DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 6, 2017

Beijing Sincoheren Science and Technology Development Co.
% Mr. Mike Gu
Guangzhou Osmunda Medical Device Technical Service Co., Ltd
7th Floor, Jingui Business Building, No.982 Congyun Rd
Baiyun District
Guangzhou, 510420 China

Re: K162398
Trade/Device Name: Co2 Laser Therapy 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: ONG, GEX
Dated: June 16, 2017
Received: June 19, 2017

Dear Mr. Gu:

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 -S3

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)*
K162398

Device Name
CO2 Laser Therapy Systems

Indications for Use *(Describe)*
The equipment is used for human tissue vaporization, coagulation in dermatology, plastic surgery, and general surgery. The fractional scanner is only for the treatment of wrinkles and skin resurfacing.

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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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

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Date prepared:	Aug 20, 2016

II. DEVICE

Name of Device:	CO_2 Laser Therapy Systems
Common/Usual Name:	CO_2 Laser Therapy Systems
Classification Names:	Powered Laser Surgical Instrument (21 CFR 878.4810)
Regulation Class:	II
Product Code:	GEX

III. PREDICATE DEVICE

CO2 Laser Therapy Machine, K161925

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The CO2 Diode Laser Therapy Systems mainly consist of console, articulated arm and a foot switch. CO2 laser wavelength is 10600nm, which is used to gasify the skin tissue based on the principle of the theory selective photothermolysis. The water in skin is the main target of the CO2 fractional laser, after absorbed the energy of the laser, the water will release heat, then be evaporated and gasified immediately, the cutaneous lesion will be eliminated instantly. By setting up the suitable energy and other parameters on skin tissue based on its specific thermal relaxation time, the healthy tissue can be prevented from being harmed.

V. INDICATIONS FOR USE

The equipment is used for human tissue vaporization, coagulation in dermatology, plastic surgery, and general surgery. The fractional scanner is only for the treatment of wrinkles and skin resurfacing.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Specification	Proposed device	Predicate device	Discussion of Differences
K number	K162398	K161925	N/A
Manufacturer	Beijing Sincoheren Science and Technology Development Co., Ltd.	Beijing ADSS Development Co., Ltd	N/A
Device name	CO2 Laser Therapy System	CO2 Laser Therapy Machine	N/A
Intended use	The equipment is used for human tissue vaporization, coagulation in dermatology, plastic surgery, and general surgery. The fractional scanner is only for the treatment of wrinkles and skin resurfacing.	The equipment is used for human tissue vaporization, coagulation in dermatology and plastic surgery, general surgery, gynecology, podiatry, dental and otorhinolaryngology.	Smaller intended use. The difference does not raise different questions of safety and effectiveness.

Specification	Proposed device	Predicate device	Discussion of Differences
Output power (Maximum)	30W	30W	Identical
Work mode	Scan (Single Pulse, Continuous, Muti-Pulse)	Surgery (Single Pulse, Continuous, Muti-Pulse)	Identical
Laser medium/energy source	CO2	CO2	Identical
CO2 laser wavelength	10600nm	10600nm	Identical
Aiming Beam wavelength	Red diode laser 635 nm	Red diode laser 650 nm	Similar aiming beam wavelength. The difference does not raise different questions of safety and effectiveness.
Aiming Beam power	< 5mW	0.5 mW	Larger aiming beam power, brighter aiming indicator, to make the operation vision clearer. 5mW does not cause heat or energy hazard to the patients during the treatment procedure. The difference does not raise different questions of safety and effectiveness.
Spot Size (Fractional)	0.5mm	0.5 mm	Identical
Dot Quantity	400 dots at most	400 dots at most	Identical
Pulse Energy	1mj-100mj is optional for each dot	1mj-100mj is optional for each dot	Identical
Pulse Length	200μs-500μs is optional	200μs-500μs is optional	Identical
Cooling	Air cooling	Air cooling	Identical
Patient contact sites	Skin	Skin	Identical
Control System	Touch screen, footswitch	Touch screen, footswitch	Identical
Laser Operation	Footswitch	Footswitch	Identical
Power input	110-240VAC, 50-60Hz	AC 110V/50-60Hz	Similar. Both devices complied with IEC 60601-1.

Specification	Proposed device	Predicate device	Discussion of Differences
			The difference does not raise different questions of safety and effectiveness.

According to the above comparison table, the proposed device is identical to the predicate device in maximum output power, working mode, laser medium, CO2 laser wavelength, fractional spot size, dot quantity, pulse energy, pulse length, patient contact sites, and laser operation. The proposed device has a smaller intended use, a larger aiming beam power, similar aiming beam wavelength and similar power input, when compared with the predicate device. However, these differences do not raise different questions of safety and effectiveness.

Beijing Sinoheren Science and Technology Development Co., Ltd believes that the CO2 Laser Therapy Systems is as safe and effective, and performs in a substantially equivalent manner to the predicate device.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the CO2 Laser Therapy Systems was conducted in accordance with the guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” as recognized by FDA. The biocompatible testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

The treatment head is considered skin and subcutaneous tissue contacting for a duration of less than 24 hours.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the CO2 Laser Therapy Systems. The device complies with the IEC 60601-1, standard for safety and the IEC 60601-1-2 standard for EMC.

Performance testing

Performance testing was conducted on the device according to IEC 60825-1.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Animal Study

The subject of this premarket submission, CO2 Laser Therapy Systems, does not require clinical studies to support substantial equivalence.

VIII. CONCLUSION

The non-clinical data support the safety of the device and the performance testing report demonstrate that the CO2 Laser Therapy Systems should perform as intended in the specified use conditions. Beijing Sincoheren considers the CO2 Laser Therapy Systems does not raise any new issues of safety or effectiveness.