November 25, 2020

Zhuolu Jontelaser Manufacturing 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, BeiJing 102401
China

Re: K202250
Trade/Device Name: Dermatological Carbon Dioxide Laser Systems
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: August 27, 2020
Received: August 31, 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,

For Purva Pandya
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)*
K202250

Device Name
Dermatological Carbon Dioxide Laser System

Indications for Use *(Describe)*
The Dermatological Carbon Dioxide Laser System 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"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."*

# 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

   11/24/2020

2. Applicant Name and Address

   **Zhuolu Jontelaser Manufacturing Technology Co., Ltd.**
   No. 31, Sanguanmiao Alley, Zhuolu Town, Zhuolu County, Zhangjiakou City, Hebei, China, 072750

3. Contact Person Information
   Karen Liu
   General Manager
   Tel: +86-13911459627
   Fax: +86-10- 57212057
   Email: 919309354@qq.com

4. Submission Correspondent

   Mr. Ray Wang
   **Beijing Believe-Med Technology Service Co., Ltd.**
   Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District，Beijing City, China, 102401
   Tel: +86-18910677558
   Fax: +86-10-56335780
   Email: ray.wang@believe-med.com

5. Identification of Proposed Device

Trade Name: Dermatological Carbon Dioxide Laser Systems

Common Name: Powered Laser Surgical Instrument

Model(s): L300

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 Machine

Manufacturer: Shangdong Huamei Technology Co., Ltd.

7. Device Description

The Dermatological Carbon Dioxide Laser Systems, and it is also a gas laser. With its own wavelength of 10600 nm, the laser energy density is high and the divergence angle is very small. The focus light beam was used to vaporization, coagulation the human tissue.

8. Indication For Use

The Dermatological Carbon Dioxide Laser Systems 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 1 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 Dermatological Carbon Dioxide Laser Systems is used for human tissue vaporization, coagulation in dermatology | The CO2 Laser Therapy Machine is used for human tissue vaporization, coagulation in dermatoloty and plastic surgery, general | SAME |

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

Table 2 Performance Comparison

| ITEM | Proposed Device | Predicate Device | Remark |
|---|---|---|---|
| **Maximum Power** | 30W | 30W | SAME |
| **work mode** | CW Mode (Continuous Mode)<br>P Mode (Muti-Pulse) | 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** | 1.576m | 1.36m | Analysis |
| **Aiming Beam** | 650nm | 630-650nm red diode laser (≤5 mW) | SAME |
| **Spot size** | 0.4 mm | 0.5 mm (±10%) | Analysis |
| **Pulse Setting** | 1-1000ms | 0.1-1000ms | SAME |
| **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% alcohol | 70% medical alcohol | SAME |
| **Patient Contacted Part** | Skin | Skin | SAME |
| **Dimension** | 52cm*40cm*125cm | 66*42*125cm (without light arm) | Analysis |
| **Weight** | 65Kg | 80 kg | Analysis |
| **Power input** | AC 100-240v~，50/60Hz | AC 110V/60Hz | SAME |

Analysis 1

The proposed device is different in light arm length from the predicate device, the different not affect the therapeutic effect. Therefore, this difference will not affect the substantially equivalency.

Analysis 2

The proposed device is different in Spot Size from the predicate device, Spot size only affects the

area of treatment, not affect the therapeutic effect. Therefore, this difference will not affect the substantially equivalency.

Analysis 3

The proposed device is different in dimension and weight from the predicate device. By complying with IEC 60601-1, the mechanical performance of the proposed device is determined to be accepted, therefore, this difference will not affect the substantially equivalency.

Table 3 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 | Aluminum | / | Analysis |
| Cytotoxicity | Comply with ISO 10993-1 | Comply with ISO 10993-1 | SE |
| Sensitization | | | |
| Irritation | | | |

Analysis

Although the materials in contact with human skin are different, they all meet the requirements of ISO 10993-1 and will not affect product safety.

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.