September 21, 2022

Shenzhen IONKA Medical Technology Co., Ltd.
℅ Amos Zou
RA Manager
Shenzhen CT Bio-Tech co., Ltd
Room 408, Comprehensive Building, Building 6,
Xusheng Building, Xixiang street, Baoan District
Shenzhen, Guangdong 518126
China

Re: K221214
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: ONF
Dated: May 31, 2022
Received: May 31, 2022

Dear Amos Zou:

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
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)*
K221214

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)*
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 – IV.

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.

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION
as required by section 21 CFR 807.92

1. Submitter of 510(K):

Sponsor

Company Name:	Shenzhen IONKA Medical Technology Co., Ltd.
Address:	Room 601, No. 3, Jiazitang Second Industrial Zone, Jiazitang Community, Fenghuang Street, Guangming District, Shenzhen，518132,China
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TEL:	+86-755-23406031
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Date of Prepared:	August 31, 2022

Application Correspondent:

Company Name:	Shenzhen CT Bio-Tech co., Ltd
Address:	Room 408,Comprehensive Building,Building 6,Xusheng Building,Xixiang street,Baoan District,Shenzhen,,Guangdong.518126,China
Contact person:	Amos Zou
TEL:	+86-15015249549
E-mail:	amos.zou@139.com
Date of Prepared:	August 31, 2022

2. Proposed Device and code:

Device Trade Name:	Hand-held IPL device (IPL Home Use Hair Removal Device) Model:FZ-608, FZ-608G, FZ-100, FZ-200
Regulation Medical Specialty	General & Plastic Surgery

Product Code:	ONF
Regulation Name	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Common Name	Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Regulation number	21 CFR 878.4810
Device Class	II

3. Predicate Device:

510(K)	Trade or Proprietary or Model Name	Manufacturer
K160968	Ipulse Smoothskin Gold Hair Removal Device	Cyden Limited
K170269	Hee HR Mini	Oriental Inspiration Limited
K213558	IPL Hair Removal Device	Ulike Co., Ltd
K212907	Aimanfun Lumea Comfort, A-3588	Kam Yuen Plastic Products Ltd

4. Description of Proposed Device:

The Hand-held IPL device are pulsed light hair removal device. Light-based hair removal is based on the theory of selective photosynthesis in which optical energy is used to disable hair growth. The Hand-held IPL device devices are composed of a hand held applicator and an external power supply. The spot size (treatment area) in the Hand-held IPL device devices is 3 cm^2， The device contains a lamp, a skin proximity sensor. If the Hand-held IPL device is not properly applied (in full contact with the skin) , the Hand-held IPL device will not trigger a pulse.

The main unit FZ-608 and FZ-608G can only be supplied by the power adaptor (model: SHCSP2402000FUS), 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.

FZ-608 and FZ-608G are identical except for model No. and enclosure colour.

The patient is an intended operator.

5. Indications for Use

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 – IV.

6. Technical and Performance

The following table compares the device to the predicate device with basic technological characteristics.

Elements of comparison	Subject Device 1# K221214	Subject Device 2# K221214	Subject Device 3# K221214	Predicate Device 1# K160968	Predicate Device 2# K170269	Predicate Device 3# K212907	Predicate Device 4# K213558	Remark
Device Name and Model	IPL home use hair removal device FZ-608&FZ-608G	IPL home use hair removal device FZ-100	IPL home use hair removal device FZ-200	Ipulse Smoothskin Gold Hair Removal Device	Hee HR Mini	Aimanfun Lumea Comfort, A-3588	IPL Hair Removal Device	/
Manufacturer	Shenzhen IONKA Medical Technology Co., Ltd.	Shenzhen IONKA Medical Technology Co., Ltd.	Shenzhen IONKA Medical Technology Co., Ltd.	Cyden Limited	Oriental Inspiration Limited	Kam Yuen Plastic Products Ltd	Ulike Co., Ltd	/
Classification Product Code	ONF	ONF	ONF	OHT, GEX	OHT	ONF	ONF	Same
Light source	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Same
Wavelength (nm)	510 – 1200	510 – 1200	510 – 1200	510 – 1100	475 - 1200	475 - 1200	550 - 1200	similar Note 1#
Spot size	3 cm^2	3 cm^2	3 cm^2	3 cm^2	3 cm^2	3 cm^2	3.3 cm^2	Same
Max fluence	3.33 J/cm^2	5.43 J/cm^2	4.5 J/cm^2	6 J/cm^2	5 J/cm^2	4.5 J/cm^2	6 J/cm^2	similar Note 2#
Energy output	Level 1: 4.16J Level 2: 4.36J Level 3: 5.1J	Level 1: 5.7J Level 2: 6.5J Level 3: 8.06J	Level 1: 4.6J Level 2: 5.7J Level 3: 6.63J	9 - 18 J	15 J max	7 – 13.5 J	7 – 20 J	Similar

Elements of comparison	Subject Device 1# K221214	Subject Device 2# K221214	Subject Device 3# K221214	Predicate Device 1# K160968	Predicate Device 2# K170269	Predicate Device 3# K212907	Predicate Device 4# K213558	Remark
	Level 4: 6.1J Level 5: 6.96J Level 6: 7.96J Level 7: 8.63J Level 8: 9.13J Level 9: 10J	Level 4: 9.73J Level 5: 11.96J Level 6: 14.1J Level 7: 15.13J Level 8: 15.33J Level 9: 16.26J	Level 4: 8.66J Level 5: 11.3J Level 6: 13.5J					Note 3#
Energy density range	1.4 – 3.3 J/cm^2	1.9 – 5.4 J/cm^2	1.5 – 4.5 J/cm^2	3 – 6 J/cm^2	Unknown	2.3 – 4.5 J/cm^2	2.1 – 6 J/cm^2	Similar Note 4#
Pulse duration	0.5 – 0.8 ms	0.5 – 0.8 ms	0.5 – 0.8 ms	2 – 10 ms	0.5 – 0.8 ms	3 ms	3 ms	similar Note 5#
Skin contact sensor	Yes	Yes	Yes	Yes	Yes	Yes	Yes	same
Cooling system	Yes (thermoelectric cooler)	Yes (thermoelectric cooler)	Yes (semiconductor refrigeration sheet)	No	No	Yes (thermoelectric cooler)	No	same
Treatment schedule	1 X/week for 12 weeks	1 X/week for 12 weeks	1 X/week for 12 weeks	1 X/week for 12 weeks	1X every 2 weeks for 4 treatments, 1X every 4 weeks for treatments 5-7, then as needed	1 X/week for 12 weeks	1 X/week for 12 weeks	Same
Use classification	Rx	Rx	Rx	OTC	OTC	Rx	Rx	Same
Ice-sensing function	Yes	Yes	No	No	No	Yes	No	Same as K212907 Note 6#

Elements of comparison	Subject Device 1# K221214	Subject Device 2# K221214	Subject Device 3# K221214	Predicate Device 1# K160968	Predicate Device 2# K170269	Predicate Device 3# K212907	Predicate Device 4# K213558	Remark
Delivery Device	Direct Illumination to Tissue	Direct Illumination to Tissue	Direct Illumination to Tissue	Direct Illumination to Tissue	Direct Illumination to Tissue	Direct Illumination to Tissue	Direct Illumination to Tissue	same
Pulsing Control	Finger switch	Finger switch	Finger switch	Finger switch	Finger switch	Finger switch	Finger switch	same
Skin Tone Sensor	Optical Measurement Integral to device. Continuous measurement.	Optical Measurement Integral to device. Continuous measurement.	Optical Measurement Integral to device. Continuous measurement.	Optical Measurement Integral to device. Continuous measurement.	Optical Measurement Integral to device. Continuous measurement.	Optical Measurement Integral to device. Continuous measurement.	Optical Measurement Integral to device. Continuous measurement.	same
Specific Indications for Use	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	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	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	The iPulse SmoothSkin Gold Hair Removal System is indicated for the removal of unwanted hair. The iPulse SmoothSkin Gold is also indicated for the permanent reduction in hair regrowth,	HEE HR Mini is an over-the-counter device intended for the removal of unwanted hair. The HEE HR Mini is also intended for permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of	The Aimanfun Lumea Comfort (Model: A-3588) is indicated for patient removal of unw anted hair by using a selective photothermal treatment under the direction of a physician, after training by a healthcare	The IPL Hair Removal Device (Model: UI04A, UI04B, UI04C) is indicated for patient removal of unwanted hair by using a selective photothermal treatment under the direction of a physician，after training by a	Same

Elements of comparison	Subject Device 1# K221214	Subject Device 2# K221214	Subject Device 3# K221214	Predicate Device 1# K160968	Predicate Device 2# K170269	Predicate Device 3# K212907	Predicate Device 4# K213558	Remark
	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 – IV.	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 – IV.	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 – IV.	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.	hairs regrowing when measured at 6, 9, and 12 months after the completion of treatment regimen.	professional. The Aimanfun Lumea Comfort 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	healthcare professional. The IPL 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.	

Comparison in Detail(s):

Note 1#,2#,3#,4#,5#:

Although it is a little different from the subject device,and is deviating from the one of the predicate device,but they all comply with IEC 60601-1,IEC 60601-2-83 requirement.So the differences of function specification will not raise any safety or effectiveness issue.

Note 6#

Although the subject device (model: FZ-608&FZ-608G) and The Aimanfun Lumea Comfort (Model: A-3588) from K212907,provides an ice-sensing function, which utilizes a thermoelectric cooler under the skin contact window, the function is only to make patients comfortable with slightly cool sensation after IPL treatment, and have no

therapeutic effect. The difference does not result in a change of IPL technical specifications, so the difference does not affect the safety and effectiveness.

Conclusion

The subject device has similar features of the predicate device for the same intended use. Thus, the differences would not raise any problem in substantial equivalence claims,the subject device is the same or similar to the predicate device.

7. PERFORMANCE DATA

The testing for Hand-held IPL device (IPL Hair Removal Device) included performance, software, electrical safety, EMC, biocompatibility and bench. Hand-held IPL device (IPL Hair Removal Device) passed all testing in support of the substantial equivalence determination:

7.1. Biocompatibility testing

The biocompatibility evaluation for the Hand-held IPL device (IPL Hair Removal Device) was conducted in accordance with

International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process." As dictated by the application and duration of contact with the intact skin, the enclosure of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

7.2. Electrical safety and electromagnetic compatibility

Electrical safety, performance and EMC testing were conducted on the Hand-held IPL device (IPL Hair Removal Device) . The device with compliance with the AAMI/ANSI ES60601-1, IEC 60601-1-11, IEC 60601-2-83 and standards for safety and the IEC 60601-1-2 standard for EMC.

7.3. Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern.

7.4. Validation testing

Bench Testing for the parameters of wavelength, pulse duration, output energy, and maximum fluence of each model at each treatment level. to verify that the proposed device met all design specifications as was the same or similar to the predicate device.

8. Conclusions:

The proposed device has the same intended use and similar technology characteristics as the predicate device, Ipulse Smoothskin Gold Hair Removal Device(K160968), Hee HR Mini (K170269),IPL Hair Removal Device (K213558),Aimanfun Lumea Comfort, A-3588(K212907). Meanwhile, performance testing, bench testing, and safety report documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Based on performance testing, the proposed device is the same or similar to the predicate device.