December 3, 2019

Shangdong Huamei Technology Co., Ltd.
% Ray Wang
Official Correspondent
Beijing Believe-Med Technology Service Co., Ltd.
Rm. 912, Building #15, XiYueHui, No.5, YiHe North Rd.,
Fangshan District
Beijing, 102401 CN

Re: K192528
Trade/Device Name: CO2 Laser Therapy 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: September 11, 2019
Received: September 13, 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,

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)*

K192528

Device Name
CO2 Laser Therapy System

Indications for Use *(Describe)*

The CO2 Laser Therapy 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.

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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: K192528

1. The Submitter Information

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Submission Correspondent

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2. Date of Preparation

11/25/2019

3. Identification of Proposed Device

Trade Name: CO2 Laser Therapy System

Common Name: Powered Laser Surgical Instrument

Model(s): HM-CL200

Regulatory Information:

Classification Name: Powered Laser Surgical Instrument

Classification: II;

Product Code: GEX;

Regulation Number: 21 CFR 878.4810;

Review Panel: General& Plastic Surgery;

4. Identification of Predicate Device

510(k) Number: K161925

Product Name: CO2 Laser Therapy Machine

Manufacturer: Beijing ADSS Development Co., Ltd

5. Device Description

The CO2 Laser Therapy System is a carbon dioxide laser used in medical and aesthetic industry. Due to the CO2 laser's high absorption of water, its high-energy beam of laser light interacts with the skin's surface causing the upper layer to peel off and and then achieve the indications.

The proposed device is mainly used for human tissue vaporization, coagulation and exposure to achieve the purpose of treatment.

6. Indication For Use Statement

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

7. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device K161925	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 equipment is used for human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.	The equipment is used for human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.	SE

Table 2 Performance Comparison

ITEM	Proposed Device	Predicate Device K161925	Remark
Maximum Power	30W	30W	SAME
work mode	Surgery (Single Pulse, Continuous, Muti-Pulse)	Surgery (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	1.32m	SIMILAR
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(0.5 mW)	SAME
Spot size	0.5 mm	0.5mm	SAME
Pulse Setting	Single Pulse: 0.1-1000ms	Pulse: 10-1000ms	SIMILAR
	Muti-Pulse: Time On: 0.1-1000ms	Repeat: Time On: 10-1000 ms	SIMILAR
	Muti-Pulse: Time Off: 0.1-1000ms	Repeat: Time Off: 10-1000 ms	SIMILAR
	Continuous: 1-30W	CW: 0-30W	SIMILAR
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
Dimension	66*42*125cm(without light arm)	FG900: 56X54X112 cm; FG900-B: 660X54X32 cm; FG900-C: 46X42X125 cm	Analysis
Weight	80 kg	FG900: 49 kg; FG900-B: 28kg; FG900-C: 34kg	Analysis
Power input	AC 110V/60Hz ;	AC 110V/50Hz-60Hz	SAME

Table 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 only difference between proposed device and predicate device is appearance (dimension, weight), which are not affect the safety and effectiveness of proposed device. Based on the nonclinical tests performed, the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device.

8. 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 60601-1:2005/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.
- Software Validation & Verification Test

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Conclusion drawn from clinical and non-clinical testing

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