April 27, 2022

Shenzhen Qianyu Technology Co., Ltd.
℅ Klem Hou
RA Manager
Guangzhou Tianke Testing Technology Service Co., Ltd.
Room 106-1, 1st Floor, Building A, No. 1, Xin'an Road,
Yonghe Economic Zone, Huangpu District
Guangzhou, Guangdong 510000
China

Re: K220645
Trade/Device Name: Hand-held IPL device (JOVS Hair Removal Device)
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 2, 2022
Received: March 4, 2022

Dear Klem Hou:

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)*
K220645

Device Name
Hand-held IPL device（JOVS Hair Removal Device）

Indications for Use *(Describe)*
Hand-held IPL device（JOVS Hair Removal Device）is an over-the-counter device intended for removal of unwanted body and/or facial hair.

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 - K220645

1. Submitter

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2. Device

Name of Device: Hand-held IPL device (JOVS Hair Removal Device)

Model(s): JR5C-E, JR5C-W, JR5C-OG, JR5-E, JR5-W, JR5-OG

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

Classification 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

3. Predicate device(s)

Manufacturer	Predicate Device	510(k) Number
CyDen Ltd	IPulse SmoothSkin Gold Hair Removal Device	K160968
SHENZHEN JVK MEDICAL INSTRUMETS CO., LTD	Hand-held IPL device (JOVS Graphene Hair Removal Device)	K214113

4. Device description

Hand-held IPL device (JOVS Hair Removal Device) is a personal, light-based, hair reduction device.

The device contains a Xenon lamp and provides hair reduction by Intense Pulsed Light (IPL) technology 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 device is for single-person use only.

Hand-held IPL device (JOVS Hair Removal Device) includes JR5C-E, JR5C-W, JR5C-OG, JR5-E, JR5-W, JR5-OG. Their intended use, performance, structure design and operation are basically identical, with the different color appearance.

5. Indications for Use

Hand-held IPL device (JOVS Hair Removal Device) is an over-the-counter device intended for removal of unwanted body and/or facial hair.

6. Comparison of Technological Characteristics with the Predicate Device(s)

Hand-held IPL device (JOVS Hair Removal Device) has the same intended use, mode of action and similar operational characteristics as the predicate devices. Any minor differences between the subject device and the listed predicate 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 for its intended use.

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

1) K160968(Primary Predicate Device), " IPulse SmoothSkin Gold Hair Removal Device ", manufactured by " CyDen Ltd " in Swansea, United Kingdom

2) K214113, "Hand-held IPL device (JOVS Graphene Hair Removal Device)", manufactured by "SHENZHEN JVK MEDICAL INSTRUMETS CO., LTD " in Guangdong, China

Comparison Elements	**Subject Device**	**Primary Predicate Device 1 (K160968)**	**Predicate Device 2 (K214113)**	**Remark**
Device name	Hand-held IPL device (JOVS Hair Removal Device)	IPulse SmoothSkin Gold Hair Removal Device	Hand-held IPL device (JOVS Graphene Hair Removal Device)	--
Model	JR5C-E, JR5C-W, JR5C-OG, JR5-E, JR5-W, JR5-OG	--	JOC-910-Yellow JOC-910-Emerald	--

Comparison Elements	Subject Device	Primary Predicate Device 1 (K160968)	Predicate Device 2 (K214113)	Remark
Classification Name	Laser surgical instrument for use in general and plastic surgery and dermatology	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology	Laser surgical instrument for use in general and plastic surgery and dermatology	SE
Product code	OHT	OHT	OHT	SE
Regulation number	878.4810	878.4810	878.4810	SE
Class	II	II	II	SE
Prescription or OTC	OTC	OTC	OTC	SE
Indications for use	Hand-held IPL device (JOVS Hair Removal Device) is an over-the-counter device intended for removal of unwanted body and/or facial 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, 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 Hand-held IPL device (JOVS Graphene Hair Removal Device) is an over-the-counter device intended for removal of unwanted body and/or facial hair.	SE
Source Energy	Supplied by external adapter	Supplied by external adapter	Supplied by external adapter	SE

Comparison Elements	Subject Device	Primary Predicate Device 1 (K160968)	Predicate Device 2 (K214113)	Remark
Technology	Intense Pulsed Light (IPL)	Intense Pulsed Light (IPL)	Intense Pulsed Light (IPL)	SE
Energy medium	Xenon lamp	Xenon lamp	Xenon lamp	SE
Pulsing Control	Finger switch	Finger switch	Finger switch	SE
Delivery device	Direct illumination to tissue	Direct illumination to tissue	Direct illumination to tissue	SE
Wavelength	590nm~1200nm	510-1100nm	590nm~1200nm	SE
Energy density	1.83~5.14 J/cm^2	3-6J/cm^2	2.9~5.4 J/cm^2	SE
Spot size	3.5cm^2	3cm^2	3.4cm^2	SE
Output energy	6.4~18 J	9.0-18.0J	9.8~18.4 J	SE
Pulse duration	5.5~9.5 ms	2~10ms	5.5~9.5 ms	SE

7. Performance Data

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

1) Electrical Safety and Eye Safety

Electrical safety and Eye safety testing has been performed to, and passed, the following standards:

- 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 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- 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

2) Software Verification and Validation

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

3)Usability

Usability testing has been performed to, and passed, the following standards:

- IEC 60601-1-6 Medical electrical equipment –Part 1-6: General requirements for safety – Collateral standard: Usability

Summary

Based on the above performance as documented in this application, the Hand-held IPL device (JOVS Hair Removal Device) is found to have a safety and effectiveness profile that is similar to the predicate device.

8. Conclusions

Based on the comparison of intended use, design, materials and performance, the Hand-held IPL device (JOVS Hair Removal Device) is considered to be substantially equivalent to its predicate device.