December 13, 2019

San He Lefis Electronics Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.
FangShan District
Beijing, 102401 Cn

Re: K192569
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: September 16, 2019
Received: September 18, 2019

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,

Purva Pandya
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)*

K192569

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.

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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: K 1 9 2 5 6 9

1. Date of Preparation

   09/16/2019

2. Sponsor

San He Lefis Electronics Co., Ltd.

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3. Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Diode Laser Therapy System
Common Name: Powered Laser Surgical Instrument
Model(s): LFS-K8

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 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，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. Power System

Power system including network power supply, laser power supply system, refrigeration power supply system and auxiliary power supply system, as shown in Fig 9-1.

The power lines and rocker switch are used to control the on -off of hair removal instrument with the outside power supply. The key switch, emergency stop switch are used to control the on-off of network power, and then through the auxiliary power supply, provide the work current for the microprocessor control system, touch screen operation display system and other functional components, meanwhile, the on-off of power system for refrigeration and laser are realized by the pick-up and switching off of the relay that controlled by micro - processor. The power-on, energizing and the light emission process of main unit are subject to microprocessor control, in order to achieve controlling the hardware with software through microprocessor, so that the appliance operation are more stable and reliable.

Laser power system adopt the power devices to constitute current regulation loop, thus can change the volume of output current through system regulation power devices of microprocessor, thereby

controlling the volume of output laser energy and work pulse width, through the feedback loop, export the current sampling signal and send to the micro - processor for real-time monitoring.

Various power supply components from the power system of laser hair removal instrument mostly adopt the safe and reliable switching power supply to achieve AC-DC conversion, these components passed through CE- certification, so that the safe effectiveness of the system get adequately guarantee, not only ensure the personal safety of users, but also ensures the long-term and reliable work of the devices itself.

The power system has the perfect self-protection function, it can continuously feed a number of important signal back to the microprocessor, once the important signal has an error, the microprocessor will promptly notify the users through the friendly man-appliance interface (Touch Screen) and take automatic protection treatment .After the error signal is released, the power system can automatically return to normal state.

b. Microprocessor Control System

Diode Laser device adopt the microprocessor control system. The microprocessor control system is composed of microprocessor, control loop and detection circuit, see Fig 9-1.

Control module of hair removal instrument is highly automated, the user just needs to turn on rocker switch and key switch and eject emergency stop switch, after power-on, the system will automatically perform the self-check for the control system (include all the preset checks against some possible damages to the appliance and the user) and the calling of treatment parameters and other a series of actions.

c. Operation Display System

Operation Display System is composed of touch screen, indicator and buzzer.

Among them, the touch screen connect directly to the host microprocessor, the operator can operate the touch screen to control the microprocessor to work, and through the information that is displayed on the screen to understand the main unit state and the relevant parameters, the hair removal instrument adopt the safe and reliable touch screen that passed through CE certification, also, the manufacturer designed a simple and intuitive operational interface, which can be easy to realize man-machine dialogue.

The indicators are used to display the work state of main unit; meanwhile, the buzzer is used as the prompt for laser output and fault alarm.

d. Cooling System

Cooling system consists of cooling fan, cooling water re-circulation system and water temperature regulation system.

After the laser hair removal instrument starting, the cooling system begins to work and adjust the water temperature to the preset temperature scale. The cooling fan give air cooling for the electric

parts and radiator in the main unit, through air flow in the appliance to take away the generated heat.

When the laser is running, internal circulating water can displace and takes away the heat and deliver to the water temperature regulation system, where the heat can be displaced and sent to the radiator for dispersion. Therefore, the circulation water temperature is maintained within a dynamic balance range, this ensures the normal working temperature of laser. By monitoring cooling water temperature in real time through temperature sampling, the control system can start the cooling components from the water temperature regulation system in due time to adjust water temperature, also, it can automatically judges whether the temperature is normal. If the temperature exceeds the early warning value that preset, the system will automatically disable laser output and give alarm so as to avoid damage to the laser.

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 semiconductor laser emits light to output energy.

6. Identification of Predicate Device and Reference Device

Primary Predicate Device
510(k) Number: K181019
Product Name: Diode Laser System
Manufacturer: Guangzhou Huafei Tongda Technology Co., Ltd.

Reference Device
510(k) Number: K162659
Product Name: Diode Laser Hair Removal System
Manufacturer: Shandong Huamei Technology 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:

- AAMI/ANIS/ES 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)

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** K181019	**Reference Device** K162659	**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 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 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.	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 7-2 Performance Comparison

Item	**Proposed Device**	**Predicate Device** K181019	**Reference Device** K162659	**Remark**
Laser Type	Diode Laser	Diode Laser	Diode Laser	SAME
Laser Classification	Class IV	Class IV	Class IV	SAME
Laser Wavelength	808 nm	808 nm	808 nm	SAME
Spot Size	2.80cm^2	1.20cm^2	1.44 cm^2	Discussion
Pulse Duration	3ms-400ms	30ms-200ms	5-400ms	Discussion
Fluence	2-40 J/cm2	5-40 J/cm2	1-120J/ cm^2	SAME
Frequency	1-10Hz	1-5Hz	0.5-15Hz	Discussion
Power Supply	110V~ 50/60Hz	100-240V~ 50/60Hz	AC 110V/60Hz	Discussion
Dimension	510mm×600mm×1000mm	510mm×600mm×1000mm	450mm×550mm×380mm	Discussion
Weight	45Kg	50Kg	52Kg	Discussion

Discussion

The proposed device has same indication for use with predicate devices, the main differences are output parameters, such as spot size, 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/cm2, the fluence of predicate device are 5-40 J/cm2. They are exactly same, that's means the proposed device has capable to achieve it's indication for use.

The Pulse duration of proposed device is 3 ms -400 ms, which is difference with the predicate device, but which is same with the reference device (K162659), since the reference device has more longer fluence (120 J/cm2), then the 400 ms maximum pulse with 40 J/cm2 of proposed device could be consider as safety.

For the other differences (Spot Size, Frequency, Power Supply, Dimension and Weight), they would not affects the safety and effectiveness of proposed device for it's indications for use. And By complying with non-clinical test conducted, the proposed device is determined to be substantially equivalency with predicate device.

Table 7-3 Safety Comparison

Item	**Proposed Device**	**Predicate Device** K162659	**Reference Device** K162659	**Remark**
Patient Contact Materials and Biocompatibility				
Patient Contact Materials	Handpiece tip	Handpiece tip	Handpiece tip	SAME
Cytotoxicity	No Cytotoxicity	No Cytotoxicity		SAME
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		SAME
EMC	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		SAME

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.