April 24, 2024

Shenzhen Shuge Medical Beauty Devices Co., Ltd.
% Yvonne Liu
Registration Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518100
China

Re: K240093
Trade/Device Name: IPL Home Use Hair Removal Device (SJ15)
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 12, 2024
Received: January 12, 2024

Dear Yvonne Liu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tanisha L. Hithe -S

Digitally signed by Tanisha L. Hithe -S
Date: 2024.04.24 15:49:25 -04'00'

Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240093

Device Name

IPL Home Use Hair Removal Device (SJ15)

Indications for Use *(Describe)*

IPL Home Use Hair Removal Device is indicated for the removal of unwanted hair. The device is also indicated for the permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs 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

Prepared on: 2024-04-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Shenzhen Shuge Medical Beauty Devices Co., Ltd
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Correspondent Contact Telephone	86-17780639776
Correspondent Contact	Ms. Yvonne Liu
Correspondent Contact Email	lq1399@feiying-china.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	IPL Home Use Hair Removal Device (SJ15)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Light Based Over-The-Counter Hair Removal
Regulation Number	878.4810
Product Code(s)	OHT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231717	IPL Home Use Hair Removal Device	OHT
K221002	IPL Hair Removal Device	OHT

Device Description Summary

21 CFR 807.92(a)(4)

IPL Home Use Hair Removal Device is indicated for the removal of unwanted hair. The device is also indicated for the permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

IPL Home Use Hair Removal Device (Model:SJ15) is an over-the-counter, home-use and single-person-use device for hair reduction by

using Intense Pulsed Light (IPL)to emit a specific wavelength of the light ranging from 550-1200nm and delivers to the skin. The device is designed to help break the cycle of hair re-growth. Light energy is transferred through the skin's surface and is absorbed by melanin present in the hair shaft. The absorbed light energy is converted to heat energy (below the surface of the skin), which disables the hair follicle preventing further growth, so as to achieve effective hair removal.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

IPL Home Use Hair Removal Device is indicated for the removal of unwanted hair. The device is also indicated for the permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device and predicate devices have the same indications for use, which is used for the removal of unwanted hair. The device is also indicated for the permanent reduction in hair regrowth, defined as the long-term, stable reduction in the number of hairs regrowing when measured at 3, 6, and 12 months after the completion of a treatment regime.

Technological Comparison 21 CFR 807.92(a)(6)

The technical characteristic of IPL Home Use Hair Removal Device (SJ15) are substantially equivalent to the predicate devices in the following aspects:
1) the same intended use, mode of action;
2) the same source energy and power supply: supplied by external adapter with 100-240V~, 50/60Hz;
3) the same light source: Intense Pulsed Light;
4) the same energy medium: Xenon Arc Flashlamp;
5) similar wavelength: The subject device's wavelength is 500-1200nm while the primary predicate device is 550-1100nm, 600-1100nm and 640-1100nm but the wavelength of secondary predicate device is 550-1200nm.

The difference between the subject device and the predicate devices mainly includes the following:
1) different spot size: the spot size of the subject device is 3.15 cm^2 while that of the primary predicate device is 3cm^2, 3.3cm^2 and 4cm^2. The spot size is related to light intensity and since the difference in light intensity is not significant, so this difference will not raise any safety or effectiveness issue.
2) different energy density: the energy density of the subject device is 2.7-4.4 J/cm^2 while that of the primary predicate device is 2-5 J/cm^2 and 2-6cm^2. The energy density of subject device is within the range of the minimum and maximum value of the predicate devices, and they all comply with IEC 60601-2-83 and IEC 62471 requirements, so this difference will not raise any safety or effectiveness issue.

Thus the technology comparison supports a decision of substantial equivalence to the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical testing have been conducted to verify that the IPL Home Use Hair Removal Device meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate devices. The testing results demonstrate that the subject device complies with the following standards:

ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012(Consolidated Text)[Including Amendment 2(2012)], Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Amendment 2.

IEC 60601-1-2 Edition 4.1 2020-09 Consolidated Version, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

IEC 60601-1-11 Edition 2.1 2020-07 Consolidated Version, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requiremnts for medical electrical equipment and medical electrical systems used in the home healthcare environment.

IEC 62471 First edition 2006-07, Photobilogical safety of lamps and lamp systems.

IEC 60601-2-83, Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment

The device has been tested for biocompatibility, it complies with the following standards:

ISO 10993-5 Third edition 2009-06-01, Biological evaluation of medical devices, Part 5: Tests for in vitro cytotoxicity.

ISO 10993-10 Fourth edition 2021-11, Biological evaluation of medical devices, Part 10: Tests for skin sensitization

ISO 10993-23 First edition 2021-01,Biological evaluation of medical devices, Part 23 Tests for irritation

We've also conducted:
Software verifcation and validation test according to the requirements of the FDA "Content of Premarket Submission for Device Software Functions"

The clinical test is not applicable, there's no clinical data.

The subject device and predicate device have the same indications for use and similar technological characteristics.

The subject device is substantially equivalent to the predicate device.