DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 5, 2016

Beijing Adss Development Co., Ltd
% Ray Wang
General Manager
Beijing Believe Technology Service Co., Ltd.
5-1206, Build 332, Dafangju, No.25 Banbidian Rd.,
Liyuan Town, Tongzhou District, Beijing, 101121 CN

Re: K161925
Trade/Device Name: CO2 Laser Therapy Machine
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: July 11, 2016
Received: July 13, 2016

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k161925

Device Name
CO2 Laser Therapy Machine

Indications for Use *(Describe)*
The CO2 Laser Therapy 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.

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

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Tab #7 510(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: _K161925_

1. Date of Preparation

   10/03/2016

2. Sponsor

Beijing ADSS Development Co., Ltd

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3. Submission Correspondent

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4. Identification of Proposed Device

Trade Name: CO2 Laser Therapy Machine
Common Name: Powered Laser Surgical Instrument
Model(s): FG 900/FG 900-B/FG 900-C

Regulatory Information:
Classification Name: Powered Laser Surgical Instrument
Classification: II;
Product Code: GEX;
Regulation Number: 21 CFR 878.4810;
Review Panel: General& Plastic Surgery;

Intended Use:

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

5. Device Description

The CO2 Laser Therapy Machine is a carbon dioxide laser used in medical and aesthetic industry for treatment of such skin conditions as fine and coarse wrinkles, scars of various origin, uneven pigmentation and dilated pores. Due to the CO_2 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 use photothermolysis to stimulate deep cell regeneration and then achieve the target of skin improvement.
The proposed device is mainly used for human tissue vaporization, carbonization, coagulation and exposure to achieve the purpose of treatment.

The CO2 Laser Therapy Machine includes three models in this submission, FG 900, FG 900-B and FG 900-C, all three models have same principle, software, operation etc., only differences are appearance.

The proposed device includes the following components:

Table 1 Main Components of Proposed Device

Components	Function Description	Applied Model(s)
Surgery tip	Deliver the laser to area to be treated	FG 900/FG 900-B/FG 900-C
Surgery tip Arm	Articulated arm for holding of Surgery tip	FG 900/FG 900-B/FG 900-C
Touchscreen	The user interface and for controlling of the system	FG 900/FG 900-B/FG 900-C
Emergency	Stop the system in case of emergency situation	FG 900/FG 900-B/FG

Switch		900-C
Key Switch	Start the system	FG 900/FG 900-B/FG 900-C
Goggles for Patient	Protect the eyes of patient	FG 900/FG 900-B/FG 900-C
Goggles for Doctor	Protect the eyes of Operator	FG 900/FG 900-B/FG 900-C
Foot Switch	Activate the laser emission	FG 900/FG 900-B/FG 900-C

6. Identification of Predicate Device

510(k) Number: K110434
Product Name: TRIXEL CO2 LASER
Manufacturer: BEIJING SYNTECH LASER CO., LTD.

7. 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: 2007, Safety of laser products - Part 1: Equipment classification and requirements.
- IEC 60601-1-2:2007, 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 10993-10:2002/Amd. 1: 2006, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity AMENDMENT 1
- Performance Testing for Spot Size Accuracy and Energy Output Accuracy.
- Software Validation & Verification Test

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Substantially Equivalent (SE) Comparison

Table 2 General Comparison

ITEM	Proposed Device	Predicate Device	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 3 Performance Comparison

ITEM	Proposed Device	Predicate Device	Remark
Maximum Power	30W	CFL-10: 12W (±20%) UFL-60: 30W (±20%)	SE
work mode	Surgery (Single Pulse, Continuous, Muti-Pulse)	Scanner (half, fast and random) Surgery (CW, repeat and pulse)	SE
Wavelength	10.6 um	10.6 um	SE
Mode Structure	TEM00	TEM00	SE
Beam delivery	7 knucklearmkey joints light arm	7 knucklearmkey joints light arm	SE
Light arm	1.32 m	CFL-10: 0.97m UFL-60: 1.17m	Analysis
Aiming Beam	650nm red diode laser (0.5 mW)	650nm red diode laser(<1mW)	SE
Spot size	0.5 mm	0.5mm （±10%）	SE
Pulse Setting	Single Pulse: 10-1000ms	Pulse: 1-999ms	SE
	Muti-Pulse: Time On: 10-1000ms	Repeat: Time On: 1-999 ms	SE
	Muti-Pulse: Time Off: 10-1000ms	Repeat: Time Off: 1-999 ms	SE
	Continuous: 0-30W	CW: CFL-10: 0.1-12W UFL-60: 0.1-30W	SE
Power calibration	Period of 1 year	Period of 1 year	SE
Control System	Touch screen, footswitch	Touch screen, footswitch	SE
Laser operation	Footswitch	Footswitch	SE
Laser medium/energy source	CO2	CO2	SE
Cooling System	Air cooling	Air cooling	SE
Clean Method	70% medical alcohol	70% medical alcohol	SE
Patient Contacted Part	Skin	Skin	SE
Dimension	FG 900: 56*46*112 cm FG 900-B: 60*54*32cm FG 900-C: 46*42*125cm	CFL-10 Trixel CO2 Laser：210 x 600x 330 (without light arm) UFL-60 Trixel II CO2 Laser：1300 x 550x 420(without light arm)	SE
Weight	FG 900: 49 kg FG 900-B: 28kg FG 900-C: 43kg	CFL-10 Trixel CO2 Laser：20kg UFL-60 Trixel II CO2 Laser：40kg	SE
Power input	AC 110V/50Hz-60Hz ;	CFL-10 Trixel CO2 Laser：120 V AC/60Hz UFL-60 Trixel II CO2 Laser：120 VAC/60Hz	SE

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

Analysis

The proposed device is substantially equivalent to the predicate device. Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device.

10. Substantially Equivalent (SE) Conclusion

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