DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 23, 2017

Shen Zhen CosBeauty Co., Ltd.
% Yuchen Che
Registered Engineer
Feiying Drug & Medical Consulting Technical Service Group
Room 3005, Area B, Bldg.1, Southward Ruifeng Business Center,
Guimiao Road
Shenzhen, 518000 CN Guangdong

Re: K161428
Trade/Device Name: PerfectSmooth
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 5, 2017
Received: January 9, 2017

Dear Mr. 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. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

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)*
K161428

Device Name
PerfectSmooth (Model: CB-014)

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

"510(k) Summary" as required by section 807.92(c).

(1) Applicant information:

Applicant:	Shen Zhen CosBeauty Co., Ltd UnitA-3F, Qiao De Industrial Park, Tian Liao, Guang Ming District, Shenzhen, China
Contact person:	Nicole Hu
Phone number:	+86 1831 685 8036
Fax number:	+86 755 8629 0505
Email:	lizan@cos-beauty.com
Application date:	2016.05.04
Application reason	New device, for the first time to apply.

(2) Device name:

Trade name/Model:	PerfectSmooth /CB-014
Common 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:	Class II
Regulation number:	21 CFR 878.4810
Product code	OHT
Review panel:	General & Plastic Surgery

(3) Predicate device:

iPulse SmoothSkin Gold Hair Removal System, cleared Apr. 14, 2016 (K160968)

(4) Description of device:

The PerfectSmooth 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 base unit and AC adapter, and a detachable lamp cap located in the IPL base unit which is the source of optical radiation, namely a Xenon flashlamp. The device is power from AC adapter via an external power.

(5) Intended use / indications:

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.

(6) Performance data:

Nonclinical, performance and usability testing has been completed on the PerfectSmooth.

Nonclinical testing included biocompatibility, electrical safety and software testing.

Biocompatibility test: The body-contacting components of the device (mainly is plastic enclosure) were tested according to ISO 10993-1 for skin-contacting biocompatibility:

- 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.

Electrical safety:

- 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 60601-2-57 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

Eye safety:

- IEC 62471 Photobiological safety of lamps and lamp systems

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.

Usability study:

- Usability testing (OTC Study) was completed in 20 subjects to evaluate device human factors and label comprehension.

In addition to the above, the Performance testing also included appearance, function, package and reliability testing of the finished product, to in order to the integrity and quality of the device.

(7) Comparison to predicate device

The PerfectSmooth has the same intended use, mode of action and similar operational characteristics as the predicate device. Any minor differences between the targeted device and the listed predicate device do not raise any issues of safety or efficacy. Performance data supports that the device is as safe and as effective as the predicate device for its intended use. Therefore, the PerfectSmooth may be found substantially equivalent to its predicate device.

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.

/	**Targeted device**	**Predicate device**
Common name	Light Based Over-The-Counter Hair Removal	Light Based Over-The-Counter Hair Removal
Trade name	PerfectSmooth	iPulse SmoothSkin Gold Hair Removal System
Energy medium	Xenon Arc Flashlamp	Xenon Arc Flashlamp
Pulse duration	11-13milliseconds	2-10milliseconds
Energy density	4.7 J/cm^2	3-6J/cm^2
Spot size	4.5	3 (3cm by 1cm)
Delivery device	Direct illumination to tissue	Direct illumination to tissue
Pulsing control	Finger switch	Finger switch
Skin tone sensor	Optical measurement removable from base unit Sensor fixed in base unit and can be moved to treatment part	Optical Measurement Integral to device. Continuous measurement.
Indications for use/Intended use	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

(8) Conclusion:

Based on the comparison and analysis, the PerfectSmooth is determined to be Substantially Equivalent (SE) to the predicate device.