October 22, 2021

Zhengzhou Bestview St 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: K211735
Trade/Device Name: CO2 Laser Machine, Model: BW-203B
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 18, 2021
Received: September 21, 2021

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)*

K211735

Device Name

CO2 Laser Machine
Model: BW-203B

Indications for Use *(Describe)*

The CO2 Laser Machine 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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K211735

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.

1. Date of Preparation

   09/17/2021

2. Applicant Name and Address

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4. Submission Correspondent

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5. Identification of Proposed Device

Trade Name: CO2 Laser Machine

Common Name: Powered Laser Surgical Instrument

Model: BW-203B

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: K200042

Product Name: CO2 Laser System

Manufacturer: Beijing Superlaser Technology Co., Ltd.

7. Device Description

The CO2 Laser Machine is used for human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.

The CO2 laser machine has two modes, continuous mode and multi-pulse mode. It utilizes CO2 laser to vaporize and heat tissue.

During the treatment, the water in skin tissues absorbs laser energy and then vaporizes.

Laser parameters and other system features are controlled from the control panel on the console, which provides an interface to the system's micro-controller through a LCD touch-screen.

8. Indication For Use

The CO2 Laser Machine 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 3 General Comparison

ITEM	Proposed Device	Predicate Device (K200042)	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 Machine is used for human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.	The CO2 Laser System is used for human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.	SAME

Table 4 Performance Comparison

ITEM	Proposed Device K211735	Predicate Device (K200042)	Remark
Maximum Power	30W	30W	SAME
work mode	Continuous, Muti-Pulse	Single Pulse, Continuous, Muti-Pulse	SAME
Wavelength	10.6 um	10.6 um	SAME
Mode Structure	TEM00	TEM00	SAME
Beam delivery	7 knucklearmkey joints light arm	7 knucklearmkey joints light arm	SAME
Light arm	1.36m	1.36m	SAME
Handpiece Type	Be part of light arm	Be part of light arm	SAME
Aiming Beam	630-650nm red diode laser (≤5 mW)	650nm red diode laser(≤ 5 mW)	SAME
Spot size	0.5 mm	0.5mm	SAME
Output Power	1-30W	1-30W	SAME
Pulse Durtion	1-1000 ms	1-1000 ms	SAME
Control System	Touch screen, footswitch	Touch screen, footswitch	SAME
Laser operation	Footswitch	Footswitch	SAME
Laser medium/energy source	CO2	CO2	SAME
Cooling System	Water + Air cooling	Air cooling	SIMILAR
Clean Method	70% isopropanol	70% isopropyl alcohol	SAME
Dimension	61 cm x 32 cm x 22 cm	37.5 cm x 29 cm x 113 cm	Analysis
Weight	35 kg	40 kg	Analysis
Power input	AC100V/60Hz	110V 60Hz or 230V 50Hz	SAME

Table 5 Safety Comparison

Item	Proposed Device	Predicate Device (K200042)	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	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
Patient Contact Materials and Biocompatibility			

Patient Contact Materials	handpiece	handpiece	SAME
Cytotoxicity	No Cytotoxicity	Comply with ISO 10993-10 and ISO 10993-5	SAME
Sensitization	No evidence of sensitization		
Irritation	No evidence of irritation		

Analysis

The difference between proposed device and predicate device lies in the appearance (dimension, weight). The difference will not affect the safety and effectiveness of proposed device in comparison to the predicate.

10. 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 60601-2-22:2007, 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.
- ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity
- ISO 10993-10:2010, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity
- Software Validation & Verification Test

11. Clinical Testing

No clinical study is included in this submission.

12. Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.