March 28, 2023

Shenzhen Fansizhe Science and Technology Co., Ltd
% You Yijie
Manager
Qimmiq Medical Consulting Service Co., Ltd.
RM.406, Building C, Run Science Park,
No.18 Shenzhou Road, Huangpu
Guangzhou, Guangdong 510663
China

Re: K223928
Trade/Device Name: Intense Pulsed Light (IPL) System, model: T023K, T023A, T023B, T023C, T023D, T023E, T021K, T021A, T001A, T001B, T001M, T001N, T011C, T016K
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: December 29, 2022
Received: December 30, 2022

Dear You Yijie:

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)*

K223928

Device Name

Intense Pulsed Light (IPL) System, model:T023K, T023A, T023B, T023C, T023D, T023E, T021K, T021A, T001A, T001B, T001M, T001N, T011C, T016K

Indications for Use *(Describe)*

The Intense Pulsed Light (IPL) System is an over-the-counter device intended for the removal of unwanted body 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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Section 5: 510(k) Summary

1. Submitters Information

Establishment Registration Information

Name:	Shenzhen Fansizhe Science And Technology Co., Ltd
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Contact Person of applicant:

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Contact Person of the Submission:

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Email:	jet.you@qimmiq-med.com

Date prepared: Dec. 29, 2022

2. Device Information

Trade Name:	Intense Pulsed Light (IPL) System
Model:	T023K, T023A, T023B, T023C, T023D, T023E, T021K, T021A, T001A, T001B, T001M, T001N, T011C, T016K
Classification name:	Light Based Over-The-Counter Hair Removal
Common or Usual Name:	Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Review panel:	General Plastic Surgery
Product code:	OHT
Regulation Class:	II
Regulation Number:	878.4810

3. Predicate Device Information

510(k) submitter/holder:	Shenzhen Yuwei Electronic Technology Co., Ltd.

510(K) Number:	K220222
Trade Name:	IPL Hair Removal Device
Model:	S1-A, S2-A, S1, S2, S3, S4
Classification name:	Light Based Over-The-Counter Hair Removal
Review panel:	General Plastic Surgery
Product code:	OHT
Regulation Class:	II
Regulation Number:	878.4810

4. Device description

Intense Pulsed Light (IPL) System, models: T023K, T023A, T023B, T023C, T023D, T023E, T021K, T021A, T001A, T001B, T001M, T001N, T011C, T016K, are a small over-the-counter device for the permanent reduction of hair growth based on Intense Pulsed Light (IPL). It works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with minimal pain. The device is only powered by the external power adapter and its IPL emission activation is by a switch or auto light emission.

Intense Pulsed Light (IPL) System, models: T023K, T023A, T023B, T023C, T023D, T023E, T021K, T021A, T001A, T001B, T001M, T001N, contains a Xenon arc flashlamp, a touch chip to detect appropriate skin contact, and a skin color sensor to detect the skin color. In “Skin Color Recognition mode”, the device’s skin sensor automatically detects skin tone for your protection. If your skin tone is not in tone table suitable for treatment, the device must not be used. You need to identify your skin tone before treatment according to skin tone table, and confirm whether the product is applicable to you after the skin color sensor detects a skin tone.

Intense Pulsed Light (IPL) System, models: T011C and T016K, contains a Xenon arc flashlamp, and a touch chip to 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.

Based on the cooling technology, Intense Pulsed Light (IPL) System, models: T023K, T023A, T023B, T023C, T023D, T023E, T021K, T021A, T011C, T016K, has cooling care functions. When the cooling care mode is enabled, it can reduce the excessive heat generated on the skin by the photon irradiation and do cooling compresses during hair removal.

The Intense Pulsed Light (IPL) System includes main unit, an adaptor and goggles.

The device is intended to be used for adults aged over 18.

Principle of operation:

Hair has a growth cycle, which can be roughly divided into incubation period, growth period and decline period. The growth period hair has a complete structure such as hair follicles and hair shafts. The hair in the incubation period and the decline period does not have the hair follicle structure. The removal of excess hair is to take advantage of the characteristics of the anatomical structure of hair. The device based on the IPL technology emits a specific wavelength of the light and delivers the light to the skin. It 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. Therefore, the device achieves effective hair removal.

5. Indications for Use

The Intense Pulsed Light (IPL) System (Model: T023K, T023A, T023B, T023C, T023D, T023E, T021K, T021A, T001A, T001B, T001M, T001N, T011C, T016K) is an over-the-counter device intended for the removal of unwanted body hair.

6. Summary of technological characteristics of device compared to the predicate devices (K220222)

SE Comparisons	**Subject device (Intense Pulsed Light (IPL) System, model: T023K, T023A, T023B, T023C, T023D, T023E, T021K, T021A, T001A, T001B, T001M, T001N, T011C, T016K)**	**Predicate device (IPL Hair Removal Device, Model: S1-A, S2-A, S1, S2, S3, S4)**	**Discussion of difference**
510K Number	/	**K220222**	***/***
Classification	21CFR 878.4810	21CFR 878.4810	**Same**
Product Code	OHT	OHT	**Same**
FDA Class	II	II	**Same**
Indications for Use	The Intense Pulsed Light (IPL) System is an over-the-counter device intended for the removal of unwanted body hair.	IPL Hair Removal Device is an over-the-counter device intended for removal of unwanted body hair.	**Same**
Model	T023K, T023A, T023B, T023C, T023D, T023E, T021K, T021A, T001A, T001B, T001M, T001N, T011C, T016K	S1-A, S2-A, S1, S2, S3, S4	***/***
Environment of Use	Home use	Home use	**Same**
Design	Hand-hold	Hand-hold	**Same**
Patient Population	Adult	Adult	**Same**
Material of Patient contact components	T023K, T023A: PC for button, PC for main housing and Probe cover, Sapphire Crystal Cooling Compress; T023B, T023C: PC for button, PC for main housing and Probe cover, Sapphire Crystal Cooling Compress; T023D, T023E: PC for button, PC for main housing and Probe cover, Sapphire Crystal Cooling Compress; T021K, T021A: PC for button, PC for main housing and Probe cover, Sapphire Crystal Cooling Compress; T001A, T001B, T001M, T001N: PC for button, PC for main housing and Probe cover; T011C: PC for main housing, aluminum for cold compress panel; T016K: PC for button, PC for main housing and Probe cover, Sapphire Crystal Cooling Compress	ABS	**Different** (Discussion is indicated in D1)
Biocompability testing	1.Type of contact: direct contact for users and patients. 2.Nature of body contact category:	1.Type of contact: direct contact for users and patients. 2.Nature of body contact category:	**Same**

	Surface Contact class: A (<24 h) 3.Meets ISO 10993- 5, ISO 10993-10	Surface Contact class: A (<24 h) 3.Meets ISO 10993- 5, ISO 10993-10	
Single Patient, multi-use	Yes	Yes	**Same**
Patient Interface	Buttons	Buttons	**Same**
Technology	Intense Pulse Light (IPL)	Intense Pulse Light (IPL)	**Same**
Dimensions	116*217.8*42mm for T023K, T023A, T023B, T023C, T023D and T023E, 73.2*81.1*202.2mm for T021K and T021A 182*78*151mm for T001A, T001B, T001M and T001N, 211*138*60mm for T011C, 90*44*225mm for T016K	185*76.5*56.5mm for S1 and S1-A 207*77.5*47.5mm for S2 and S2-A 192.5*73*46.5mm for S3 199*76.5*46.5mm for S4	**Different** (Discussion is indicated in D2)
Power source	an external power supply	an external power supply	**Same**
Light source	Xenon Arc Flashlamp	Xenon Arc Flashlamp	**Same**
Wavelength	510nm~1200nm	610-1100nm	**Different** (Discussion is indicated in D3)
Spot Size	3.0cm^2 for T023K, T023A, T023B, T023C, T023D, T023E, T021K and T021A, 4.0cm^2 for T001A, T001B, T001M and T001N, 3.6cm^2 for T011C, 3.3cm^2 for T016K	3.0 cm^2 for S1-A and S2-A 4.1cm^2 for S1, S2, S3, and S4	**Different** (Discussion is indicated in D4)
Max. Fluence (J/cm^2)	5.5J/cm^2 for T023K, T023A, T023B, T023C, T023D and T023E, 4.8J/cm^2 for T021K and T021A, 4.7J/cm^2 for T001A, T001B, T001M and T001N, 5.75J/cm^2 for T011C, 5.73J/cm^2 for T016K	5.6 J/cm^2	**Different** (Discussion is indicated in D5)
Pulse duration	4 ~ 12ms	8~14ms	**Different** (Discussion is indicated in D6)
Output energy	6.5J ~16.6J for T023K, T023A, T023B, T023C, T023D and T023E, 5.6J~14.5J for T021K and T021A, 7.3J~18.6J for T001A, T001B, T001M and T001N, 5.3 J ~ 20.7J for T011C, 4.8J~18.9J for T016K	8.7 ~ 16.8J for S1-A and S2-A 9.02~16.81J for S1, S2, S3, and S4	**Different** (Discussion is indicated in D7)
Pulsing Control	Finger switch	Finger switch	**Same**

Output Channel	One channel	One channel	**Same**
Delivery	Direct Illumination to Tissue	Direct Illumination to Tissue	**Same**
Software Control	Yes	Yes	**Same**
Electrical safety, EMC, Biological Evaluation	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 62471 ISO 10993-5 ISO 10993-10	**Different** (Discussion is indicated in D8)

7. Discussion of Non-Clinical Tests Performed for Safety and effectiveness are as follows

The recognized consensus standards for safety of medical electrical equipment: ANSI AAMI ES60601-1, IEC 60601-1-11 for safety, IEC 60601-1-2 for electromagnetic compatibility, IEC 60601-2-83:2011 for performance and IEC 62304 for software verification are complied. See below table for details:

Standards	Standards Name
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
ANSI AAMIES60601-1:2005/(R)2012 A1:2012, C1:2009/(R)2012 A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
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
IEC 60601-1-2: 2014+A1:2020	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: 2015	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: 2015/AMD1:2020	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
IEC 60601-2-83:2019	Medical electrical equipment Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
IEC 62471: 2006	Photobiological safety of lamps and lamp systems
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
IEC 62304:2006+A1:2015	Medical device software - Software life cycle processes

Software verification and validation was performed for the subject device in accordance with Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 2005.

8. Discussion of Clinical Accuracy Testing Performed

There was no clinical testing performed.

9. Conclusions

Based on performance testing, comparison and analysis, the subject device Intense Pulsed Light (IPL) System, model: T023K, T023A, T023B, T023C, T023D, T023E, T021K, T021A, T001A, T001B, T001M, T001N, T011C and T016K, is substantially equivalent to the predicate devices.