June 30, 2022

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: K221569
Trade/Device Name: Intense Pulsed Light (IPL) System, model: T013C, T015C, T015K
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, ONF
Dated: May 15, 2022
Received: May 31, 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 and Part 809); 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
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)*

K221569

Device Name
Intense Pulsed Light (IPL) System, model:T013C, T015C, T015K

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. Submitter's Information

Establishment Registration Information:

Name:	Shenzhen Fansizhe Science And Technology Co., Ltd
Address:	2nd and 3rd floors, No.17, Xinfa 2nd Road, Xinqiao Community, Xinqiao Street, Baoan District, Shenzhen, Guangdong, China

Contact Person of applicant:

Name:	Endang Cheng
Address:	2nd and 3rd floors, No.17, Xinfa 2nd Road, Xinqiao Community, Xinqiao Street, Baoan District, Shenzhen, Guangdong, China
TEL:	+86 0755-85275266
Email:	ChengEndang1001@163.com

Contact Person of the Submission:

Name:	You Yijie
Address:	RM.406, Building C, Run Science Park, No.18 Shenzhou Road, Huangpu, Guangzhou, Guangdong 510663 P.R.China
TEL:	(+86)020-82245821
FAX:	(+86)020-82245821
Email:	jet.you@qimmiq-med.com

Date prepared: May 13, 2022

2. Device Information

Trade Name:	Intense Pulsed Light (IPL) System
Model:	T013C, T015C, T015K
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
Subsequent Product code:	ONF
Regulation Class:	II
Regulation Number:	878.4810

3. Predicate Device Information

510(k) submitter/holder:	Shenzhen Fansizhe Science And Technology Co., Ltd
510(K) Number:	K212881
Trade Name:	Intense Pulsed Light (IPL) System
Model:	T012C
Classification name:	Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Review panel:	General & Plastic Surgery
Product code:	OHT, ONF
Regulation Class:	II
Regulation Number:	878.4810

4. Device description

Intense Pulsed Light (IPL) System is 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 Intense Pulsed Light (IPL) System includes main unit, an adaptor and goggles. The device is only powered by the external power adapter and its IPL emission activation is by a switch or auto light emission.

Based on the ice-cool technology, the hair removal device with ice-cold compress functions.

5. Indications for Use

The Intense Pulsed Light (IPL) System 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 (K212881)

SE Comparisons	**Subject device (Intense Pulsed Light (IPL) System, model: T013C, T015C, T015K)**	**Predicate device (Intense Pulsed Light (IPL) System, model: T012C)**	**Discussion of difference**
510K Number	K221569	K212881	***/***
Classification	21CFR 878.4810	21CFR 878.4810	**Same**
Product Code	OHT, ONF	OHT, ONF	**Same**
FDA Class	II	II	**Same**
Model	T013C, T015C, T015K	T012C	***/***
Indications for Use	The Intense Pulsed Light (IPL) System is an over-the-counter device intended for the removal of unwanted body hair.	The Intense Pulsed Light (IPL) System is an over-the-counter device intended for the removal of unwanted body hair.	**Same**
Type of use	Over-The-Counter Use	Over-The-Counter Use	**Same**
Environment of Use	Home use	Home use	**Same**

Design	Hand-hold	Hand-hold	**Same**
Patient Population	Adult	Adult	**Same**
Material of Patient contact components	The patients' skin or operator contact: T013C: PC for shell(Lamp shell, button, light guide column, right shell, face shell, front upper shell), aluminum for cold compress panel T015C&T015K: ABS for ABS shell and buttons, aluminum for cold compress panel	The patients' skin or operator contact: ABS for ABS shell and buttons, aluminum for cold compress panel	The material of T015C and T015K is identical with predicate device, T013C is different with predicate device, (Discussion is indicated in D1)
Biocompatibility testing	1.Type of contact: direct contact for users and patients. 2.Nature of body contact category: Surface Contact class: A (<24 h) 3.Meets ISO 10993- 5, ISO 10993-10	1.Type of contact: direct contact for users and patients. 2.Nature of body contact category: Surface Contact class: A (<24 h) 3.Meets ISO 10993- 5, ISO 10993-10	**Same**
Single Patient, multi-use	Yes	Yes	**Same**
Patient Interface	Buttons	Buttons	**Same**
Technology	Intense Pulse Light (IPL)	Intense Pulse Light (IPL)	**Same**
Dimensions	171×76×50mm for T013C 206×113×91.5mm for T015C 206×113×91.5mm for T015K	148×190×56mm	Different(Discussion is indicated in D2)
Power source	an external power supply Input: 100-240V ~ 50/60Hz，1.5A Max. Output: 24Vdc 2.2A	an external power supply Input: 100-240V ~ 50/60Hz，1.5A Max. Output: 24Vdc 2.2A	**Same**
Light source	Xenon Arc Flashlamp	Xenon Arc Flashlamp	**Same**
Wavelength	510nm~1200nm	510nm~1200nm	**Same**
Spot Size	4cm² for T013C 3.5cm² for T015C 3.7cm² for T015K	Light outlet: 4cm² Lamp cover: 1.85cm²	Minor different(Discussion is indicated in D3)
Max. Fluence (J/cm^2)	4.03J/cm² for T013C 4.69J/cm² for T015C 3.6J/cm² for T015K	5.18J/cm² (Attach Probe Cover:3.41J/cm²)	Different(Discussion is indicated in D4)
Pulse duration	4~12ms for T013C and T015C 3~10ms for T015K	4~12ms	The parameter of T013C and T015C is identical with predicate device, T013K is minor different with predicate device (Discussion is indicated in D5)

Output energy	3.8J~16.1J for T013C 4.1J~16.4J for T015C 5.2J~13.4J for T015K	5.5J~20.7J	Different(Discussion is indicated in D6)
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**
Operating environment	Temperature: 5-30℃ Relative humidity: 20-90%, without condensation Atmospheric Pressure: 70 kPa to 106 kPa	Temperature: 5-30℃ Relative humidity: 20-90%, without condensation Atmospheric Pressure: 70 kPa to 106 kPa	**Same**
Storage and transportation environment	Temperature: -20 -55 ℃ Relative humidity: 5-95%, without condensation Atmospheric Pressure:70 kPa to 106 kPa	Temperature: -20 -55 ℃ Relative humidity: 5-95%, without condensation Atmospheric Pressure:70 kPa to 106 kPa	**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	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471 ISO 10993-5 ISO 10993-10	**Same**

Based on the comparison chart above, there have been no changes to the intended use or product specifications of subject device from those of the predicate device, the fundamental operating principle of the device is identical to that of the predicate device. The change associated with the updated industrial design which include a different PCB layout and some different hardware components, patient contact material, and minor different specifications, have been verified and validated via laboratory testing. Through the verification and validation process, it has been shown that the differences do not raise new questions of safety and effectiveness.

The discussion of differences exist between the subject and predicate devices is listed in following:

D1: The material of T015C and T015K is identical with predicate device,T013C is different with predicate device. The subject devices have been validated for cytotoxicity per ISO 10993- 5 and Irritation as well as Sensitization per ISO 10993-10 with positive results, therefore, the material difference of subject device with Predicate device TB-1755 (K183217) do not raise new questions of safety and effectiveness.

D2: The difference of dimensions will not affect the safety and effectiveness.

D3: Spot Size of subject device is same or similar with predicate device. The safety and effectiveness of the subject device is verified via tests according to ANSI AAMI ES60601-1, IEC60601-1-2, IEC60601-1-11, IEC 62471 and IEC 60601-2-83, so the differences do not affect the safety and effectiveness.

D4: Max. Fluence of subject device is within the range of predicate device. The safety and effectiveness of the subject device is verified via tests according to ANSI AAMI ES60601-1, IEC60601-1-2, IEC60601-1-11, IEC 62471 and IEC 60601-2-83, so the differences do not affect the safety and effectiveness.

D5: Pulse duration of T013C and T015C is identical with predicate device,T013K is minor different with predicate device, but similar and within the range of predicate device. The safety and effectiveness of the subject device is verified via tests according to ANSI AAMI ES60601-1, IEC60601-1-2, IEC60601-1-11, IEC 62471 and IEC 60601-2-83, so the differences do not affect the safety and effectiveness.

D6: Output energy of subject device is within the range of predicate device. The safety and effectiveness of the subject device is verified via tests according to ANSI AAMI ES60601-1, IEC60601-1-2, IEC60601-1-11, IEC 62471 and IEC 60601-2-83, so the differences do not affect the safety and effectiveness.

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

The modifications to the device have been designed and assessed under design control processes compliant with FDA 21 CFR 820. Based on modification clearance, a risk analysis was conducted to assess the impact of the changes on the subject device using internal design control procedures and a fault tree analysis described in the FDA-recognized version of ISO 14971.

These risks were mitigated using planned measures that included testing to recognized FDA consensus standards. Changes in software were verified and validated using the software development process.

Non-clinical testing as below table has been performed to demonstrate that the safety and efficacy of the device remains substantially equivalent to its predicate.

Standards	Standards Name	**Results**
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance	Pass
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	Pass
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	Pass

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	Pass
IEC 62471: 2006	Photobiological safety of lamps and lamp systems	Pass
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Pass
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Pass
IEC 62304:2006+A1:2015	Medical device software - Software life cycle processes	Pass

8. Discussion of Clinical Accuracy Testing Performed

There was no clinical testing performed.

9. Conclusions

A risk analysis was performed to identify risks associated with the device modifications. Verification and validation tests have been performed to demonstrate that the identified risks have been mitigated. Thus, based on the information provided in this premarket notification, it is concluded that the modified device Intense Pulsed Light (IPL) Systems, model: T013C, T015C, T015K are substantially equivalent to the legally marketed predicate device.