DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 16, 2017

Shandong Huamei Technology Co.,ltd.
% Ray Wang
General Manager
Beijing Believe Technology Service Co., Ltd.
5-1206, Build 332, Dafangju, No.25 Banbidian Rd.
Liyuan Town, Tongzhou District, Beijing
Beijing, 101121 CN

Re: K162659
Trade/Device Name: 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: October 13, 2016
Received: October 17, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162659

Device Name
Diode Laser System

Indications for Use *(Describe)*

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.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Tab #5 510(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: K162659

1. Date of Preparation

   05/19/2017

2. Sponsor

Shandong Huamei Technology Co., Ltd.

588, Changning Street, High-tech District, WeiFang, ShanDong, China, 261000

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3. Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Diode Laser Hair Removal System
Common Name: Powered Laser Surgical Instrument
Model(s): HM-DL100

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 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.

5. Device Description

The proposed device, Diode Laser Hair Removal System, is a surgical device, which is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI);

Function module description

a. Control Panel

The module uses the microcontroller as the heart, utilizes the LCD screen to display all prompt information and the system state information to complete the human-machine interaction function, and realizes the device parameters settings and accurate control of the output laser energy by the operator.

b. Main Control Module

The module uses the microcontroller as the heart, receives the laser energy parameters and work instructions from the control panel and detects the footswitch state; Utilizes the sensors of temperature, humidity, liquid level and flow to detect the parameters such as temperature, humidity and water flow during system working, and according to the detected values to calculate the dew point temperature; Controls and detects the work state of constant current board module as well as the temperature and humidity control system; Uploads the state data and alarm information of water circulation system, cooling system, handpiece module and constant current board module during system working.

c. Constant current board module

The module uses the high-power MOS as the heart, receives the laser energy parameters from the main control module, supplies the semiconductor laser with constant drive current which corresponding to the received laser energy parameters to drive the semiconductor laser to emit light. The module also has the detection function of over-current, overvoltage, over-temperature and handpiece state, and uploads the detected data to the control module.

d. Temperature and humidity control system

The system mainly includes the condenser, cold plate, water circulation subsystem and fans. The microcontroller of main control module according to the temperature, humidity parameter detected by the sensors to control the working state of the condenser, cold plate and cooling fan to meet the temperature and humidity requirements during the semiconductor laser working.

e. Handpiece module

Handpiece module is the heart of the device, which is the execution unit of the device and completes the laser emission function. The module is mainly composed of semiconductor laser, sapphire, temperature and humidity sensor, data storage chips, cooling components and water flow path. The semiconductor laser emits light to output energy, temperature and humidity sensors detects the temperature and humidity parameters during handpiece working, the cooling components and water flow path take away the heat of the semiconductor laser to prevent it from being damaged caused by over-temperature, so prolongs the service life of the semiconductor laser.

6. Identification of Predicate Device

Predicate 1#
510(k) Number: K141973
Product Name: Diode Laser Hair Removal System
Manufacturer: Beijing Anchorfree Technology Co., Ltd

Predicate 2#
510(k) Number: K123483
Product Name: Diode Laser
Manufacturer: Beijing Syntech Laser Co., Ltd

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:

- IEC 60601-1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-2-2:2007, 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: 2007, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-2:2007, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests.
- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity
- ISO 10993-10:2002/Amd. 1: 2006, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity AMENDMENT 1
- Performance Testing for Spot Size Accuracy and Energy Output Accuracy.

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** K141973	**Predicate Device** K123483	**Remark**
Product Code	GEX	GEX	GEX	SE
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SE
Intended Use	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 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.	The Diode Laser is intended for use in dermatologic and general surgical procedures. The Standard Mode is intended for hair removal, permanent hair reduction. The FHR Mode is intended for hair removal, permanent hair reduction. The diode laser system is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.	SE
Configuration	Main Unit	Main Unit	Main Unit	SE
	Handpiece	Handpiece	Handpiece	SE
	Foot Control	Foot Control	Foot Control	SE
Principle of Operation	Diode Laser	Diode Laser	Diode Laser	SE

Table 2 Performance Comparison

Item	**Proposed Device**	**Predicate Device** K141973	**Predicate Device** K123483	**Remark**
Laser Type	Diode Laser	Diode Laser	Diode Laser	SE
Laser Classification	Class IV	Class IV	Class IV	SE
Laser Wavelength	808 nm	808 nm	808 nm	SE
Spot Size	1.44 cm^2	1.44 cm^2	1.2 cm^2	SE
Fluence	1-120J/ cm^2	1-120 J/cm^2	1-120 J/cm^2	SE
Irradiance	0.7-347.8 W/cm^2	347.2 W/cm^2	600 W/cm^2	SE
Frequency	0.5-15Hz	1Hz，2Hz, 3Hz,10Hz	≤10 Hz	Discussion
Pulse Duration	5-400ms	2.9-348ms	5-200 ms	Discussion
Power Supply	AC 110V/60Hz	AC220V，50Hz/ AC110V，60Hz	100-240 V 50/60Hz	SE
Dimension	450mm× 550mm×380mm	380mm×540mm×1200mm	460X 365 X350 mm	Discussion
Weight	52	55kg	25 kg	Discussion

Discussion

The proposed device is different in frequency range, pulse duration, dimension and weight from the predicate device. By complying with non-clinical test conducted, the proposed device is determined to be substantially equivalency with predicate device.

Table 3 Safety Comparison

Item	**Proposed Device**	**Predicate Device** K141973, K123483	**Remark**
Patient Contact Materials and Biocompatibility			
Patient Contact Materials	Sapphire in handpiece	Sapphire in handpiece	SE
Cytotoxicity	No Cytotoxicity	Comply with ISO 10993-1	SE
Sensitization	No evidence of sensitization		
Irritation	No evidence of irritation		
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	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Laser Safety	Comply with IEC 60601-2-22, IEC 60825	Comply with IEC 60601-2-22, IEC 60825	SE

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.