June 26, 2023

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

Re: K231215
Trade/Device Name: IPL Hair Removal Device Model: Skin Expert Pro IPL 008, Skin Expert Pro IPL 008S
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: April 20, 2023
Received: April 28, 2023

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)*

K231215

Device Name

IPL Hair Removal Device Model: Skin Expert Pro IPL 008, Skin Expert Pro IPL008S

Indications for Use *(Describe)*

The IPL Hair Removal device (Model: Skin Expert Pro IPL 008, Skin Expert Pro IPL 008S) 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K231215

1. Submitters Information

Establishment Registration Information

Name:	Zhongshan Qizhe Technology Co., Ltd
Address:	23 Tongji West Road,Nantou Town,Zhongshan City (Room 902, Building 8, Hongji Industrial City Phase II)

Contact Person of applicant:

Name:	Gan Guiping
Address:	23 Tongji West Road,Nantou Town,Zhongshan City (Room 902, Building 8, Hongji Industrial City Phase II)
TEL:	+86 13902957808
Email:	peter@r-d.com.cn

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 of the summary prepared: Jun. 15, 2023

2. Device Information

Trade Name:	IPL Hair Removal device
Model:	Skin Expert Pro IPL 008 Skin Expert Pro IPL 008S
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

Primary Predicate Device 1

510(k) submitter/holder:	Touchbeauty Beauty & Health (Shenzhen) Co., Ltd
510(K) Number:	K183217
Trade Name	IPL Hair Removal Device
Model	TB-1755
Classification name	Light Based Over-The-Counter Hair Removal
Review panel	General & Plastic Surgery
Product code	OHT, ONF
Regulation Class	II
Regulation Number	878.4810

Primary Predicate Device 2

510(k) submitter/holder:	Shenzhen Fansizhe Science and Technology Co., Ltd
510(K) Number:	K223928
Trade Name	IPL Hair Removal Device
Model	T016K
Classification name	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Review panel	General & Plastic Surgery
Product code	OHT
Regulation Class	II
Regulation Number	878.4810

4. Device description

IPL Hair Removal device, models: Skin Expert Pro IPL 008, Skin Expert Pro IPL 008S are a small over-the-counter device for the 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 powered by the external power adaptor or built-in battery and its IPL emission activation is by a switch or auto light emission.

IPL Hair Removal device, models: Skin Expert Pro IPL 008, Skin Expert Pro IPL 008S, contains a Xenon arc flashlamp, one built-in battery, a capacitive sensor to detect appropriate skin contact, and a skin color sensor to detect the skin tone. The skin color sensor is fixed in “Skin color recognition Window” of IPL Hair Removal device, and the device’s skin color sensor automatically detects skin tone for your protection when the device is powered on. 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. The capacitive sensor is assembled in the device probe of IPL Hair Removal device, 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, IPL Hair Removal device, models: Skin Expert Pro IPL 008, Skin Expert Pro IPL 008S, 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 IPL Hair Removal device, models: Skin Expert Pro IPL 008, Skin Expert Pro IPL 008S can be powered on built-in battery or cable adaptor. The built-in lithium battery can be recharged. When the capacity of battery is low, the battery icon "▭" display red on the screen. When the When battery icon " ▭ " display red with blinking for about 20s the device will turn off. The recharge time of the battery is about 3 hours and when full charged and turn on level 5 to treatment the using time about 45 mins.
When the device is turned on under battery-powered and insert the adaptor with the device, the device will be shut down and to charge. If you want to treatment, you shall turn on the device again with the cable adaptor.
When device is turned on under cable adaptor, then take off the adaptor, the device will be shut down. If you still want to treatment, you shall turn on the device again.

The IPL Hair Removal Device includes main unit (including built-in battery), an adaptor, goggles and shaver.

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

IPL Hair Removal device, models: Skin Expert Pro IPL 008, Skin Expert Pro IPL 008S 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 device1 (K183217) and predicate device2(K160968)

SE Comparisons	**Subject device (IPL Hair Removal device, model: Skin Expert Pro IPL 008, Skin Expert Pro IPL 008S)**	**Predicate device 1 (IPL Hair Removal Device, Model: TB-1755)**	**Predicate device 2 (IPL Hair Removal Device, Model: T016K)**	**Discussion of difference**
510K Number	/	K183217	K223928	**/**
Classification	21CFR 878.4810	21CFR 878.4810	21CFR 878.4810	**Same**
Product Code	OHT	OHT, ONF	OHT	**Same**
FDA Class	II	II	II	**Same**
Indications for Use	The IPL Hair Removal device(model: Skin Expert Pro IPL 008, Skin Expert Pro IPL 008S) is an Over the Counter device intended for the removal of unwanted body hair.	The IPL Hair Removal device (model: TB-1755) is an Over the Counter device intended for the removal of unwanted body hair.	The IPL Hair Removal Device is an over-the-counter device intended for the removal of unwanted body hair.	**Same**
Environment of Use	Home use	Home use	Home use	**Same**
Design	Hand-hold	Hand-hold	Hand-hold	**Same**
Patient Population	Adult	Adult	Adult	**Same**
Material of Patient contact components	ABS for button, ABS for main housing, PC for Probe cover, PC for Light Exit Window, PC for Touch key-press , Sapphire Crystal Cooling Compress	Not public	PC for button, PC for main housing and Probe cover, Sapphire Crystal Cooling Compress	**Different** (Discussion is indicated in D1)
Biocompability 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	Not public	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	Yes	**Same**
Patient Interface	Buttons	Buttons	Buttons	**Same**
Technology	Intense Pulse Light (IPL)	Intense Pulse Light (IPL)	Intense Pulse Light (IPL)	**Same**

SE Comparisons	**Subject device (IPL Hair Removal device, model: Skin Expert Pro IPL 008, Skin Expert Pro IPL 008S)**	**Predicate device 1 (IPL Hair Removal Device, Model: TB-1755)**	**Predicate device 2 (IPL Hair Removal Device, Model: T016K)**	**Discussion of difference**
Dimensions	153*185*52mm for Skin Expert Pro IPL 008S 140*191*54mm for Skin Expert Pro IPL 008S	182*72.4*69.2mm	90*44*225mm	**Different** (Discussion is indicated in D2)
Power source	An external power supply and built-in battery	An external power supply	An external power supply	**Different** (Discussion is indicated in D3)
Light source	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	**Same**
Wavelength	510nm~1100nm	510-1100nm	510nm~1200nm	**Different** (Discussion is indicated in D4)
Spot Size	3.1cm^2	3.1 cm^2	3.3cm^2	**Different** (Discussion is indicated in D5)
Max. Fluence (J/cm^2)	3.8-5.5 J/cm^2	3.8-5.2 J/cm^2	1.45-5.73J/cm^2	**Different** (Discussion is indicated in D6)
Pulse duration	3ms -9ms	3ms	4ms-12ms	**Different** (Discussion is indicated in D7)
Output energy	12J -18J	12J-16J	4.8J~18.9J	**Different** (Discussion is indicated in D8)
Pulsing Control	Finger switch	Finger switch	Finger switch	**Same**
Output Channel	One channel	One channel	One channel	**Same**
Delivery	Direct Illumination to Tissue	Direct Illumination to Tissue	Direct Illumination to Tissue	**Same**
Software Control	Yes	Yes	Yes	**Same**
Electrical safety, EMC, Biological Evaluation	ANSI AAMI ES60601-1 IEC 60601-1-2 ANSI/AAMI HA60601-1-11 IEC 60601-2-83 IEC 62471	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 62471	ANSI AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83 IEC 62471	**Different** (Discussion is indicated in D9)

SE Comparisons	Subject device (IPL Hair Removal device, model: Skin Expert Pro IPL 008, Skin Expert Pro IPL 008S)	Predicate device 1 (IPL Hair Removal Device, Model: TB-1755)	Predicate device 2 (IPL Hair Removal Device, Model: T016K)	Discussion of difference
	ISO 10993-5 ISO 10993-10 IEC 62133-2	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	

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

D1: The subject device has 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 2 (K223928, Model: T016K) do not raise new questions of safety and effectiveness.

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

D3: The subject device has demonstrated electromagnetic compatibility and electrical safety by ANSI AAMI ES60601- 1 and ANSI AAMI IEC 60601-1-2 testing. Therefore, the difference does not raise the issue of product's safety and effectiveness.

D4: Wavelength of subject device is same with predicate device 1 and similar with predicate device 2. The safety and effectiveness of the subject device is verified via tests according to ANSI AAMI ES60601-1, IEC60601-1-2, ANSI/AAMI HA60601-1-11, IEC 62471 and IEC 60601-2-83, so the differences do not affect the safety and effectiveness.

D5: Spot Size of subject device is same with predicate device 1 but similar with predicate device 2. The safety and effectiveness of the subject device is verified via tests according to ANSI AAMI ES60601- 1, IEC60601-1-2, ANSI/AAMI HA60601-1-11, IEC 62471 and IEC 60601-2-83, so the differences do not affect the safety and effectiveness.

D6: Max. Fluence of subject device is similar or within the range of predicate devices. The lower limit value of subject device is the same with predicate device 1, the range of subject device is covered by predicate device 2. The safety and effectiveness of the subject device is verified via tests according to ANSI AAMI ES60601-1, IEC60601-1-2, ANSI/AAMI HA60601-1-11, IEC 62471 and IEC 60601-2-83, so the differences do not affect the safety and effectiveness.

D7: Pulse duration of subject device similar with predicate devices. The lower limit value of subject device is the same with predicate device 1, and the Pulse duration of subject device is similar with the range of predicate device 2. The safety and effectiveness of the subject device is verified via tests according to ANSI AAMI ES60601-1, IEC60601-1-2, ANSI/AAMI HA60601-1-11, IEC 62471 and IEC 60601-2-83, so the differences do not affect the safety and effectiveness.

D8: Output energy of subject device is similar with predicate device1, and the range of subject device is covered by predicate device 2. The safety and effectiveness of the subject device is verified via tests according to ANSI AAMI ES60601-1, IEC60601-1-2, ANSI/AAMI HA60601-1-11, IEC 62471 and IEC 60601-2-83, so the differences do not affect the safety and effectiveness.

D9: One of IEC 60601-2-83 and IEC 60601-2-57 is applicable for IPL Hair Removal device, so the difference does not affect the safety and effectiveness. The IEC 62133-2 is applicable for the built-in Lithium battery, and subject device is verified via tests according to ANSI AAMI ES60601-1, IEC60601-1-2, ANSI/AAMI HA60601-1-11, IEC 62471 and IEC 60601-2-83, so the difference does not affect the safety and effectiveness.

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, ANSI/AAMI HA60601-1-11, IEC 62133-2 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 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
ANSI/AAMI HA60601-1-11:2015 + A1:2021	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 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10 Third Edition 2010-08-01	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
IEC 62133-2 Edition1.0 2017-02	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	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 IPL Hair Removal device,

model: Skin Expert Pro IPL 008, Skin Expert Pro IPL 008S, is substantially equivalent to the predicate devices.