May 26, 2023

Shenzhen IONKA Medical Technology Co., Ltd.
Yu Yeap
Registered Engineer
Room 601, No. 3, Jiazitang Second Industrial Zone,
Jiazitang Community, Fenghuang Street, Guang
Shenzhen, Guangdong 518132
China

Re: K230739
Trade/Device Name: Hand-held IPL device (IPL Home Use Hair Removal Device), Model: FZ-608, FZ-608G, FZ-100, FZ-200
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: March 7, 2023
Received: March 17, 2023

Dear Yu Yeap:

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)*
K230739

Device Name
Hand-held IPL device (IPL Home Use Hair Removal Device), Model: FZ-608, FZ-608G, FZ-100, FZ-200

Indications for Use *(Describe)*
Hand-held IPL 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K230739

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1 Submitter Information

Company Name: Shenzhen IONKA Medical Technology Co., Ltd.
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Contact Person (including title): Chen Dongfa (General Manager)
E-mail: info@tzwm.com

2 Subject Device Information

Type of 510(k) submission: ***Traditional 510(k) Device Submission***
Trade Name: Hand-held IPL device (IPL Home Use Hair Removal Device)
Model: FZ-608, FZ-608G, FZ-100, FZ-200
Common Name: Light Based Over-The-Counter Hair Removal
Classification Name: Laser surgical instrument for use in general and plastic surgery and indermatology
Review Panel: General & Plastic Surgery
Product Code: OHT
Regulation Number: 878.4810
Regulation Class: 2

3 Predicate device Information

Legally existing device K221214
Trade Name: Hand-held IPL device (IPL Home Use Hair Removal Device)
Model: FZ-608, FZ-608G, FZ-100, FZ-200
Common Name: Powered Light Based Non-Laser Surgical Instrument WithThermal Effect
Classification Name: Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Review Panel: General & Plastic Surgery
Product Code: ONF
Regulation Number: 878.4810
Regulation Class: 2

Reference device K222432

Trade Name: IPL Hair Removal Device

Model: KCA423, KCA437, KCA439

Common Name: Light Based Over-The-Counter Hair Removal

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Review Panel: General & Plastic Surgery

Product Code: OHT

Regulation Number: 878.4810

Regulation Class: 2

4 Device Description

The IPL Home Use Hair Removal Device is a personal, light-based, hair reduction device intended to be sold over-the-counter directly to the end user. The device provides hair reduction using Intense Pulsed Light (IPL) technology, and it works below the skin's surface and does not involve any cutting or pulling, reducing hair growth with minimal pain.

The IPL Home Use Hair Removal Device is composed of a hand-held applicator and an external power supply. The spot size (treatment area) in the IPL Home Use Hair Removal Device is 3cm². The device contains a lamp, a skin proximity sensor. If the IPL Home Use Hair Removal Device is not properly applied (in full contact with the skin), the device will not trigger a pulse.

The IPL Home Use Hair Removal Device includes FZ-608, FZ-608G, FZ-100, and FZ-200 four models. Their intended use, performance, structure design and operation are basically identical, with the differences mainly contains product appearance, energy output range and its equipped power supply model. The model difference is embodied in: #1) energy output level of model FZ-608 and FZ-608G has 9 levels, corresponding to an output range of 4.16J~10J; model FZ-100 has 9 levels, corresponding to an output range of 5.7J~16.26J, and model FZ-200 has 6 levels, corresponding to an output range of 4.6J~13,5J; #2) the main unit FZ-608 and FZ-608G can be supplied by the power adaptor (model: SHCSP2402000FUS), and the main unit FZ-100 and FZ-200 can only be supplied by the power adaptor (model: SHCY-SP2401500EUS), the adapters have been approved in accordance with IEC 62368-1 and tested with equipment, considering as a part of this ME equipment.

5 Intended Use

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.

6 Complied Standards

Hand-held IPL device (IPL Home Use Hair Removal Device), Model: FZ-608, FZ-608G, FZ-100, FZ-200 complies with the following FDA recognized consensus standards:

- ✉ Electrical safety test according to AAMI/ANSI ES60601-1, IEC60601-1-11 and IEC 60601-2-83 standards
- ✉ Electromagnetic compatibility test according to IEC 60601-1-2 standard
- ✉ ISO 10993-5:2009/(R) 2014, 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.

7 Device modification description

The only modification of subject device is Intended Use. The device has changed to over-the-counter use. Therefore, the User Manual and Box labelling has been adding corresponding use instructions for lay person user.

8 Performance Testing

As the modification of subject device as above, results in no technological characteristics changes, the tests and data utilized to demonstrate safety and efficacy of the predicate device (legally existing device) are suitable for use in the assessment of the subject devices.

As there have been no changes to the performance of the subject device from the predicate device, this submission leverages performance and electrical testing provided in previous submission.

Meanwhile, self-select and usability testing (OTC Study) was completed in 24 subjects to evaluate device human factors and label comprehension. These study tests demonstrate that the subject device and its labeling can meet the requirement: 1) the lay user can self-select themselves as being appropriate users of this device by the external box labeling, 2) the lay user can apply the treatment safely and correctly according to the instructions for use, and 3) the lay user can understand all indications, contraindications, warnings and precautions, and be able to identify whether they are within any contraindicated group; and be able to understand the user manual.

9 Biocompatibility

All the modified device materials which come in direct contact with the patient skin are biocompatible and identical to the materials used in the predicate device manufacturing. No biocompatibility test report is provided in this submission.

10 Clinical performance

Clinical performance is not deemed necessary.

11 Comparison with predicate device

Compare with predicate device (Hand-held IPL device (IPL Home Use Hair Removal Device) K221214), the subject device is same in design principle, functions, material and the applicable standards. And the intended use of subject device is same to Reference device K222432. The differences between subject device and predicate devices do not raise any new questions of safety or effectiveness.

Item	Subject Device	Predicate Device	Reference Device
Manufacturer	Shenzhen IONKA Medical Technology Co., Ltd.	Shenzhen IONKA Medical Technology Co., Ltd.	Hunan Guangye Biotechnology Co., Ltd.
K number	K230739	K221214	K222432
Product Name	Hand-held IPL device (IPL Home Use Hair Removal Device) Model: FZ-608, FZ-608G, FZ-100, FZ-200	Hand-held IPL device (IPL Home Use Hair Removal Device) Model: FZ-608, FZ-608G, FZ-100, FZ-200	IPL Hair Removal Device Model: KCA423, KCA437, KCA439
Regulation & Classification	Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology Review Panel: General & Plastic Surgery Product Code: OHT Regulation Number: 878.4810 Regulation Class: 2	Classification Name: Powered Light Based Non-Laser Surgical Instrument With Thermal Effect Review Panel: General & Plastic Surgery Product Code: ONF Regulation Number: 878.4810 Regulation Class: 2	Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology Review Panel: General & Plastic Surgery Product Code: OHT Regulation Number: 878.4810 Regulation Class: 2
Indications for Use	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 is indicated for patient removal of unwanted hair by using a selective photothermal treatment under the direction of a physician, after training by a healthcare professional. The IPL home use hair removal device is also intended for permanent reduction in unwanted hair. Permanent hair reduction is 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 regimen. The device is used for adults with Fitzpatrick skin types I	IPL 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 reductionin the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

Item	Subject Device			Predicate Device			Reference Device
				– IV.			
	OTC Use			Prescription Use			OTC Use
Source Energy	Supplied by external adapter			Supplied by external adapter			Supplied by external adapter
Device Type	Intense Pulsed Light			Intense Pulsed Light			Intense Pulsed Light
Wavelength (nm)	510nm~1200nm			510nm~1200nm			475-1200nm
Spot Size	3 cm^2			3 cm^2			3 cm^2
Energy output range	FZ-608, FZ-608G: Level 1: 4.16J Level 2: 4.36J Level 3: 5.1J Level 4: 6.1J Level 5: 6.96J Level 6: 7.96J Level 7: 8.63J Level 8: 9.13J Level 9: 10.0J	FZ-100: Level 1: 5.7J Level 2: 6.5J Level 3: 8.06J Level 4: 9.73J Level 5: 11.96J Level 6: 14.1J Level 7: 15.13J Level 8: 15.33J Level 9: 16.26J	FZ-200: Level 1: 4.6J Level 2: 5.7J Level 3: 6.63J Level 4: 8.66J Level 5: 11.3J Level 6: 13.5J	FZ-608, FZ-608G: Level 1: 4.16J Level 2: 4.36J Level 3: 5.1J Level 4: 6.1J Level 5: 6.96J Level 6: 7.96J Level 7: 8.63J Level 8: 9.13J Level 9: 10J	FZ-100: Level 1: 5.7J Level 2: 6.5J Level 3: 8.06J Level 4: 9.73J Level 5: 11.96J Level 6: 14.1J Level 7: 15.13J Level 8: 15.33J Level 9: 16.26J	FZ-200: Level 1: 4.6J Level 2: 5.7J Level 3: 6.63J Level 4: 8.66J Level 5: 11.3J Level 6: 13.5J	7.35J to 15J
Max. energy output density	FZ-608, FZ-608G: 3.33 J/cm^2 FZ-100: 5.43 J/cm^2 FZ-200: 4.5 J/cm^2			FZ-608, FZ-608G: 3.33 J/cm^2 FZ-100: 5.43 J/cm^2 FZ-200: 4.5 J/cm^2			5 J/cm^2
Pulse duration	0.5~0.8 ms			0.5~0.8 ms			7~10ms
Energy medium	Xenon Arc Flashlamp			Xenon Arc Flashlamp			Xenon Arc Flashlamp
Pulsing Control	Finger switch			Finger switch			Finger switch
Delivery device	Direct illumination to tissue			Direct illumination to tissue			Direct illumination to tissue

Item	Subject Device	Predicate Device	Reference Device
Skin proximity sensor	Sensor fixed in device and can be moved to treatment part	Sensor fixed in device and can be moved to treatment part	Sensor fixed in device and can be moved to treatment part
Number of output channel	One channel	One channel	One channel
Energy output level	FZ-608, FZ-608G: 9 levels FZ-100: 9 levels FZ-200: 6 levels	FZ-608, FZ-608G: 9 levels FZ-100: 9 levels FZ-200: 6 levels	7 levels
Software Control?	Yes	Yes	Yes
Structure design	Handheld	Handheld	Handheld
Weight	FZ-608, FZ-608G: 1.515kg FZ-100: 1.515kg FZ-200: 1.1kg	FZ-608, FZ-608G: 1.515kg FZ-100: 1.515kg FZ-200: 1.1kg	KCA423: 223g KCA437: 255g KCA439: 235g
Dimensions	FZ-608, FZ-608G: 98*147*60(mm) FZ-100: 198*71*44(mm) FZ-200: 216*68*52(mm)	FZ-608, FZ-608G: 98*147*60(mm) FZ-100: 198*71*44(mm) FZ-200: 216*68*52(mm)	KCA423: 164.82*76.4*40mm KCA437: 162*76.7*43.2mm KCA439: 162.2*77.9*42.4mm
Electrical safety, EMC	AAMI/ANSI ES60601-1 IEC 60601-1-11 IEC 60601-2-83 IEC 60601-1-2	AAMI/ANSI ES60601-1 IEC 60601-1-11 IEC 60601-2-83 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-11 IEC 60601-2-83 IEC 60601-1-2
Biocompatibility	ISO10993-5 ISO10993-10	ISO10993-5 ISO10993-10	ISO10993-5 ISO10993-10

Although the indication for use of subject device is different to predicate device K221214, but it is only to simplify the statement of the legally existing predicate device and remove the prescription use statement, which is not involved with technical specifications. The revised indication for use of subject device in this submission also had been covered by the indication for use of the legally existing predicate device; which is same to Reference device K222432. And the subject device had been verify by usability study for its OTC use. So the difference does not affect the safety and effectiveness.

12 Summary Prepared Date

7 March. 2023