December 22, 2021

Shenzhen GSD Tech Co., Ltd.
Huifang Yao
Regulatory Engineer
Building A, JUNSD Hi-Tech Park, West of Bao'An RD.
Watch & Clock Base, Guangming District
Shenzhen, Guangdong 518106
China

Re: K213225
Trade/Device Name: Diode Laser System GP900A8, Diode Laser System GP900Q8
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 24, 2021
Received: September 29, 2021

Dear Huifang Yao:

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213225

Device Name
Diode Laser System

Indications for Use *(Describe)*
The Diode Laser System is intended for use in dermatologic and general surgical procedures. The Fast Mode is intended for hair removal of unwanted hair, and permanent hair reduction in hair regrowth. The Free Mode is intended for hair removal of unwanted hair, and permanent hair reduction in hair regrowth. The Diode Laser System is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.

The permanent reduction in hair regrowth is defined as long-term, stable reduction in the number of hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

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

Date Prepared: Sept. 24, 2021

This 510(k) Summary is being submitted in accordance with requirements of Title 21 CFR Section 807.92.

1. Submitter information

Shenzhen GSD Tech Co., Ltd
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Establishment Registration Number: 3006580954

Contact Person: Huifang Yao
Position: Regulatory Engineer
Phone: +86 15018526594
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2. Device information

Trade name: Diode Laser System
Model number: GP900A8, GP900Q8
Regulation number: 21CFR 878.4810
Regulation name: Powered Laser Surgical Instrument
Regulatory class: II
Panel: General & Plastic Surgery
Product code: GEX

3. Predicate device information

510(k) Number: K142186
Device Name: Diode Laser Hair Removal System
Manufacturer: Shenzhen GSD Tech Co., Ltd.

4. Device description

The Diode Laser System is a surgical device intended for use in dermatologic and general surgical procedure. It utilizes a semiconductor diode with invisible infrared radiation as a laser source (810 nm). The laser power is delivered to the treatment area via a laser handpiece. The emission laser is activated by a footswitch.

The proposed Diode Laser System has two models, GP900A8 and GP900Q8. Both GP900A8 and GP900Q8 have the same functions modules, such as the power supply system, central control system, cooling system, laser delivery system and safety feature, and same working mode, such as Fast mode and Free

mode.

The GP900A8 is a standard case with wheels to allow easy movement on the floor. The GP900Q8 is a desktop case.

5. Intended use

The Diode Laser System is intended for use in dermatologic and general surgical procedures. The Fast Mode is intended for hair removal of unwanted hair, and permanent hair reduction in hair regrowth. The Free Mode is intended for hair removal of unwanted hair, and permanent hair reduction in hair regrowth. The Diode Laser System is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin.

The permanent reduction in hair regrowth is defined as long-term, stable reduction in the number of hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

6. Technological characteristics and substantial equivalence:

Description	Subject device	Predicate device	Remark
Company	Shenzhen GSD Tech Co., Ltd.	Shenzhen GSD Tech Co., Ltd.	/
Device name and model	Diode Laser System Models: GP900A8, GP900Q8	Diode Laser Hair Removal System Models: GP900A, GP900Q	/
510 (k) number	/	K142186	/
Classification name	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument	SE
Product code	GEX	GEX	SE
Regulation number	21 CFR 878.4810	21 CFR 878.4810	SE
Class	II	II	SE
Indications for use/ Intended use	The Diode Laser System is intended for use in dermatologic and general surgical procedures. The Fast Mode is intended for hair removal of unwanted hair, and permanent hair reduction in hair regrowth. The Free Mode is intended for hair removal of unwanted hair, and permanent hair reduction in hair regrowth. The Diode Laser System is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin. The permanent reduction in hair regrowth is defined as long-term, stable reduction in the number of hair	The Diode Laser System is intended for use in dermatologic and general surgical procedures. The Fast Mode is intended for hair removal of unwanted hair, and permanent hair reduction in hair regrowth. The Free Setting Mode is intended for hair removal of unwanted hair, and permanent hair reduction in hair regrowth. The Diode Laser System is intended for use on all skin types (Fitzpatrick skin types I-VI), including tanned skin. The permanent reduction in hair regrowth is defined as long-term,	SE

	regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.	stable reduction in the number of hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.	
Configuration	Main unit Handpiece Foot control	Main unit Handpiece Foot control	SE
Energy source	Diode laser	Diode laser	SE
Laser classification	Class IV	Class IV	SE
Wavelength	810nm±5nm	808nm	SE
Spot size	2cm^2 (10mm*20mm)	1.44cm^2(12mm*12mm)	Note 1
Working mode	Fast mode & Free mode	Fast mode & Free setting mode	SE
Fluency (energy density)	5~50J/cm^2	1~120J/cm^2	Note 2
Repetition rate	1~10Hz	1~10Hz	SE
Pulse duration	13-200ms	5-200ms	Similar
Product appearance design	GP900A8: Standard case GP900Q8: Desktop case	GP900A: Standard case GP900Q: Desktop case	SE
Dimension	GP900A8: 450mmx540mmx1080mm GP900Q8: 650mmx460mmx370mm	GP900A: 445mmx554mmx1228mm GP900Q: 505mmx363mmx344mm	Note 3
Weight	GP900A8: 54kg GP900Q8: 30kg	GP900A: 52kg GP900Q: 22kg	Note 4
Electrical Safety	Comply with IEC 60601-1, IEC 60601-2-22 and IEC 60825-1	Comply with IEC 60601-1, IEC 60601-2-22 and IEC 60825-1	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE
Biocompatibility	Comply with ISO 10993-5 and ISO 10993-10	Comply with ISO 10993-5 and ISO 10993-10	SE

Note 1: Spot size only affects the area of treatment, not the therapeutic effect. Therefore, this difference will not affect the safety and effectiveness.

Note 2: The fluence of the subject device is within the range of the predicate devices. And the subject device has passed the IEC60601-1 test, IEC60601-1-2 test, IEC60601-2-22 test and IEC60825-1 test, the safety and performance of the product can be ensured. So the subject device is determined to be as safe, as effective, and performs as well as the legally marketed predicate devices.

Note 3/4: The subject 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 safety and effectiveness.

7. Nonclinical tests submitted

- Safety test

IEC 60601-1: 2005/A1: 2012
Medical electrical equipment Part1: General requirements for basic safety and essential performance

- EMC test

IEC 60601-1-2: 2014
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances-Requirements and tests

- Reliability test

IEC 60601-2-22: 2019
Medical Electrical Equipment - Part 2-22: Particular requirements for the 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.

- Biocompatibility test

ISO 10993-5: 2009
Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10: 2010
Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

None of the tests demonstrated any design characteristics that violate the requirements of the Reviewer Guidance or show any safety hazards. It is our conclusion that the subject device tested met all relevant requirements of the aforementioned tests.

8. Conclusion

The subject devices have the same intended use and same technological characteristics as the predicate device. Moreover the differences between the subject and predicate don't raise new questions of safety or effectiveness. Thus, the subject device is substantially equivalent to the Predicate Device.