March 25, 2020

Beijing Globalipl Development 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: K193328
Trade/Device Name: IPL + Diode Laser Machine
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: ONF, GEX
Dated: November 29, 2019
Received: December 2, 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,

Jessica Mavadia-Shukla, PhD
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)*
K193328

Device Name
Trade Name: IPL + Diode Laser machine
Model: US419

Indications for Use *(Describe)*
The IPL + Diode Laser machine (inclusive of the handpiece used to deliver pulsed-light energy) is indicated for use in surgical, and aesthetic applications in permanent hair reduction, reduction of benign pigmented lesions and benign vascular lesions, and (inclusive of the handpiece used to deliver diode laser energy) 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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"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 #8 510(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: K193328

1. Date of Preparation

   02/28/2020

2. Sponsor

Beijing Globalipl Development Co.,Ltd.

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3. Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: IPL + Diode Laser machine
Common Name: Powered Light Based Non-Laser Surgical Instrument With Thermal Effect；Powered Laser Surgical Instrument
Model(s): US419

Regulatory Information:
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology；
Classification: II;
Product Code: ONF, GEX;
Regulation Number: 21 CFR 878.4810；
Review Panel: General & Plastic Surgery;

Indication For Use:

The IPL + Diode Laser machine (inclusive of the handpiece used to deliver pulsed-light energy) is indicated for use in surgical, and aesthetic applications in permanent hair reduction, reduction of benign pigmented lesions and benign vascular lesions，and (inclusive of the handpiece used to deliver diode laser energy)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, IPL + Diode Laser machine (inclusive of the handpiece used to deliver pulsed-light energy) is indicated for use in surgical, and aesthetic applications in permanent hair removal, reduction of benign pigmented lesions and benign vascular lesions，and (inclusive of the handpiece used to deliver diode laser energy)is intended for hair removal, permanent hair reduction on all skin types (Fitzpatrick skin type I-VI), including tanned skin.

IPL are intense pulsed light system which delivers intense pulsed light at a wavelength ranging from 480nm-1200nm. Intense Pulsed Light (IPL) systems work on the principles of selective thermolysis. That is, causing thermal damage to target chromophores by using light of appropriate wavelength in pulses that exceeds the chromophores' thermal relaxation time but sparing normal skin by limiting the pulse width below the thermal relaxation time for skin.

IPL are different from lasers in that they deliver many wavelengths in each pulse of light instead of just one wavelength. Generally, IPL enhances penetration without using excessive energy levels and enables targeting of specific chromophores.

Diode Laser machine is based on the principles of selective photothermolysis (SPTL): a combination of the appropriate laser wavelength, pulse duration, and fluence can obtain optimal effect on a targeted tissue with minimal effect on surrounding tissue.

Wavelengths of 808 nanometers (nm) are widely used in hair removal treatment, it is selectively absorbed by melanin in the hair shaft, damaging the follicular epithelium, and further causes hair loss, while the competing chromophores (oxyhemoglobin and water) absorb less energy at these wavelengths.

The user could power on the device and use the key switch to start the system, and then set the output parameter, when the setting is done, the user could use the handpiece to aim the area to be treated by 808 nm laser delivering , the laser emitting could be triggered by foot switch controlled by user.

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 IPL/laser energy by the operator.

b. Main Control Module

The module uses the microcontroller as the heart, receives the IPL/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 IPL/laser energy parameters from the main control module, supplies the IPL/laser with constant drive current which corresponding to the received IPL/laser energy parameters to drive the IPL/laser to emit light. The module also has the detection function of over-current, over-voltage, 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 IPL/laser working.

e. Handpiece module

Handpiece module is the heart of the device, which is the execution unit of the device and completes the IPL/laser emission function. The module is mainly composed of IPL/laser, sapphire, temperature and humidity sensor, data storage chips, cooling components and water flow path. The IPL/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 IPL/laser to prevent it from being damaged caused by over-temperature, so prolongs the service life of the IPL/laser.

6. Identification of Predicate Device

Predicate Device 1:

510(k) Number: K161286

Product Name: IPL Therapy Machine

Manufacturer: BEIJING ADSS DEVELOPMENT CO., LTD.

Predicate Device 2:

510(k) Number: K192516

Product Name: Diode Laser 808nm

Manufacturer: Beijing Superlaser 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:

- 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.
- IEC60601-2-57:2011, Medical electrical equipment -- Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems
- 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 1** K161286	**Predicate Device 2** K192516	**Remark**
Product Code	ONF;GEX	ONF	GEX	SE
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	SE
Intended Use	The IPL + Diode Laser machine (inclusive of the handpiece used to deliver pulsed-light energy) is indicated for use in surgical, and aesthetic applications in permanent hair reduction, reduction of benign pigmented lesions and benign vascular lesions，and (inclusive of the handpiece used to deliver diode laser energy)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 VE2000 device is indicated for use in surgical, aesthetic applications in permanent hair reduction, reduction of benign pigmented lesions and benign vascular lesions. 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 regimen	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.	SE
Configuration	Main Unit	Main Unit	Main Unit	SE
	Handpiece	Handpiece	Handpiece	SE
	Foot Control	Foot Control	Foot Control	SE

Table 7-2 Performance Comparison(IPL)

ITEM	Proposed Device	Predicate Device1 IPL Therapy Machine(K161286)	Remark
Light source	Intense pulsed light	Intense pulsed light	SE
Wavelength	480-1200 nm 590-1200 nm 640-1200 nm	480nm—1200nm 590nm—1200nm 640nm—1200nm	SE
Deliver system	Sapphire	Sapphire	SE
Energy density	1~40J/cm2	1-50J/cm²	Analysis 1
Max. Power	2200VA	2200W	SE
permanent hair reduction			
Wavelength Range (nm)	640-1200	640-1200	SE
Energy Range (J/cm^2)	11-40	10-44	Analysis 1
Pulse Width (ms)	16-32	3-14	Analysis 1
Pulse Delay (ms)	5-14	16-32	Analysis 1
Spot Size (mm^2)	15*50	12*30	Analysis 1
pigmented lesions			
Wavelength Range (nm)	480-1200	480-1200	SE
Energy Range (J/cm^2)	10-40	12-44	Analysis 1
Pulse Width (ms)	16-32	3-9	Analysis 1
Pulse Delay (ms)	3-8	16-32	Analysis 1
Spot Size (mm^2)	15*50	12*30	Analysis 1
vascular lesions			
Wavelength Range (nm)	590-1200	590-1200	SE
Energy Range (J/cm^2)	10-40	10-42	Analysis 1
Pulse Width (ms)	16-32	3-8	Analysis 1
Pulse Delay (ms)	5-9	16-32	Analysis 1
Spot Size (mm^2)	15*50	12*30	Analysis 1

Analysis 1

The proposed device is different in energy density, energy range, pulse width and pulse delay from the predicate device. Buy the IPL system of the proposed device has passed the IEC60601-2-57 and IEC62471 test, the IPL performance of the proposed device can be guaranteed. By complying with non-clinical test conducted, the proposed device is determined to be substantially equivalency with predicate device.

Table 7-3 Performance Comparison (Diode Laser)

Item	**Proposed Device**	**Predicate Device 2** Diode Laser 808nm K192516	**Remark**
Laser Type	Diode Laser	Diode Laser	SE
Laser Classification	Class IV	Class IV	SE
Laser Wavelength	808 nm	808 nm	SE
Spot Size	13*13mm^2	1.2 cm^2	Analysis 2
Fluence	1~69J/c m^2	1-70J/ cm^2	Analysis 2
Frequency	SHR:1-10Hz LHR:1-3 Hz	1-20 Hz	Analysis 2
Pulse Duration	5~400ms	5~400ms	SE

Analysis 2

The proposed device is different in Spot Size，Fluence，Frequency and Pulse Duration from the predicate device. Buy the Diode Laser system of the proposed device has passed the IEC60601-2-22 and IEC60825-1 test, the Diode Laser performance of the proposed device can be guaranteed. By complying with non-clinical test conducted, the proposed device is determined to be substantially equivalency with predicate device.

Table 7-4 Safety Comparison

Item	**Proposed Device**	**Predicate Device1 IPL Therapy Machine (K161286)**	**Predicate Device 2 Diode Laser 808nm (K192516)**	**Remark**
Patient Contact Materials and Biocompatibility				
Patient Contact Materials	IPL + Diode Laser handpiece	IPL handpiece	Diode Laser handpiece	SE
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	No Cytotoxicity	SE
Sensitization	No evidence of sensitization	No evidence of sensitization	No evidence of sensitization	
Irritation	No evidence of 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，IEC60601-2-57	Comply with IEC 60601-1	Comply with IEC 60601-1, IEC 60601-2-22	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Laser Safety	Comply with IEC 60601-2-22, IEC 60825 , IEC60601-2-57	Comply with IEC60601-2-57	Comply with IEC 60601-2-22, IEC 60825	SE
Power Supply	AC110V， 50/60Hz	AC 110V 50Hz	AC 110V/60Hz or 250V 50Hz	SE
Dimension	620x610x1290mm	430x 590 x 1360 mm	598x440x1093mm	Analysis 3
Weight	78kg	45kg	60Kg	Analysis 3

Analysis 3

The proposed device is different in Dimension and Weight from the predicate device. but the proposed device has passed the IEC 60601-1-2，IEC 60601-1，IEC 60601-2-22, IEC60601-2-57，IEC 60825 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.