June 9, 2020

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 CN

Re: K200042
Trade/Device Name: CO2 Laser 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: May 8, 2020
Received: May 12, 2020

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,

Colin Kejing Chen
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)*

K200042

Device Name

CO2 Laser System

Indications for Use *(Describe)*

The CO2 Laser System is used for human tissue vaporization, coagulation in dermatoloty 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Section 807.92.

1. Date of Preparation
   05/07/2020

2. Applicant Name and Address
   Beijing Superlaser Technology Co., Ltd.
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4. Submission Correspondent
   Mr. Ray Wang
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   Tel: +86-18910677558
   Fax: +86-10-56335780
   Email: ray.wang@believe-med.com

5. Identification of Proposed Device
   Trade Name: CO2 Laser System
   Common Name: Powered Laser Surgical Instrument
   Model(s): SL-LC01

   Classification Name: Powered Laser Surgical Instrument
   Class: II
   Product Code: GEX
   Regulation Number: 21 CFR 878.4810
   Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
   Review Panel: General & Plastic Surgery

6. Identification of the Primary Predicate
   510(k) Number: K192528
   Device Name: CO2 Laser Therapy System
   Manufacturer: Shangdong Huamei Technology Co., Ltd.

7. Device Description

The device emits CO2 laser at the wavelength of 10.6μm, which is the spectral line in the far infrared range. The device is used for human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.

8. Indications for Use

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

9. Substantially Equivalent (SE) Comparison

Tab 1 General Comparison

| ITEM | Proposed Device | Predicate Device K192528 | Remark |
|---|---|---|---|
| **Product Code** | GEX | GEX | SE |
| **Regulation No.** | 21 CFR 878.4810 | 21 CFR 878.4810 | SE |
| **Class** | 2 | 2 | SE |
| **Where used** | hospital | hospital | SE |
| **Intended Use** | The CO2 Laser System 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 dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology. | SE |

Tab 2 Performance Comparison

| ITEM | Proposed Device | | Predicate Device K192528 | | Remark |
|---|---|---|---|---|---|
| **Maximum Power** | 30W | | 30W | | SAME |
| **Work Mode** | Surgery (Single Pulse, Continuous, Pulse) | | Surgery (Single Pulse, Continuous, Muti-Pulse) | | SAME |
| **Wavelength** | 10.6 um | | 10.6 um | | SAME |
| **Beam Delivery** | 7 joint light guide arm | | 7 knuckle arm key joints light arm | | SAME |
| **Aiming Beam** | Red indicator light (650nm, ≤5 mW) | | 630-650nm red diode laser (≤5 mW) | | SAME |
| **Spot Size** | 0.5 mm | | 0.5 mm | | SAME |
| **Output Power** | pulse, | 1-30W | Single Pulse | 1-30W | SAME |
| | single | 1-30W | Muti-Pulse | 1-30W | |
| | continuous | 1-30W | Continuous | 1-30W | |
| **Pulse Duration** | Single Pulse Mode: 1-1000 ms<br>Pulse mode: 1-1000 ms | | Single Pulse Mode: 0.1-1000 ms<br>Muti-Pulse Mode: 0.1-1000 ms | | SIMILAR |
| **Control System** | Touch screen, footswitch | | Touch screen, footswitch | | SAME |
| **Laser Operation** | Footswitch | | Footswitch | | SAME |
| **Laser medium/energy source** | CO2 | | CO2 | | SAME |
| **Cooling System** | Closed inner circulating water cooling | | Air cooling | | SIMILAR |

| | | | |
|---|---|---|---|
| **Cleaning Method** | 70% isopropyl alcohol | 70% medical alcohol | SAME |
| **Dimension** | 37.5 cm x 29 cm x 113 cm | 66*42*125cm(without light arm) | Analysis |
| **Weight** | 40kg | 80 kg | Analysis |
| **Power input** | 110V 60Hz or 230V 50Hz | AC 110V/60Hz ; | SIMILAR |

Tab 3 Safety Comparison

| **Item** | **Proposed Device** | **Predicate Device K161925** | **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 |

Analysis

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

10. Non-Clinical Testing

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 60601-1:2005/A1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance;
- IEC 60601-2-22:2012, 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.

In Addition, the following non-clinical tests were performed to make sure that the device performs as intended:

- Software Validation & Verification Test
- Bench Performance Tests

11. Clinical Testing

No clinical study is performed to support substantial equivalence.

12. Conclusion

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