510(k) Summary #K251000

"510(k) Summary" as required by 21 CFR Part 807.92.

I. Submitter

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II. **Preparation date:** 6/30/2025

III. Device

Name of Device: Hand-held Hair Removal Device
Model(s): FZ-200A, FZ-201, FZ-202, CT05, CT06, CT07, CT08, CT09.
Common or Usual Name: Light Based Over-The-Counter Hair Removal
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: OHT
Regulation Number: 21 CFR 878.4810

IV. Predicate Device and Reference Devices

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shenzhen IONKA Medical Technology Co., Ltd.	Hand-held IPL device (IPL Home Use Hair Removal Device), (Model: FZ-608, FZ-608G, FZ-100, FZ-200)	K230739	May 26, 2023

Reference devices:

Manufacturer	Reference Devices	510(k) Number	Approval Date
Shen Zhen CosBeauty Co., Ltd	IPL Hair Removal Device Joy Version, CB-027	K173813	Sept. 07, 2018
Shenzhen Ulike Smart Electronics Co.,Ltd	IPL Hair Removal Device Model(s): UI06 PL, UI06 PN, UI06 JL, UI06 BR, UI06 DB, UI06 PR, UI06 OG, UI06 RD	K223618	Feb 28, 2023

V. Device Description

Hand-held Hair Removal Device, is an over-the-counter, home-use device for unwanted hair reduction by using Intense Pulsed Light (IPL), and it has been designed eight models with the same IPL technology for hair removal, which is model FZ-200A, FZ-201, FZ-202, CT05, CT06, CT07, CT08, CT09. The device 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 finger switch.

The Hand-held Hair Removal Device has an irreplaceable light exit and it can cover an area of 3.0cm^2 (Model BFZ-200A, FZ-201, FZ-202, CT05, CT06, CT07, CT08, CT09) that is suitable for multiple hair removal areas, such as upper lip, chin, underarms, legs, arms, bikini area, chest, back, abdomen.

The device contains a skin sensor to detect appropriate skin contact, if the light exit is not in full contact with the skin, the device cannot emit the treatment light pulses. Besides, the Hand-held Hair Removal Device has the cooling function (suitable for model CT05, CT06, CT07, CT08, CT09), which can be activated throughout the whole hair removal process to cool down the treatment area's temperature and provide the user with a better using experience.

VI. Indications for Use

Hand-held 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.

VII.Materials

Component name	Material of Component	Body Contact Category	Contact Duration
Hand-held Hair Removal Device	PC, ABS, POM	Surface-contacting device: Intact skin	Less than 24 hours

VIII. Comparison of Technological Characteristics With the Predicate Device

The Hand-held Hair Removal Device has the same intended use, mode of action and similar operational characteristics as the predicate device. Any minor differences between the subject device and the listed predicate device and reference devices do no raise any issues of safety or efficacy. Performance data supports that the device is safe and as effective as the predicate device and reference devices for its intended use. Therefore, the Hand-held Hair Removal Device may be found substantially equivalent to its predicate device and reference devices.

Hand-held Hair Removal Device is compared with the following Predicate Device and Reference Devices in terms of intended use, design, material, specifications, and performance:

Comparison Elements	Subject Device	Predicate Device	Reference device 1	Reference device 2	Remark
510(k) Number	K251000	K230739	K173813	K223618	/
Trade name	Hand-held Hair Removal Device Model: FZ-200A, FZ-201, FZ-202, CT05, CT06, CT07, CT08, CT09	Hand-held IPL device (IPL Home Use Hair Removal Device) Model: FZ-608, FZ-608G, FZ-100, FZ-200	IPL Hair Removal Device Joy Version, CB-027	IPL Hair Removal Device	/
Manufacturer	Shenzhen Chuangtong Yigou Technology Co., Ltd.	Shenzhen IONKA Medical Technology Co., Ltd.	Shen Zhen CosBeauty Co., Ltd	Shenzhen Ulike Smart Electronics Co.,Ltd.	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHT	OHT	OHT	OHT	Same
Device classification	Class II	Class II	Class II	Class II	Same
Indication for use/ Intended use	Hand-held 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 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.	The IPL Hair Removal Device Joy Version 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. The device is used for adults with Fitzpatrick skin types I - IV.	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 reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.	Same
Prescription or OTC	OTC	OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick skin types I-V	Fitzpatrick skin types I-V	Fitzpatrick skin types I-IV	Fitzpatrick skin types I-V	Same
Treatment area	upper lip, chin, underarms, l egs, arms, bikini area, chest, back, abdomen	Unknown	Large areas (legs, arms, back and abdomen), face (upper lip, chin and sideburns)	Large areas (e.g. arms, legs, chest) and small areas (e.g. lip)	Same

Dimension	FZ-200A: 199*68*58(mm) FZ-201: 179*64*39mm FZ-202: 202*132*93mm CT05, CT06: 179*640*39(mm) CT07: 204*173*54(mm) CT08: 192*140*54(mm) CT09: 177*120*91(mm)	FZ-608, FZ-608G: 98*147*60(mm) FZ-100: 198*71*44(mm) FZ-200: 216*68*52(mm)	126*78*200mm	58×34×179mm (W x H x D)	Difference **Note 1**
Power supply	100-240V, 50/60Hz, 0.8AMax	Unknown	100-240 VAC, 50/60Hz	100-240 VAC, 50/60Hz	Same
Sterilization	Not required	Not required	Not required	Not required	Same
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc lamp	Xenon Arc lamp	Xenon Arc Flash lamp	Xenon Arc Flash lamp	Same
Wavelength range	590-1200nm	510-1200mm	510-1200nm	560-1200nm	Similar **Note 2**
Energy density	2-4.3 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	1.8~5.1J/cm^2	3~6 J/cm^2	Similar **Note 3**
Output energy	6-13 J	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	Body lamp cartridge: 11.77~22.21J, 510-1200nm Facial lamp cartridge: 3.65-7.04J, 512-1197nm Bikini lamp cartridge: 3.84-7.22J, 511-1200nm	9.9~19.8J	Similar **Note 3**
Spot size	3cm^2	3cm^2	Body: 4.2cm^2 Bikini and face: 2.0cm^2	3.3cm2	Similar **Note 4**
Pulse duration	2-6 ms	0.5-0.8ms	9.2~11.2ms	1ms~7ms	Similar **Note 5**
Pulsing control	Finger switch	Finger switch	Finger switch	Finger switch	Same
Output intensity level	9 levels	FZ-608, FZ-608G: 9 levels FZ-100: 9 levels	5	3	Same

		FZ-200: 6 levels			
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Yes	Same
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57	ANSI AAMI ES 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	Same
Eye safety	IEC 62471	Unknown	Unknown	IEC 62471	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

IX. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Evaluation

- The biocompatibility evaluation for the body-contacting components of the Hand-held Hair Removal Device was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process, Document Issued on September 4, 2020", as recognized by FDA.

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed to, and passed, as per the following standards:

- IEC 60601-1-2, Edition 4.1 2020-09, Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility.
- IEC 60601-1, Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance .
- IEC 60601-1-11, Edition 2.1 2020-07, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

- IEC 60601-2-83, 2019+AMD1:2022, Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment.

3) Eye Safety

- IEC 62471, First edition 2006-07, Photobiological safety of lamps and lamp systems

4) Software Verification and Validation

Software documentation consistent with ***basic documentation level*** of concern was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

5) Usability

The product usability has been evaluated and verified according to the following FDA guidance

- Applying Human Factors and Usability Engineering to Medical Devices, issued on FEBRUARY 2016.

X. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device Hand-held Hair Removal Device is as safe, as effective, and performs as well as the legally marketed predicate device.

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)*
K251000

Device Name
Hand-held Hair Removal Device (FZ-200A, FZ-201, FZ-202, CT05, CT06, CT07, CT08, CT09)

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

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" as required by 21 CFR Part 807.92.

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II. **Preparation date:** 6/30/2025

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Name of Device: Hand-held Hair Removal Device
Model(s): FZ-200A, FZ-201, FZ-202, CT05, CT06, CT07, CT08, CT09.
Common or Usual Name: Light Based Over-The-Counter Hair Removal
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: OHT
Regulation Number: 21 CFR 878.4810

IV. Predicate Device and Reference Devices

Predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shenzhen IONKA Medical Technology Co., Ltd.	Hand-held IPL device (IPL Home Use Hair Removal Device), (Model: FZ-608, FZ-608G, FZ-100, FZ-200)	K230739	May 26, 2023

Reference devices:

Manufacturer	Reference Devices	510(k) Number	Approval Date
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Shenzhen Ulike Smart Electronics Co.,Ltd	IPL Hair Removal Device Model(s): UI06 PL, UI06 PN, UI06 JL, UI06 BR, UI06 DB, UI06 PR, UI06 OG, UI06 RD	K223618	Feb 28, 2023

V. Device Description

Hand-held Hair Removal Device, is an over-the-counter, home-use device for unwanted hair reduction by using Intense Pulsed Light (IPL), and it has been designed eight models with the same IPL technology for hair removal, which is model FZ-200A, FZ-201, FZ-202, CT05, CT06, CT07, CT08, CT09. The device works below the skin’s surface and does not involve any cutting or pulling, reducing hair growth with minimal pain.

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VII.Materials

Component name	Material of Component	Body Contact Category	Contact Duration
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Hand-held Hair Removal Device is compared with the following Predicate Device and Reference Devices in terms of intended use, design, material, specifications, and performance:

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510(k) Number	K251000	K230739	K173813	K223618	/
Trade name	Hand-held Hair Removal Device Model: FZ-200A, FZ-201, FZ-202, CT05, CT06, CT07, CT08, CT09	Hand-held IPL device (IPL Home Use Hair Removal Device) Model: FZ-608, FZ-608G, FZ-100, FZ-200	IPL Hair Removal Device Joy Version, CB-027	IPL Hair Removal Device	/
Manufacturer	Shenzhen Chuangtong Yigou Technology Co., Ltd.	Shenzhen IONKA Medical Technology Co., Ltd.	Shen Zhen CosBeauty Co., Ltd	Shenzhen Ulike Smart Electronics Co.,Ltd.	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHT	OHT	OHT	OHT	Same
Device classification	Class II	Class II	Class II	Class II	Same
Indication for use/ Intended use	Hand-held 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 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.	The IPL Hair Removal Device Joy Version 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. The device is used for adults with Fitzpatrick skin types I - IV.	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 reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.	Same
Prescription or OTC	OTC	OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick skin types I-V	Fitzpatrick skin types I-V	Fitzpatrick skin types I-IV	Fitzpatrick skin types I-V	Same
Treatment area	upper lip, chin, underarms, l egs, arms, bikini area, chest, back, abdomen	Unknown	Large areas (legs, arms, back and abdomen), face (upper lip, chin and sideburns)	Large areas (e.g. arms, legs, chest) and small areas (e.g. lip)	Same

Dimension	FZ-200A: 199*68*58(mm) FZ-201: 179*64*39mm FZ-202: 202*132*93mm CT05, CT06: 179*640*39(mm) CT07: 204*173*54(mm) CT08: 192*140*54(mm) CT09: 177*120*91(mm)	FZ-608, FZ-608G: 98*147*60(mm) FZ-100: 198*71*44(mm) FZ-200: 216*68*52(mm)	126*78*200mm	58×34×179mm (W x H x D)	Difference **Note 1**
Power supply	100-240V, 50/60Hz, 0.8AMax	Unknown	100-240 VAC, 50/60Hz	100-240 VAC, 50/60Hz	Same
Sterilization	Not required	Not required	Not required	Not required	Same
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc lamp	Xenon Arc lamp	Xenon Arc Flash lamp	Xenon Arc Flash lamp	Same
Wavelength range	590-1200nm	510-1200mm	510-1200nm	560-1200nm	Similar **Note 2**
Energy density	2-4.3 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	1.8~5.1J/cm^2	3~6 J/cm^2	Similar **Note 3**
Output energy	6-13 J	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	Body lamp cartridge: 11.77~22.21J, 510-1200nm Facial lamp cartridge: 3.65-7.04J, 512-1197nm Bikini lamp cartridge: 3.84-7.22J, 511-1200nm	9.9~19.8J	Similar **Note 3**
Spot size	3cm^2	3cm^2	Body: 4.2cm^2 Bikini and face: 2.0cm^2	3.3cm2	Similar **Note 4**
Pulse duration	2-6 ms	0.5-0.8ms	9.2~11.2ms	1ms~7ms	Similar **Note 5**
Pulsing control	Finger switch	Finger switch	Finger switch	Finger switch	Same
Output intensity level	9 levels	FZ-608, FZ-608G: 9 levels FZ-100: 9 levels	5	3	Same

		FZ-200: 6 levels			
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Yes	Same
Electrical safety	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57	ANSI AAMI ES 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-83	Same
Eye safety	IEC 62471	Unknown	Unknown	IEC 62471	Same
Biocompatibility	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10	Same

IX. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

1) Biocompatibility Evaluation

- The biocompatibility evaluation for the body-contacting components of the Hand-held Hair Removal Device was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process, Document Issued on September 4, 2020", as recognized by FDA.

2) Electrical Safety and EMC

Electrical safety and EMC testing was performed to, and passed, as per the following standards:

- IEC 60601-1-2, Edition 4.1 2020-09, Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility.
- IEC 60601-1, Edition 3.2 2020-08, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance .
- IEC 60601-1-11, Edition 2.1 2020-07, Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

- IEC 60601-2-83, 2019+AMD1:2022, Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment.

3) Eye Safety

- IEC 62471, First edition 2006-07, Photobiological safety of lamps and lamp systems

4) Software Verification and Validation

Software documentation consistent with ***basic documentation level*** of concern was submitted in this 510(k). System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

5) Usability

The product usability has been evaluated and verified according to the following FDA guidance

- Applying Human Factors and Usability Engineering to Medical Devices, issued on FEBRUARY 2016.

X. Conclusions

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device Hand-held Hair Removal Device is as safe, as effective, and performs as well as the legally marketed predicate device.