July 16, 2018

Guangzhou Huafei Tongda Technology Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Services Co., Ltd.
Rm. 912, Building #15, Xi Yue Hui, No.5, Yi He North Rd.
Fang Shan District
Beijing, 102401 Cn

Re: K181019
Trade/Device Name: Diode Laser 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: April 13, 2018
Received: April 17, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181019

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.

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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: K181019

1. Date of Preparation

   06/19/2018

2. Sponsor

Guangzhou Huafei Tongda Technology Co., Ltd.

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3. Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Diode Laser System
Common Name: Powered Laser Surgical Instrument
Model(s): HF-108

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 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 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

510(k) Number: K162659
Product Name: Diode Laser Hair Removal System
Manufacturer: Shandong Huamei Technology Co.,ltd.

510(k) Number: K142845
Product Name: SILKPRO Laser Hair Removal System
Manufacturer: Wuhan Lotuxs Technology Co., Ltd.

510(k) Number: K112031
Product Name: Alma Lasers Modified Diode Laser Module with SHR Treatment Mode for use with Family of Soprano XL Multi-Application Platforms
Manufacturer: Alma Lasers, Inc.

510(k) Number: K153718
Product Name: Spirit Hair Removal Laser Family. Spirit-918/cFactor -918/mFactor-918
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 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 60601-2-22 Edition 3.1 2012-10, 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
- ISO 10993-5 Third Edition 2009-06-01, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility)
- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization. (Biocompatibility)
- 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 7-1 General Comparison

Item	**Proposed Device**	**Predicate Device** K162659	**Predicate Device** K142845	**Predicate Device** K112031	**Predicate Device** K153718	**Remark**
Product Code	GEX	GEX	OHT	GEX	GEX	SE
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	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 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 SILKPRO is an over-the-counter device intended for adjunctive use with shaving for hair removal sustained with periodic treatments. SILKPRO is also intended for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime. permanent hair reduction is defined as long term, stable reduction in the number of hairs regrowing when measured out to 6, 9, and 12 months after the completion of the treatment regimen	The Alma Lasers Family of Soprano XL Multi-Application Platforms is intended for use in dermatologic and general surgical procedures. The Alma Lasers Modified Diode Laser Module (used with Alma Lasers Family of Soprano XL Multi-Application Platforms): The HR modes is intended for hair removal, permanent hair reduction. The SHR Mode is intended for hair removal, permanent hair reduction. The LaserBlanche Mode is intended for the treatment of benign vascular and pigmented lesions. The Alma Lasers Family of Soprano XL Multi-Application Platforms is intended for use on all skin types	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 after the completion of the treatment regimen.	SE

				(Fitzpatrick skin types I-VI), including tanned skin.		
Configuration	Main Unit	Main Unit	/	Main Unit	/	SE
	Handpiece	Handpiece	Handpiece	Handpiece	Handpiece	SE
	Foot Control	Foot Control	/	Foot Control	/	SE
Principle of Operation	Diode Laser	Diode Laser	Diode Laser	Diode Laser	Diode Laser	SE

Table 7-2 Performance Comparison

Item	**Proposed Device**	**Predicate Device** K162659	**Predicate Device** K142845	**Predicate Device** K112031	**Predicate Device** K153718	**Remark**
Laser Type	Diode Laser	Diode Laser	Diode Laser	Diode Laser	Diode Laser	SE
Laser Classification	Class IV	Class IV	Class IV	Class IV	Class IV	SE
Laser Wavelength	808 nm	808 nm	810 nm	810 nm	810 nm	SE
Spot Size	1.20cm^2	1.44 cm^2	9 x 9 mm (0.81 cm^2)	1.20cm^2	12 x 16 mm (1.92 cm^2) (Model 918)	Discussion
Pulse Duration	30ms-200ms	5-400ms	/	5-200ms (HR Mode); ≤ 20ms (SHR Mode)	Up to 310 ms (Model 918)	Discussion
Fluence	5-40 J/cm2	1-120J/ cm^2	5 - 25J/ cm^2	1-120J/ cm^2 (HR Mode); ≤ 10 J/ cm^2 (SHR Mode)	6-90 J/cm^2 (Model 918)	Discussion
Frequency	1-5Hz	0.5-15Hz	/	≤ 3 Hz (HR Mode); ≤ 10 Hz (SHR Mode)	≤ 10 Hz (Model 918)	Discussion
Power Supply	100-240V~ 50/60Hz	AC 110V/60Hz	/	/	/	Discussion
Dimension	510mm×600mm×1000mm	450mm×550mm×380mm	/	/	/	Discussion
Weight	50Kg	52Kg	/	/	/	Discussion

Discussion

The proposed device has same indication for use with 4 predicate devices, the main differences are output parameters, such as spot size, fluence, frequency range, pulse duration.

For these output parameters, the Fluence and Pulse duration are most important parameters which may decides that how much and how long time the energy will deliver to

the patient's skin, it may effects the safety (too much energy and/or too long action time) may burn patient's skin, and effectiveness (too low energy and/or too short action time) may make the device could not achieve it's indication for use.

From the comparison above, the fluence of proposed device is 5-40 J/cm^2, the fluence of predicate device are 1-120J/ cm^2, 5 - 25J/ cm^2, $\leq$ 10 J/ cm^2, and 6-90 J/cm^2. They are not exactly same, but the fluence of proposed device is covered or limited the fluence of predicate device. Because the maximum fluence of proposed are lower than some predicate device (120 J/cm^2, 90J/cm^2), it can be considered as the proposed device has acceptable safety; and the maximum fluence of proposed are higher than some predicate device (25J/ cm^2, 10 J/ cm^2), it can be considered as the proposed device has capable to achieve it's indication for use. The Pulse duration of proposed device is 30 ms -200 ms, which is similar with the predicate device, and it is also covered or limited the pulse duration of predicate device, which is longer or same than some predicate device (200 ms, 400 ms, 310 ms), and less than some predicate device (20 ms), so same reason as fluence, the pulse duration of proposed device has acceptable safety and has capable to achieve it's indication for use.

As the justification above, the difference of pulse duration and fluence ranges does not affect the safety or effectiveness of proposed device for it's indications for use.

Table 7-3 Safety Comparison

Item	**Proposed Device**	**Predicate Device** K162659	**Predicate Device** K142845	**Predicate Device** K112031	**Predicate Device** K153718	**Remark**
Patient Contact Materials and Biocompatibility						
Patient Contact Materials	Sapphire and aluminum alloy in handpiece	Sapphire in handpiece				Discussion
Cytotoxicity	No Cytotoxicity	No Cytotoxicity				SE
Sensitization	No evidence of sensitization	No evidence of sensitization				
Irritation	No evidence of 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

Discussion

The proposed device is different in Patient Contact Materials from the predicate device. but both the predicate device and the proposed device has passed the ISO10993 series test, we believe these differences will not affect the effectiveness and safety compared with the predicate device., the proposed device is determined to be substantially equivalency with predicate device.

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.