March 3, 2023

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: K230060
Trade/Device Name: Light Based Hair Removal Device GP592
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: OHT,
Dated: January 9, 2023
Received: January 9, 2023

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,

Jianting Wang -S

Jianting Wang
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230060

Device Name
Light Based Hair Removal Device GP592

Indications for Use *(Describe)*
Light based hair removal device is an over-the-counter device intended for removal of unwanted hair such as but not limited to small areas such as underarm and facial hair below the chin line and large areas such as legs, excluding patients with Fitzpatrick Skin Phototypes VI.

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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510(k) Summary

Date Prepared: 2023-01-09

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
Add.: Building A, JUNSD Hi-Tech Park, West of Bao'An RD. Watch & Clock Base, Guangming District, Shenzhen, China 518106
Establishment Registration Number: 3006580954

Contact Person: Huifang Yao
Position: Regulatory Engineer
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2. Device information

Device name: Light Based Hair Removal Device GP592
Trade name: Light Based Hair Removal Device
Model number: GP592
Regulation number: 21CFR 878.4810
Regulation name: Light Based Over-The-Counter Hair Removal
Regulatory class: II
Panel: General & Plastic Surgery
Product code: OHT

3. Predicate device information

510(k) Number: K180383
Device Name: Light Based Hair Removal Device
Manufacturer: Shenzhen GSD Tech Co., Ltd.

4. Device description

The Light Based Hair Removal Device is a personal, light-based, hair reduction device intended to be sold over-the counter directly to the end user. The device provides hair reduction using IPL technology. The device consists of IPL main body and adapter two parts, and a lamp cap located in the main body which is the source of optical radiation, namely a Xenon flashlamp. Meanwhile, the device is powered from adapter via an external power.

5. Intended use

The Light based hair removal device is an over-the-counter device intended for removal of unwanted hair such as but not limited to small areas such as underarm

and facial hair below the chin line and large areas such as legs, excluding patients with Fitzpatrick Skin Phototypes VI.

6. Technological characteristics and substantial equivalence:

Description	Subject device	Predicate device	Remark
510 (k) number	Pending	K180383	/
Common name	Light Based Over-The-Counter Hair Removal	Light Based Over-The-Counter Hair Removal	Same
Trade name/model No.	Light Based Hair Removal Device Model: GP592	Light Based Hair Removal Device Model: GP586	/
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Same
Pulse duration	1~3milliseconds	2~3milliseconds	Similar Note 1
Energy density	4.93J/cm^2 Max.	4.2J/cm^2 Max.	Similar Note 1
Spot size	1.05cm*2.95cm (3.1cm^2)	1.05cm*2.95cm (3.1cm^2)	Same
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Same
Pulsing control	Finger switch	Finger switch	Same
Indication for use/Intended use	Light based hair removal device is an over-the-counter device intended for removal of unwanted hair such as but not limited to small areas such as underarm and facial hair below the chin line and large areas such as legs, excluding patients with Fitzpatrick Skin Phototypes VI.	Light based hair removal device is an over-the-counter device intended for removal of unwanted hair such as but not limited to small areas such as underarm and facial hair below the chin line and large areas such as legs, excluding patients with Fitzpatrick Skin Phototypes VI.	Same
Location for use	OTC	OTC	Same

Note 1: Though the pulse duration and energy density are little different from the predicate device, they comply with the requirements of safety and performance related standards, and the differences are not likely to raise different questions of safety or effectiveness issue or adversely affect patient safety.

7. Nonclinical tests submitted

- Safety test

IEC 60601-1: 2005+A1: 2012+A2:2020
Medical electrical equipment - Part1: General requirements for basic safety and essential performance
IEC 60601-1-11: 2015
Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare

environment

- EMC test

IEC 60601-1-2: 2020
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances-Requirements and tests

- Reliability test

IEC 62471: 2006
Photobiological safety of lamps and lamp systems
IEC 60601-2-83: 2019
Medical electrical equipment - Part 2-83: General requirements for basic safety and essential performance of home light therapy equipment

- Biocompatibility test

ISO 10993-5: 2009
Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10: 2021
Biological evaluation of medical devices – Part 10: Tests for skin sensitization
ISO 10993-23：2021
Biological evaluation of medical device — Part 23: Tests for skin irritation

None of the tests demonstrated any design characteristics that may adversely affect patient safety. 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 different questions of safety or effectiveness. Thus, the subject device is substantially equivalent to the Predicate Device.