September 12, 2019

Feiying Drug & Medical Consulting Technical Service Group
Becky Chen
Registered Engineer
B-3F 3005, Bldg.1, Southward Ruifeng Business Center, No. 22 Guimiao Rd.
Shenzhen, CN 518000 Guangdong

Re: K191518
Trade/Device Name: CO2 Laser System (Model: GP900F)
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 15, 2019
Received: August 19, 2019

Dear Becky Chen:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K191518

Device Name
CO2 Laser System (Model: GP900F)

Indications for Use *(Describe)*
The equipment is used for human tissue vaporization, coagulation in dermatology, plastic surgery, and general surgery. The classical 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

This "510(k) Summary" of 510(k) safety and effectiveness information is submitted in accordance with requirements of Title 21, CFR Section 807.92.

(1) Applicant information:

510(k) owner's name:	SHENZHEN GSD TECH CO., LTD
Address:	BUILDING A JUNSD HI-TECH PARK, WEST OF BAO'AN RD. WATCH & CLOCK BASE, GUANGMING DISTRICT, SHENZHEN, GUANGDONG, CHINA
Contact person:	Jiancheng zhang
Phone number:	+86-13632740353
Fax number:	+86-0755-29109786
Email:	535140627@qq.com
Date of summary prepared:	2019-09-11

(2) Proprietary name of the device

Trade name/model:	CO2 Laser System (Model: GP900F)
Common name:	Laser Surgical Instrument for Use In General And Plastic Surgery And In Dermatology
Regulation number:	21CFR 878.4810
Product code:	GEX
Review panel:	General & Plastic Surgery
Regulation class:	II

(3) Predicate devices

	Primary Predicate	Reference Predicate
Sponsor	Beijing Sincoheren Science and Technology Development Co., Ltd.	Jeisys Medical Inc.
Device Name	CO2 Laser Therapy System	EdgeOne CO2 Laser
510(k) Number	K162398	K162169
Product Code	GEX	GEX, ONG
Regulation Number	21 CFR 878.4810	21 CFR 878.4810
Regulation	II	II

Class		

(4) Description/ Design of device:

The subject device, CO2 Laser System (Model: GP900F) 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 absorbs laser energy and evaporates. By setting up the suitable energy and other parameters on skin tissue, the device can be used for human tissue vaporization and coagulation as well as for the treatment of wrinkles and skin resurfacing.

(5) Intended use / Indications for use:

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

(6) Materials

Component name	Material of Component	Body Contact Category	Contact Duration
Treatment hand piece	Stainless steel 316L	Surface skin contact	Less than 24 hours

The treatment hand piece used in the CO2 Laser Systems has passed the Biocompatibility test. For details, please refer to "Biocompatibility Discussion".

(7) Technological characteristics and substantial equivalence:

Item	Proposed device	Primary Predicate	Reference Predicate	Remark
Trade name	CO2 Laser System (Model: GP900F)	CO2 Laser Therapy System	EdgeOne CO2 Laser	/
Manufacturer	SHENZHEN GSD CO., LTD	Beijing Sincoheren Science and Technology Development Co., Ltd.	JEISYS MEDICAL INC.	/
510 (k) number	/	K162398	K162169	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same

Regulation description	Laser surgical instrument for use in general and plastic surgery and in dermatology.	Laser surgical instrument for use in general and plastic surgery and in dermatology.	Laser surgical instrument for use in general and plastic surgery and in dermatology.	Same
Product code	GEX	GEX	GEX	Same
Class	II	II	II	Same
Indications for use/ Intended use	The equipment is used for human tissue vaporization, coagulation in dermatology, plastic surgery, and general surgery. The classical scanner is only for the treatment of wrinkles and skin resurfacing.	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.	It is indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology(ENT), gynaecology, neurosurgery, orthopaedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery. The use with the scanning unit is indicated for ablative skin resurfacing.	Same
Location for use	Prescription Use	Prescription Use	Prescription Use	Same
Basic unit specifications				
Power supply	110-240VAC, 50-60Hz	110-240VAC, 50-60Hz	230V~, 50/60Hz	Same
Dimensions	480mm*380mm*1053mm	460mm×430mm×1170mm	NA	Different Note 1
Weight	46kg	65kg	NA	Different

				Note 1
Major components	Console, articulated arm and a foot switch.	Console, articulated arm and a foot switch.	Main console unit, articulated arm and a foot switch.	Same
Compliance with voluntary standards	IEC 60601-1 IEC 60601-2-22 IEC 60825-1 IEC 60601-1-2	IEC 60601-1 IEC 60825-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-2-22 IEC 60601-1-2	Same
Performance specification				
Output Power (Maximum)	30W	30W	30W	Same
Work Mode	Classical mode, Surgical mode (Single Pulse, Continuous, Muti-Pulse)	Scan (Single Pulse, Continuous, Muti-Pulse)	Fractional mode, normal mode (CW, Pulse, Single Pulse, Repeat, Group pulse, Ultra)	Same
Laser Medium/Energy Source	CO2	CO2	CO2	Same
CO2 Laser Wavelength	10600nm	10600nm	10600nm	Same
Aiming Beam Wavelength	Red diode laser 650nm±10nm	Red diode laser 635 nm	Red diode laser 655 +/- 10nm	Similar Note 2
Aiming Beam Power	< 5mW	< 5mW	NA	Same
Spot Size (Classical)	0.5mm	0.5mm	120um, 350um, 800um	Same
Classical Pulse Energy	0.1mJ~300mJ	1mj-100mj is optional for each dot	1-300mJ	Same
Pulse Duration	Classical mode: 0.1ms~10ms Surgical mode: 0.5ms~1000ms	NA	1-1000ms	Same
Repetition rate	10-500Hz	NA	10-500Hz	Same
Cooling	Air cooling	Air cooling	Water cooling	Same
Control System	Touch screen, footswitch	Touch screen, footswitch	Touch screen, footswitch	Same
Laser	Footswitch	Footswitch	Footswitch	Same

Operation				
Patient Contact Sites	Skin	Skin	Skin	Same
Biocompatibility	Passed the test as per ISO 10993-5 and ISO 10993-10	Passed the test as per ISO 10993-5 and ISO 10993-10	Passed the test as per ISO 10993-5 and ISO 10993-10	Same
Electrical Safety	Passed the test as per IEC 60601-1 and IEC 60601-2-22	Passed the test as per IEC 60601-1	Passed the test as per IEC 60601-1 and IEC 60601-2-22	Same
EMC	Passed the test as per IEC 60601-1-2	Passed the test as per IEC 60601-1-2	Passed the test as per IEC 60601-1-2	Same
Performance	Passed the test as per IEC 60601-2-22 and IEC 60825-1	Passed the test as per and IEC 60825-1	Passed the test as per IEC 60601-2-22	Same
Compliance with 21CFR 898	Yes	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Same

Note 1:

Although the appearance, weight and dimension are different between the target device, predicate devices, these differences are insignificant and do not adversely affect safety and effectiveness of the subject device compared to the predicate.

Note 2:

Similar aiming beam wavelength between the target device and predicate devices. The difference does not raise different questions of safety and effectiveness.

Conclusion:

CO2 Laser System (Model: GP900F) is substantial equivalent to the predicate device.

(8) Non-clinical studies and tests performed:

Non-clinical testing is conducted to verify that the CO2 Laser System meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate device. The testing results demonstrate that the Proposed device complies with the following standards:

- IEC60601-1, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-22, Medical electrical equipment-Part2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser

equipment

- IEC 60825-1, Safety of Laser Products- Part 1: Equipment classification and requirements
- IEC60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests

The body-contacting components of this device are the treatment head. The biocompatibility evaluation for the CO2 Laser 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 treatment head is considered skin and subcutaneous tissue contacting for a duration of less than 24 hours. The biocompatible testing included In Vitro Cytotoxicity, Skin Sensitization and Intracutaneous Reactivity was conducted in compliance with:

- ISO 10993-5, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization

We have also conducted:

- Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices". The software for this device was considered as a "moderate" level of concern. Software validation demonstrated that the software functions as specified in the software requirement specifications.
- Bench performance testing to show that the device delivers set laser energy parameters within specifications.

(9) Conclusion

Based on the above analysis and tests performed, it can be concluded that the subject device CO2 Laser System (Model: GP900F) is Substantially Equivalent (SE) to the predicate devices.