October 7, 2021

Guangzhou Haoxingwan Technology Co., Ltd.
℅ Iris Wang
Consultant
Shenzhen Joyantech Consulting Co.,Ltd.
1713A, Block A, Zhongguan Times Square, Liuxian Avenue,
Xil Town
Shenzhen, Guangdong 518000
China

Re: K210376
Trade/Device Name: Superior Hair Remover
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: August 21, 2021
Received: August 27, 2021

Dear Iris Wang:

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)*
K210376

Device Name
Superior Hair Remover

Indications for Use *(Describe)*
The Superior Hair Remover is an over the-counter device intended for removal of unwanted body and/or facial hair.

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

K210376

This summary of 510(K) safety and effectiveness information is submitted As Required by requirements of SMDA and 21 CFR §807.92.

1. Administrative Information

Submission Date	February04, 2021
Manufacturer	Guangzhou Haoxingwan Technology Co., Ltd. Address: Room 718, No.9, Linhe West Road, Tianhe District, Guangzhou, Guangdong, 510000, China. Contact person: Mr. Chun Tao TEL: +86-18929315726 E-Mail: taoc@myusmile.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. 1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong Province, China. Contact person: Mr. Field Fu; Ms. Iris Wang; E-Mail: iris@cefda.com; field@cefda.com
Establishment registration number	3015527463

2. Device Information

Type of 510(K) Submission:	Traditional
Device Name:	Superior Hair Remover
Model:	T31, T61
Classification Name:	Light Based Over-The-Counter Hair Removal
Review Panel:	General & Plastic Surgery
Device Class:	2

Regulation Number:	878.4810
Product Code:	OHT

3. Predicate Device

Manufacturer:	Shenzhen Bosidin Technology Co. Ltd.
Device Name:	IPL Home Use Hair Removal Device
Model:	D-1128, D-1103, D-1119, D-1129, D-1130
510(k) Number:	K192432
Product Code:	OHT

4. Device Description

The Superior Hair Remover, an over-the-counter device, is a home-use device for the removal of unwanted hair from body parts. The device provides hair reduction using Intense Pulse Light(IPL) technology. It works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with minimal pain. The device can detect appropriate skin contact. If the device is not properly applied to the treatment area (in full contact with the skin), the device cannot emit the treatment light pulses. The device can flash for 300,000 times.

The device is composed of a hand-held handle, a main unit, an external power cord, and eye protector, two attachable flash heads. It is used AC Powered (100-240V AC, 50/60Hz).

The Superior Hair Remover includes T31 and T61 two models. Their indications for use, working principle, mode of action, operating mode, over-temperature protection function, structure design, button function, skin contact detection function, treatment area, spot size and operation are basically identical, with the minor differences contains product appearance, control buttons on touch panel, light intensity levels.

5. Intended Use/ Indications for Use

The Superior Hair Remover is an over the-counter device intended for removal of unwanted body and/or facial hair.

6. Comparison with Predicate Device

The subject device The Superior Hair Remover, Model: T31, T61 is substantially equivalent to the predicate device(K192432). This conclusion is based upon comparison on intended use, technological characteristics, materials and applicable safety standards. The difference between the subject device and predicate device do not raise any issues on the device safety and effectiveness. The detailed device comparison information is described in VOL_012.

Items	Subject Device	Predicate Device (K192432)	Comparison
Device Name and Model	Superior Hair Remover, Model: T31, T61	IPL Home Use Hair Removal Device, Model(s): D-1128, D-1103, D-1119, D-1129, D-1130	N/A
Product code	OHT	OHT	SE
Regulation number	878.4810	878.4810	SE
Device class	2	2	SE
Location for use	OTC	OTC	SE
Intended Use	The Superior Hair Remover is an over the-counter device intended for removal of unwanted body and/or facial hair.	IPL Home Use Hair Removal Device is an over-the-counter device intended for removal of unwanted body and/or facial hair.	SE
Source Energy	AC mains	Powered by external power adapter	Different Note 1
Device Type	Intense Pulsed Light	Intense Pulsed Light	SE
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	SE
Wavelength (nm)	510nm~1100nm	Regular window: 510nm~1100nm Filter window: 600-1100nm	SE
Energy density (J/cm^2)	3.1~5.0 J/cm^2 (applicable for model T31) 2.6~5.1 J/cm^2 (applicable for model T61)	2.0~4.0J/cm² (applicable for model D-1128, D-1119, D-1129, D-1130) 2.5~4.5J/cm² (applicable for model D-1103)	Different Note 2
Spot Size (cm2)	Standard flash head: 3.6cm², Attachable flash heads: 2cm², 1cm²	Regular window: 4.5cm², 2.0cm², 3.0cm² Filter window: 2.5cm²	Different Note 3

Pulse duration	11milliseconds	7.5~14milliseconds	SE
Pulsing Control	Finger switch	Finger switch	SE
Delivery device	Direct illumination to tissue	Direct illumination to tissue	SE

Discussion of Comparable Items:

1) Note1:

“Source Energy” is a little different between subject device and predicate device, but the subject device comply with IEC 60601-1 requirements. So the differences will not raise new safety or effectiveness issue.

2) Note2:

The maximum energy density of subject device is minor different from predicate device.

But the subject device complies with IEC 60601-1, IEC60601-2-57 requirements. So the differences of function specification will not raise new safety or effectiveness issue.

3) Note3:

Although it is a little different between subject device and predicate device, the spot size of device only affects the treatment target skin area per each pulse flashing, and the light density of different spot size is also in the range of energy density declared by subject device. And the subject device complies with IEC60601-1, IEC60601-2-57 requirement.

Therefore, the differences of spot size will not raise new safety or effectiveness issue.

7. Non-Clinical Test Summary

7.1. Electromagnetic Compatibility and Electrical Safety Test

The subject device has been tested in compliance with the following standards:

1) AAMI/IEC 60601-1:2005+AMD 1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

2) 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

3) 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

4) IEC 62471: 2006 Photobiological safety of lamps and lamp systems

5) IEC 60601-2-57:2011 Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

7.2. Biocompatibility Test

The subject device has been tested in compliance with the following standards:
1) ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2) ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

7.3. Performance Test-Bench

Nonclinical, performance testing has been completed on the subject device.

7.4. Software Verification

The software documentation of the subject device was provided in accordance with FDA guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued May 11, 2005.

7.5. Usability study

Usability testing was completed in 60 subjects to evaluate device human factors and labeling comprehension.
A Human Factors Usability study was conducted using 60 participants to demonstrate the participants were capable of reading the instructions for use and labeling, and were then able to use the Superior Hair Remover correctly. The Usability study of Superior Hair Remover was conducted to ensure that the device user interface has been designed such that use errors that occur during use of the device that could cause harm or degrade medical treatment are either eliminated or reduced to the extent possible.

7.6. Clinical Study

No clinical testing was performed.

8. Conclusion

The subject device Superior Hair Remover (Model: T31, T61) is substantially equivalent to the predicate device (K192432). This conclusion is based upon comparison on intended use, technological characteristics and applicable safety standards. Any difference in the technological characteristics does not raise any new issues or concerns of safety or effectiveness.