.

7. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device conforms with the following standards:

- IEC 60601-1:2005/A1:2012 Medical Electrical Equipment - Part 1: 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 compatibility- Requirements and tests.
- Software Validation & Verification Test

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device K181019	Predicate Device K153718	Remark
Product Code	GEX	GEX/ILY	GEX/ILY	SAME
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	2	2	2	SAME
Intended Use	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.	The Diode Laser 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 Spirit Hair Removal Laser Family is generally intended for dermatological use. The devices are specifically indicated for hair removal, permanent hair reduction by using selective laser energy. The Spirit Hair Removal Laser Family is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.Permanent reduction in hair regrowth is defined as long term, stable reduction in the number of hairs regrowing when measured out to 6, 9, and 12 months	SAME

			after the completion of the treatment regimen.	

510(k) Summary

Table 2 Performance Comparison

ITEM	Proposed Device	Predicate Device K181019	Predicate Device K153718	Remark
Wavelength	808 nm	808nm	810nm	SAME
Light/Laser source	Diode	Diode	Diode	SAME
How supplied	Non-sterile, cleanable	Non-sterile, cleanable	Non-sterile, cleanable	SAME
Fluence (Energy Density) [J/cm2]	48	40	6-90 (Model 918)	SIMILAR
Rep Rate [Hz]	1-10	1-5	≤ 10 (Model 918)	SAME
Pulse Duration [ms]	1-300	30-200	Up to 310 ms (Model 918)	SIMILAR
Spot Size	1.44cm2 (1.2 x 1.2 cm)	1.20cm2	1.92 cm2 (12 x 16 mm) (Model 918)	SIMILAR

Table 3 Safety Comparison

Item	Proposed Device	Predicate Device K181019	Predicate Device K153718	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	Comply with IEC 60601-1, IEC 60601-2-22	SAME
EMC	Comply with IEC 60601-1-2	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	Comply with IEC 60601-2-22, IEC 60825	SAME

Analysis

The proposed device has similar indication for use with predicate devices, the main differences are output parameters, such as spot size, fluence, frequency range, pulse duration.

10. Substantially Equivalent (SE) Conclusion

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