October 21, 2022

Shenzhen Desida Technology Co., Ltd.
℅ Amos Zou
RA Engineer
Shenzhen CT Bio-Tech Co., Ltd.
Room 408, Comprehensive Building, Building 6,
Xusheng Building, Xixiang Street, Baoan District
Shenzhen, Guangdong 518102
China

Re: K221643
Trade/Device Name: Hair Removal Device (Model: IPL-D26, IPL-D19)
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: May 30, 2022
Received: June 6, 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)*
K221643

Device Name
Hair Removal Device
(Model:IPL-D26,IPL-D19)

Indications for Use *(Describe)*
The Hair Removal Devices (models IPL-D26 and IPL-D19) are over the counter devices intended for the removal of unwanted hair. The devices are intended for permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of treatment regimen.

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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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

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 Desida Technology Co., Ltd.
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Date of Prepared:	May 30,2022

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:	May 30, 2022

2. Proposed Device and code:

Device Trade Name:	Hair Removal Device(Model:IPL-D26,IPL-D19)
Regulation Medical Specialty	General & Plastic Surgery
Product Code:	OHT

Device classification Name:	Light Based Over-The-Counter Hair Removal
Regulation number	21 CFR 878.4810
Regulation Description	Laser surgical instrument for use in general and plastic surgery and in dermatology.
Device Class	II
Sterilization facility	Not applicable
Type:	Traditional

3. Predicate Device:

510(K)	Trade or Proprietary or Model Name	Manufacturer
K160968	Ipulse Smoothskin Gold Hair Removal Device	Cyden Limited

4. Description of Proposed Device:

The Hair Removal Devices (Model:IPL-D26,IPL-D19) are pulsed light hair removal devices. The IPL-D26 and IPL-D19 models use the same components and have the same features except for their color. The IPL-D26 is white and IPLD19 is red. The device uses light pulses to produce hair removal, and the effect of the device is based on the theory of selective photothermolysis in which optical energy is used to disable hair growth. The IPL-D26 and IPL-D19 devices are each composed of a hand held applicator and an external power supply. Each applicator contains a xenon lamp, a skin color sensor and a skin proximity sensor. The xenon lamp emits the pulsed light flashes to produce hair removal. The skin color sensor is to ensure that the light will be emitted only to skin color appropriate for the device. The contact sensor is to ensure that the light pulses will not be emitted unless the applicator in full contact with the skin. The spot size (treatment area) in the Hair Removal Device devices is 3 cm^2

5. Indications for Use

The Hair Removal Devices (models IPL-D26 and IPL-D19) are over the counter devices intended for the removal of unwanted hair. The devices are intended for permanent reduction in hair regrowth, defined as a long -term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of treatment regimen.

6. Device Comparison Table

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

	Subject Device 1	Predicate Device	Remark
510(k) Number	K221643	K160968	--
Device Name and Model	Hair Removal Device (Model:IPL-D26,IPL-D19)	Ipulse Smoothskin Gold Hair Removal Device	--
Manufacturer	Shenzhen Desida Technology Co., Ltd.	Cyden Limited	--
Enerty Medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	same
Wavelength Range	500nm-1200nm	510-1100nm	Similar
Pulse Duration	2-4 milliseconds	2ms to 10ms	Similar
Energy Density	1.8-4.9 J/cm^2	3-6J/cm^2	Similar
Treatment window	3cm^2 (3cm by 1cm)	3cm^2 (3cm by 1cm)	Same

Delivery Device	Direct Illumination to Tissue	Direct Illumination to Tissue	Same
Pulsing Control	Finger switch	Finger switch	Same
Skin Tone Sensor	Optical Measurement Integral to device. Continuous measurement.	Optical Measurement Integral to device. Continuous measurement.	Same
Indications for Use	The Hair Removal Devices (models IPL-D26 and IPL-D19) are over the counter devices intended for the removal of unwanted hair. The devices are intended for permanent reduction in hair regrowth, defined as a long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of 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
Use Environment	Over-the-counter	Over-the-counter	Same

7. PERFORMANCE DATA

The testing for Hair Removal Device included performance, software, electrical safety, EMC, biocompatibility and bench. Hair Removal Device passed all testing in support of the substantial equivalence determination:

7.1. Biocompatibility testing

The biocompatibility evaluation for the Hair Removal Devicewas 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 Hair Removal Device. The device with compliance with the IEC 60601-1, IEC 60601-1-11, IEC 60601-2-57,IEC 60601-2-83 and IEC 62471 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 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

8. Conclusions:

The proposed IPL Hair Removal Device models IPL-D26 and IPL-D19 in this 510(k) use the same IPL technology that is used in the K160968 predicate device and the proposed device models are for the same intended use as the predicate device. Differences between the proposed device models and predicate device do not raise new types of questions regarding safety and effectiveness, and performance testing supports that

the proposed device can be used safely and effectively for the proposed indications for use. The proposed IPL Hair Removal Device models IPL-D26 and IPL-D19 are considered to be substantially equivalent to the K160968 predicate device.