December 10, 2019

Beijing Superlaser Technology 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 China

Re: K192516
Trade/Device Name: Diode Laser 808nm, Model: SL-HR10
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 10, 2019
Received: September 13, 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
OHT5: 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)*

K192516

Device Name

Diode Laser 808nm, Model: SL-HR10

Indications for Use *(Describe)*

The Diode Laser 808nm 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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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:

1. Date of Preparation

   09/10/2019

2. Sponsor

   Beijing Superlaser Technology Co., Ltd.

   No.2 Zhongfu Street, Economic and Technological Industrial Zone, Xihongmen Town, Daxing District, Beijing, 100076, China

   Contact Person: Shi Shuang
   Position: Registration Specialist
   Tel: 86-10-81284899 to 806
   Fax:86-10-81284899
   Email: 672257488@qq.com

3. Submission Correspondent

   Ray Wang
   General Manager

   Beijing Believe-Med Technology Service Co., Ltd.
   Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
   FangShan District, BeiJing, China 102401

   Tel: +86-18910677558
   Fax: +86-10-56335780
   Email: ray.wang@believe-med.com

4. Identification of Proposed Device

Trade Name: Diode Laser 808nm
Common Name: Powered Laser Surgical Instrument
Model(s): SL-HR10

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 808nm 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 Diode Laser 808nm 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 proposed device has six main function modules as following:
Water cooling system:
Through refrigeration compressor to achieve heat and cold exchange of air, the internal water tank by the water and water pump for cooling water cycle, with cooling water to cool the parts of the tools, the system to achieve this function is called water cooling system.

Power system:
Through the main circuit control system, according to the control requirements to provide the size of laser energy, the system to achieve this function is called the power system.

User Interface system:
Through the display screen and touch screen, 1. Provide users with relevant information about display equipment; 2. Users operate or set relevant parameters or functions; 3. Display fault information. The system that realizes this function is called human-machine switching system.

Handpiece system:
According to the choice of different treatment methods to choose the appropriate treatment tools, the system to achieve this function is called the handpiece system.

Main circuit power supply system:
The system that realizes the power supply of equipment and the control switch or stops the power supply is called the main circuit power supply system.

Main circuit control system:
It is used to control the parts of the equipment to work in a reasonable sequence and provide fault or warning sound. The system that realizes this function is called the main circuit control system.

6. Identification of Predicate Device

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

510(k) Number: K180353
Product Name: Diode laser hair removal device
Manufacturer: Zhengzhou PZ Laser Slim 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/ANSI/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** K180353	**Predicate Device** K181019	**Remark**
Product Code	GEX	GEX	GEX	SAME
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SAME
Intended Use	The Diode Laser 808nm 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 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 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.	SAME
Configuration	Main Unit	Main Unit	Main Unit	SAME
	Handpiece	Handpiece	Handpiece	SAME
	Foot Control	Foot Control	Foot Control	SAME
Principle of Operation	Diode Laser	Diode Laser	Diode Laser	SAME

Table 7-2 Performance Comparison

Item	**Proposed Device**	**Predicate Device** K180353	**Predicate Device** K181019	**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	1.2 cm^2	1.44 cm^2	1.2 cm^2	SAME
Fluence	1-70J/ cm^2	1-100J/ cm^2	5-40J/ cm^2	Discussion
Frequency	1-20 Hz	1-20 Hz	1-5 Hz	SAME
Pulse Duration	5~400ms	10~400ms	30-200ms	SAME
Power Supply	110V 60 Hz or 230V 50Hz	AC 110V/60Hz	100-240V 50/60Hz	SAME
Dimension (L*W*H)	598mm x 440mm x 1093mm	560mm x 380mm x1 180mm	450mm x 550mm x380mm	SIMILAR
Weight	60Kg	60Kg	50 Kg	SAME

Discussion

The proposed device is different in fluence from the predicate device, the difference is very slight, and only in the range, the max. fluence of proposed device is between the two predicate devices, which means the proposed device could accomplishment the same indication for use with two predicate device.

And the proposed device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test , IEC60825-1 test and performance test(Energy density and Spot Size), the safety and performance of the product can be ensured.

So the proposed device is determined to be substantially equivalency with predicate device.

Table 11-3 Safety Comparison

Item	**Proposed Device**	**Predicate Device** K180353	**Predicate Device** K181019	**Remark**
Patient Contact Materials and Biocompatibility				
Patient Contact Materials	Sapphire in handpiece	Sapphire in handpiece		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 60825-1	Comply with IEC 60601-2-22, IEC 60825-1		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.