February 1, 2022

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, Beijing 102401
China

Re: K212611
Trade/Device Name: CO2 Laser Equipment
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: January 4, 2022
Received: January 10, 2022

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212611

Device Name
CO2 Laser Equipment

Indications for Use *(Describe)*
The CO2 Laser Equipment is used for human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.

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 is submitted in accordance with the requirements of 21 CFR Section 807.92.

The assigned 510(k) Number: K212611

1. Date of Preparation

   1/31/2022

2. Applicant Name and Address

   Beijing Globalipl Development Co., Ltd.

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4. Submission Correspondent

   Mr. Ray Wang

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5. Identification of Proposed Device

Trade Name: CO2 Laser Equipment

Common Name: Powered Laser Surgical Instrument

Model(s): US800/US800N

Classification Name: Powered Laser Surgical Instrument

Classification: II;

Product Code: GEX

Regulation Number: 21 CFR 878.4810

Review Panel: General & Plastic Surgery

6. Identification of Primary Predicate

510(k) Number: K192528

Product Name: CO2 Laser Therapy System

Manufacturer: Shangdong Huamei Technology Co., Ltd.

7. Device Description

The subject device CO2 Laser Equipment is a carbon dioxide laser used in medical and aesthetic industry. The device emits laser energy at 10.6 μm wavelength to induce human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.

The CO2 Laser Equipment includes two models US800 and US800N, the two models have same mechanism of action, structure, material, motherboard, PCB layout, software, principle and specification. The difference is appearance and size. The detailed difference shown as following:

Table 1 The Difference of Models

Item	US800	US800N
Size	480mm*540mm*1240mm	440mm*540mm*1020mm

8. Indication For Use

The CO2 Laser Equipment is used for human tissue vaporization, coagulation in dermatology and

plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.

9. Substantially Equivalent (SE) Comparison

Table 2 General Comparison

ITEM	Proposed Device	Predicate Device	Remark
Product Code	GEX	GEX	SAME
Regulation No.	21 CFR 878.4810	21 CFR 878.4810	SAME
Class	2	2	SAME
Where used	hospital	hospital	SAME
Intended Use	The CO2 Laser Equipment is used for human tissue vaporization,coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.	The CO2 Laser Therapy Machine is used for human tissue vaporization, coagulation in dermatoloty and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.	SAME

Table 3 Performance Comparison

ITEM	Proposed Device		Predicate Device		Remark
Maximum Power	30W		30W		SAME
Work mode	Single Pulse Mode, Continuous Pulse Mode, Multi Pulse Mode		Surgery (Single Pulse, Continuous, Muti-Pulse)		SAME
Wavelength	10.6 um		10.6 um		SAME
Beam delivery	7 joint Light guide arm		7 knucklearmkey joints light arm		SAME
Light arm	1.36m		1.36m		SAME
Aiming Beam	650nm/0.5mW		630-650nm red diode laser (≤5 mW)		SAME
Spot size	0.5 mm		0.5 mm		SAME
Pulse Setting	Single Pulse / Multi Pulse	0.1ms-1000ms.	Single Pulse / Multi Pulse	0.1ms-1000ms.	SAME
	Continuous	1-30W	Continuous	1-30W	
Power calibration	Period of 1 year		Period of 1 year		SAME
Control System	Touch screen, footswitch		Touch screen, footswitch		SAME
Laser operation	Footswitch		Footswitch		SAME
Laser medium/ energy source	CO2		CO2		SAME
Cooling System	Air cooling		Air cooling		SAME
Clean Method	70% medical alcohol		70% medical alcohol		SAME
Patient Contacted Part	Skin		Skin		SAME
Dimension	US800:48x54x124cm US800N:44x54x102cm		66*42*125cm (without light arm)		Analysis
Weight	65Kg		80 kg		Analysis
Power input	AC 110V， 50/60Hz		AC 110V/60Hz		SAME

Analysis

The proposed device is different in dimensions and weight from the predicate device. By complying with IEC 60601-1, the mechanical performance of the subject device is determined to be acceptable. Therefore, this difference is not likely to adversely affect the safety and effectiveness of the subject device in comparison to the predicate device.

Table 4 Safety Comparison

Item	Proposed Device	Predicate Device	Remark
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
Patient Contact Materials and Biocompatibility			
Patient Contact Materials	No patient contacting components/materials claimed	/	Analysis

10. Non-Clinical Testing

Non clinical tests were conducted to verify that the subject device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The following tests were conducted:

- AAMI ES60601-1:2005+A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Safety And Essential Performance;
- IEC 60601-2-22:2007+A1:2012, 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 compatibility- Requirements and tests.
- Software Validation & Verification Test
- Bench Testing to verify the performance

11. Clinical Testing

No clinical study is needed or included in this submission.

12. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device CO2 Laser Equipment (US800/US800N) is substantially equivalent to the legally marketed predicate device K192528.