September 1, 2021

Shenzhen Qiaochengli Technology Co., Ltd.
℅ Jet Li
Regulation Manager
Guangzhou KEDA Biological Tech Co., Ltd.
6F, No.1 TianTai road, Science City, LuoGang District
GuangZhou, Guangdong
China

Re: K211174
Trade/Device Name: IPL Hair Removal
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: July 18, 2021
Received: July 23, 2021

Dear Jet Li:

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,

Purva Pandya
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)*
K211174

Device Name
IPL HAIR REMOVAL

Indications for Use *(Describe)*
The IPL HAIR REMOVAL Device (Model: TFDA06S) is indicated for the removal of unwanted hair under the direction of a physician, after training by a healthcare professional. The device is also indicated for the permanent reduction in hair regrowth, 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 regime. The device is used for adults.

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

Date of the summary prepared: August 27, 2021

510(k) Summary

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

1. Submitter's Information

Sponsor

- Company Name: Shenzhen Qiaochengli Technology Co., Ltd.
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- Phone: +86-0755-23072580
- Fax: +86-0755-23072580
- Contact Person (including title): LiPing Zhou
- E-mail: 2323980316@qq.com

Application Correspondent:

- Company Name: Guangzhou KEDA Biological Tech Co., Ltd.
- Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhou City, China
- Contact Person: Mr. Jet Li
- Tel: +86-18588874857
- Email: Med-jl@foxmail.com

2. Subject Device Information

Trade Name:	IPL HAIR REMOVAL, Model: TFDA06S
Common Name:	Powered Light Based Non-Laser Surgical Instrument With Thermal Effect
Classification name:	Laser Surgical Instrument For Use In General And Plastic Surgery And Dermatoloty
Review Panel:	General & Plastic Surgery
Product Code:	ONF
Regulation Class:	2
Regulation Number:	878.4810

3. Predicate Device Information

Sponsor	Medical Device Branch of Zhangzhou Easepal Industrial Co.,Ltd.	Kam Yuen Plastic Products Ltd.
Device Name	IPL Salon Hair Reduction System	Aimanfun Lumea Comfort
510(k) Number	K181568	K190820
Regulation Number	878.4810	878.4810
Regulation Class	2	2

4. Device Description

IPL HAIR REMOVAL, Model: TFDA06S, a portable device, is a prescription home-use device for the permanent 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. It is a personal Light-Based Hair Removal System. 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. Emission activation is by finger switch. Device includes IPL DEVICE, Power supply and User manual. It is used AC Powered (100-240 V AC). The weight of the device is 260g, and the size is 185.4 × 68.5 × 41.4mm (H*W*D). The device adopts the international photonic beauty IPL technology. The purpose of the light is to heat the root where the hair grows.

5. Indications for Use

The IPL HAIR REMOVAL Device (Model: TFDA06S) is indicated for the removal of unwanted hair under the direction of a physician，after training by a healthcare professional. The device is also indicated for the permanent reduction in hair regrowth, 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 regime. The device is used for adults.

6. Test Summary

Non clinical testing:

IPL HAIR REMOVAL (Model: TFDA06S) has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1, IEC60601-1-11 and IEC 60601-2-57 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.

- Software verification and validation test according to the requirements of the FDA "Guidance for PreMarket Submissions and for Software Contained in Medical Devices"

Clinical testing: No clinical trial is necessary in the submission.

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of IPL HAIR REMOVAL (Model: TFDA06S) is substantially equivalent to the predicate devices quoted above.

The Substantial equivalence decision was based on the following comparison with the predicate devices:

Elements of Comparison	Subject Device	Predicate Device I (Primary)	Predicate Device (II)	Remark
Device Name and Model	IPL HAIR REMOVAL, Model: TFDA06S	IPL Salon Hair Reduction System, Model: F60001	Aimanfun Lumea Comfort (Model: A-2788)	--
510(k) Number	K211174	K181568	K190820	--
Manufacturer	Shenzhen Qiaochengli Technology Co., Ltd.	Medical Device Branch of Zhangzhou Easepal Industrial Co., Ltd.	Kam Yuen Plastic Products Ltd.	--
Indications for Use	The IPL HAIR REMOVAL Device (Model: TFDA06S) is indicated for the removal of unwanted hair under the direction of a physician，after training by a healthcare professional. The device is also indicated for the permanent reduction in hair regrowth, 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 regime. The device is used for adults.	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 Aimanfun Lumea Comfort (Model: A-2788) 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 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	Same

Elements of Comparison	Subject Device	Predicate Device I (Primary)	Predicate Device (II)	Remark
			months after the completion of a treatment regimen.	
Source Energy	Supplied by external adapter	Supplied by external adapter	Supplied by external adapter	Same
'Use' Classification	Prescription use	OTC	Prescription use	Same
Device Classification	Class II	Class II	Class II	Same
Device Type	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	Same
Wavelength (nm)	470nm~1200nm	475nm~1200nm	475~1200nm	Similar
Max. Fluence (J/cm^2)	Max 4.83 [Joules/cm²]	Max 5.0 [Joules/cm²]	Max 4.5 [Joules/cm²]	Similar
Spot Size (cm^2)	3 cm²	1.72 cm² or 3.02 cm²	3.0 cm²	Same
Pulse duration	11-12 ms	11-12 ms	3 milliseconds	Same
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Same
60601Compliance with Voluntary Standards	Yes Comply with IEC 60601-1 and IEC 60601-1-2, IEC60601-2-57	Yes Comply with IEC 60601-1 and IEC 60601-1-2, IEC60601-2-57	Yes Comply with IEC 60601-1 and IEC 60601-1-2,IEC60601-2-57	Same
Weight	260g	650g	200g	Similar
Dimensions	185.4*68.5*41.4 mm (H*W*D)	143*69.5*43mm(H*W*D)	138.9*82*47.3mm(H*W*D)	Similar

Finial Conclusion:

Based on the nonclinical testing conducted, the subject device "IPL HAIR REMOVAL, Model: TFDA06S" is as safe, as effective, and performs as well as the legally marketed predicate devices.