February 12, 2018

Shenzhen Mareal Tech Co., Ltd
% Rain Yip
Official Correspondent
Feiying Drug & Medical Consulting Technical Service Group
Rm. 3005, Area B, Bldg.1, Southward Ruifeng Business Center
Guimiao Road
Shenzhen, 518000 Cn

Re: K172883
Trade/Device Name: Home Use Hair Removal Device/T1, T2, T3
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: January 12, 2018
Received: January 16, 2018

Dear Rain Yip:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172883

Device Name
Home Use Hair Removal Device

Indications for Use *(Describe)*
The Home Use Hair Removal Device is an over-the-counter device intended for removal of unwanted hair from small areas such as, but not limited to, underarm and facial hair below the chin line and large areas such as legs, in patients with Fitzpatrick Skin Phototypes I-V.

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

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

Date: 2017.09.16

I. Submitter

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II. Device

Name of Device: Home Use Hair Removal Device
Common or Usual Name: Light Based Over-The-Counter Hair Removal
Regulation Description: 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

1） The predicate devices are listed as below:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Shen Zhen CosBeauty Co., Ltd	Perfectsmooth	K161428	March 23, 2017
CyDen Limited	iPulse SmoothSkin Gold Hair Removal System	K160968	April 04, 2016

2） No reference devices were used in this submission.

IV. Device Description

The Home Use Hair Removal Device is a personal, light-based, hair reduction device intended to be sold over-the-counter directly to the end user. The device provides hair reduction using IPL

technology. And it consists of IPL main device and AC adapter, and a detachable lamp cap located in the IPL main device which is the source of optical radiation, namely a Xenon flashlamp.

The Home Use Hair Removal Device includes three models, T1, T2 and T3. All three models are exactly the same with the exception of the LCD display contents (mainly as the symbol of treatment level). T1 and T3 both adopt shape identification to display the treatment levels, which T1 adopts fan-shaped display and T3 adopts rectangle-shaped display. And T2 direct adopts digital symbol to display treatment levels.

V. Indications for Use

The Home Use Hair Removal Device is an over-the-counter device intended for removal of unwanted hair from small areas such as, but not limited to, underarm and facial hair below the chin line and large areas such as legs, in patients with Fitzpatrick Skin Phototypes I-V.

VI. Comparison of Technological Characteristics With the Predicate Device

The Home Use 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 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. Therefore, the Home Use Hair Removal Device may be found substantially equivalent to its predicate device.
Home Use Hair Removal Device is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.
1) K161428, "PerfectSmooth", manufactured by "Shen Zhen CosBeauty Co., Ltd" in Guangdong, China
2) K160968, "iPulse SmoothSkin Gold Hair Removal System ", manufactured by "CyDen Limited" in Wales, UK

The following table shows similarities and differences of use, design, material, safety and effectiveness between the subject device and predicate devices.

Information for predicate device was obtained from publicly available sources, including the 510(k) Summary and device instruction manual. A technical comparison to the predicate is provided below:

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**
K Number	Pending	K161428	K160968
Common name	Light Based Over-The-Counter Hair Removal	Light Based Over-The-Counter Hair Removal	Light Based Over-The-Counter Hair Removal

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**
Trade name	Home Use Hair Removal Device	PerfectSmooth	iPulse SmoothSkin Gold Hair Removal System
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp
Pulse duration	11-13 milliseconds	11-13 milliseconds	2-10 milliseconds
Energy density	4.8 J/cm ²	4.7J/cm ²	3~6 J/cm ²
Spot size	3.9 cm ²	4.5 cm ²	3 (3cm by 1cm)
Delivery device	Direct illumination to tissue	Direct illumination tissue	Direct illumination tissue
Pulsing control	Finger switch	Finger switch	Finger switch
Indication for use/Intended use	The Home Use Hair Removal Device is an over-the-counter device intended for removal of unwanted hair such as but not limited to small areas such as underarm and facial hair below the chin line and large areas such as legs, with Fitzpatrick Skin Phototypes I-V.	The PerfectSmooth is an over-the-counter device intended for removal of unwanted hair such as but not limited to small areas such as underarm and facial hair below the chin line and large areas such as legs.	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.
Location for use	OTC	OTC	OTC

VII.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 Home Use 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 June 16, 2016", as recognized by FDA. The battery of testing was performed to, and passed, including:

- ISO 10993-5:2009/(R)2014, Biological Evaluation of Medical Devices –Par t 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010, Biological Evaluation of Medical Devices –Par t 10: Tests for Irritation and Skin Sensitization

2) Electrical Safety and Eye Safety

Electrical safety and Eye safety testing was 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 60601-2-57 Medical electrical equipment –Part 2-57: Particular requirements for the basic safety and essential performance of non-laser source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

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.

Summary

Based on the above performance as documented in this application, Home Use Hair Removal Device was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the Home Use Hair Removal Device is to be concluded substantial equivalent to its predicate devices.