October 11, 2022

Hunan Guangye Biotechnology Co., Ltd.
% Tracy Che
Registration Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K222432
Trade/Device Name: IPL Hair Removal Device, Model(s): KCA423, KCA437, KCA439
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: August 12, 2022
Received: August 12, 2022

Dear Tracy Che:

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)*
K222432

Device Name
IPL Hair Removal Device
Model(s): KCA423, KCA437, KCA439

Indications for Use *(Describe)*
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.

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

K222432

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

I. Submitter

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II. Device

Name of Device: IPL Hair Removal Device
Model(s): KCA423, KCA437, KCA439
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

III. Predicate Device

Primary predicate device:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Medical Device Branch of Zhangzhou Easepal Industrial Co., Ltd.	IPL Salon Hair Reduction System, Model: F60001	K181568	September 11, 2018

Reference devices:

Manufacturer	Reference Device	510(k) Number	Approval Date
Cyden Limited.	iPulse SmoothSkin Gold Hair Removal System	K160968	April 14, 2016

IV. Device Description

IPL Hair Removal Device (Model: KCA423, KCA437, KCA439), is an over-the-counter, home-use and single-person-use device for hair reduction by using 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 only powered by the external power adapter and its IPL emission activation is by finger switch. This product adopts irreplaceable flash window and is suitable for multiple hair removal areas (such as: underarms, bikini lines, arms, legs, etc.). It contains a skin proximity sensor to detect appropriate skin contact, if the device is not in full contact with the skin, the device cannot emit the treatment light pulses. Models KCA437 and KCA439 have skin tone sensor to identify user's skin tone. Only user with suitable skin tone can use this device.

IPL Hair Removal Device, model: KCA423, KCA437, KCA439 have the same indication for use, performance, structure design and operation, the only differences are appearance, capacitor and whether it's equipped with skin tone sensor (KCA437 and KCA439 have skin tone sensor while KCA423 does not).

V. Indications for Use

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.

VI. Materials

Component name	Material of Component	Body Contact Category	Contact Duration
IPL Hair Removal Device KCA423	ABS	Surface-contacting device: Intact skin	Less than 24 hours
IPL Hair Removal Device KCA437 and KCA439	ABS, PC	Surface-contacting device: Intact skin	Less than 24 hours

We have tested the device for biocompatibility by a reliable third-party lab. For details, please refer to Section 16 "Biocompatibility Discussion".

VII. Technological characteristics and substantial equivalence:

Item	Subject Device	Predicate Device	Reference Device	Remark
510(k) Number	K222432	K181568	K160968	/
Trade name	IPL Hair Removal Device (KCA423, KCA437, KCA439)	IPL Salon Hair Reduction System, Model: F60001	iPulse SmoothSkin Gold Hair Removal System	/

Item	Subject Device	Predicate Device	Reference Device	Remark
Manufacturer	Hunan Guangye Biotechnology Co., Ltd.	Medical Device Branch of Zhangzhou Easepal Industrial Co., Ltd.	Cyden Limited.	/
Regulation number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810	Same
Product code	OHT	OHT	OHT	Same
Device classification	Class II	Class II	Class II	Same
Indication for use/ Intended use	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.	The IPL Salon Hair Reduction System (Model: F60001) is an over the Counter device intended for the removal of unwanted body and/or facial hair in adults. It 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 re-growing when measured at 6. 9. and 12 months after the completion of a treatment regimen.	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, 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, only wording difference
Prescription or OTC	OTC	OTC	OTC	Same
Applicable skin	Fitzpatrick Skin Types I-V	Unknown	Unknown	Different **Note 1**
Treatment area	Large areas (e.g. arms, legs, underarms) and small areas (e.g. facial hair below the chin line)	The device is designed for use on the legs, underarms, bikini line, chest, stomach, back, arms	Unknown	Similar

Item	Subject Device	Predicate Device	Reference Device	Remark
		and on the face below the cheekbones.		
Device design				
Source energy	Supplied by external adapter	Supplied by external adapter	External Power supply	Same
Power supply	100-240V~, 50/60Hz	100-240 V AC; 50/60 Hz	110V or 230V, 50/60Hz	Same
Product compositions	The device mainly includes main unit and adapter.	Device includes a treatment window head, a facial adaptor and battery charger/ AC cord.	The device mainly include handset and external power supply.	Similar
Structure design	Handheld	Handheld	Handheld	Same
Dimension	KCA423: 164.82*76.4*40mm KCA437: 162*76.7*43.2mm KCA439: 162.2*77.9*42.4mm	143 x69.5 x 43mm (H*W*D)	Unknown	Different **Note 2**
Weight	KCA423: 223g KCA437: 255g KCA439: 235g	650g	Unknown	Different **Note 2**
Sterilization	Not required	Not required	Not required	Same
Output specification				
Light source	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Same
Wavelength range	475-1200mm	475nm~1200nm	510-1100nm	Same
Energy density	2.45-5J/cm²	Max 5J/cm²	3-6J/cm²	Similar **Note 3**
Spot size	3cm²	1.72 cm² or 3.02 cm²	3cm² (3cm by 1cm)	Same
Pulse duration	7~10ms	11-12ms	2ms to 10ms	Similar **Note 3**

Item	Subject Device	Predicate Device	Reference Device	Remark
Pulsing control	Finger switch	Finger switch	Finger switch	Same
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	Same
Number of output channels	One channel	One channel	One channel	Same
Output intensity level	7 Levels	5 levels	Unknown	Different **Note 4**
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	Same
Skin tone sensor	Yes	No	Yes	Same
Software/ Firmware/ Microprocessor Control?	Yes	Yes	Yes	Same
Additional features				
Skin-contacting components	Enclosure and Skin Contact Surface	IPL Lamp output window	Enclosure and lamp window	Similar
Materials of skin-contacting components	KCA423: ABS KCA437 and KCA439: ABS, PC	ABS	Unknown	Different **Note 5**
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	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 IEC60601-2-57	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57	Similar
Eye safety	IEC 62471	Unknown	IEC 62471	Same

Note 1:
Though the applicable skin tone type of the predicate device is unknown, the commonly recognized applicable skin tone types for IPL hair removal device is mostly Fitzpatrick skin types I-IV or I-V. The applicable skin tone types of the subject device is Fitzpatrick skin types I-V and usability evaluation has been conducted to verify these skin types can use the device safely and effectively, so this difference and will not raise any safety/ effectiveness problems.

Note 2:
Though the dimension and weight are different from the predicate device, this difference is insignificant and do not raise any safety/ effectiveness problems.

Note 3:
Though the energy density and pulse duration of subject device is a little different from the predicate device, they are both basically within the range of the reference device, and they all comply with IEC 60601-2-83 and IEC 62471 requirement, so this difference will not raise any safety or effectiveness issue.

Note 4:
Though the number of energy level is different from the predicate device, this difference is insignificant and do not raise any safety/ effectiveness problems since the the range of the energy density is similar to the predicate device and within the range of the reference device.

Note 5:
Though the contacting materials are not entirely same with the predicate device, both products have been tested against ISO 10993 standards and passed the tests, so this difference will not raise any safety or effectiveness issue.

VIII. Performance Data

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

1) Biocompatibility Testing

The biocompatibility evaluation for the body-contacting components of the IPL 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. The following testing was performed and passed, including:

- ISO 10993-5: 2009, 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

2) Electrical Safety and EMC

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

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility
- IEC 60601-1-11 Medical Electrical Equipment –Part 1: 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 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 Photobiological safety of lamps and lamp systems

4) Software Verification and Validation

Software documentation consistent with ***moderate 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 FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices, issued on FEBRUARY 2016".

IX. Conclusion

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