September 7, 2018

Shen Zhen CosBeauty Co., Ltd
Ms. Iris Fung
Regulation manager
SGS-CSTC Standards Technical Services Co., Ltd.
198 KEZHU Road, SCIENTECH Park Guangzhou
Guangzhou, Cn

Re: K173813
Trade/Device Name: IPL Hair Removal Device Joy Version
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: August 28, 2018
Received: August 31, 2018

Dear Ms. Iris Fung:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173813

Device Name
IPL Hair Removal Device Joy Version, Model: CB-027

Indications for Use *(Describe)*
The IPL Hair Removal Device Joy Version is indicated for the removal of unwanted hair. The device 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 device is used for adults with Fitzpatrick skin types I – IV.

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: September 7, 2018

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 CosBeauty Technology Co., Ltd.
- Address: UnitA-3F, Qiao De Industrial Park, Tian Liao, Guang Ming District, Shenzhen, China
- Phone: +86 1831 685 8036
- Fax: +86 755 8629 0505
- Contact Person (including title): Nicole Hu
- E-mail: lizan@cos-beauty.com

Application Correspondent:

- SGS-CSTC Standards Technical Services Co., Ltd.
- Address: 198 KEZHU Road, SCIENTECH Park Guangzhou Economic & Technology Development District, Guangzhou, Guangdong, CHINA
- Contact Person: Ms. Iris Fung
- Tel: +86-20-32136908
- Email: Iris.Fung@sgs.com

2. Subject Device Information

Trade Name:	IPL Hair Removal Device Joy Version, Model: CB-027
Common Name:	Light Based Over-The-Counter Hair Removal
Classification name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Review Panel:	General & Plastic Surgery
Product Code:	OHT
Regulation Class:	2
Regulation Number:	878.4810

3. Predicate Device Information

Sponsor	Cyden Limited	Shenzhen CosBeauty Technology Co., Ltd.
Device Name	Ipulse Smoothskin Gold Hair Removal Device	PerfectSmooth
510(k) Number	K160968	K161428
Product Code	ONF	OHT
Regulation Number	878.4810	878.4810
Regulation Class	2	2

2. Device Description

IPL Hair Removal Device Model: CB-027, a small over-the-counter, is a 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. A personal Light-Based Hair Removal System. Emission activation is by finger switch. Device includes a treatment window head, a facial adaptor and battery charger/AC cord.It is used AC Powered(100-240 V AC; 50/60 Hz).The weight of the device is 402g, and the size is 126 x 78 x 200mm (H x W x D).The device incorporates Intense Pulse Light (IPL) technology. The purpose of the light is to heat the root where the hair grows.

5. Intended Use / Indications for Use

The IPL Hair Removal Device Joy Version is indicated for the removal of unwanted hair. The device 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 device is used for adults with Fitzpatrick skin types I – IV.

6. Design

The device contains a Xenon Lamp and a skin proximity sensor to detect appropriate skin contact. If the IPL Hair Removal Device is not properly applied to the treatment area (in full contact with the skin), the device cannot be triggerred a pulse emitting. Body lamp cartridge can be used for body hair below the neck. It can cover an area of 4.2cm2, and it is specially designed for large areas on legs, arms, back and abdomen. It can remove hair in a large scope rapidly. Do not use Body lamp cartridge on face. A filter has been installed in the face lamp cartridge. It can cover an area of 2cm2, and it can be used to remove hair on upper lip, chin and sideburns. Do not use this lamp cartridge on the areas around eyes or near eyelid. The product can flash for 300,000 times, and it shall not be used when the flash counter is displaying “000000”.

7. Materials

There are two patient- directly contracting components in the subject device as the following list.

Component of Device Requiring Biocompatibility	Material of Component	Body Contact Category (ISO 10993-1)	Contact Duration (ISO 10993-1)
Housing	ABS	Surface-contacting device: skin	Maximum 30 minutes(< 24hours)
Plastic plate of lamp cartridge	ABS	Surface-contacting device: skin	Maximum 30 minutes(< 24hours)

Both materials is identical to the material of the device PerfectSmooth, which is cleared by FDA with K161428, produced by us. So these parts' biocompatibility is safe.

8. Physical characteristics

Basic Unit Characteristics	
Compliance* with 21 CFR 898	No
Main Unit Weight	402g
Main Unit Dimension	126*78*200mm
Housing Materials of main unit	PC2805
Indicator	Indicates power information, intensity level information.
Environment for operation	Temperature: 5°C~35°C
Storage and Transport Conditions	Temperature: -10°C~55°C
Compliance with Voluntary Standards	Yes, Comply with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-57,
Patient leakage current	Comply with IEC 60601-1
Power Source	Supplied by external adapter
Software/Firmware/Microprocessor Control?	Yes
Specification	
Output Intensity Level	5
Output energy with body lamp cartridge	Level 1: 11.77J Level 2: 14.12J Level 3: 17.12J Level 4: 19.95J Level 5: 22,21J
Output energy with facial lamp cartridge	Level 1: 3.65J Level 2: 4.59J Level 3: 5.33J Level 4: 6.16J Level 5: 7.04J
Output energy with bikini lamp cartridge	Level 1: 3.84J Level 2: 4.92J

	Level 3: 5.43J Level 4: 6.23J Level 5: 7.22J
Emitted Light Spectrum	510nm~1200nm Max
Max Energy density:	5.1 J/cm²,
Pulse duration	9.20~11.20milliseconds
Treatment Area (regular window)	Body: 4.2 [cm²], Bikini area and Face: 2 [cm²]
Flashes:	300,000 times
Power Supply	100-240 VAC, 50/60Hz
Technology	IPL

10. Test Summary

IPL Hair Removal Device Joy Version, Model: CB-027 has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1 and IEC 60601-2-57 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Software verification and validation test according to the requirements of the FDA "Guidance for PreMarket Submissions and for Software Contained in Medical Devices"
- Usability study:

Usability testing (OTC Study) was completed in 78 subjects to evaluate device human factors and label comprehension.

These usability study tests demonstrate that the device and its labeling can meet with the requirement:

1) the lay user can self-select themselves as being appropriate users of this device by the external box labeling, 2) the lay user can apply the treatment safely and correctly according to the instructions for use, and 3) the lay user can understand all indications, contraindications, warnings and precautions, and be able to identify whether they are within any contraindicated group; and be able to understand the user manual.

11. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of IPL Hair Removal Device Joy Version, model: CB-027 is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device II	Remark
Device Name and Model	IPL Hair Removal Device Joy Version, Model: CB-027	iPulse SmoothSkin Gold	PerfectSmooth (CB-014)	--
510(k) Number	Applying	K160968	K161428	--
Manufacturer	*Shenzhen CosBeauty Technology Co., Ltd.*	CyDen Ltd	*Shenzhen CosBeauty Technology Co., Ltd.*	--
Intended Use	The IPL Hair Removal Device Joy Version is indicated for the removal of unwanted hair. The device 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 device is used for adults with Fitzpatrick skin types I – IV.	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 IPL Hair Removal Device Joy Version 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.	SE
Source Energy	Supplied by external adapter	AC Mains	an external power supply	SE Note 1
'Use' Classification	OTC	OTC	OTC	SE
Device Classification	Class II	Class II	Class II	SE
Device Type	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	SE
Wavelength (nm)	510nm~1200nm	510nm~1100nm	475nm~1200nm	SE Note 2
Max. Fluence (J/cm2)	5.1 [Joules/cm^2]	3-6 [Joules/cm^2]	4.7[Joules/cm^2]	SE Note 3
Spot Size (cm2)	Body: 4.2 [cm^2], Bikini and Face: 2 [cm^2]	3[cm^2]	4.5[cm^2]	SE Note 4
Pulse duration	9.20-11.20milliseconds	2 ms- 10 ms	11-13milliseconds	SE

Elements of Comparison	Subject Device		Predicate Device I	Predicate Device II	Remark
Energy medium	Xenon Arc Flashlamp		Xenon Arc Flashlamp	Xenon Arc Flashlamp	SE
Pulsing Control	Finger switch		Finger switch	Finger switch	SE
Number of Output Channels	One channel		One channel	One channel	SE
Output energy AND Energy spectrum	body lamp cartridge	Level 1: 11.77J@ 510nm~1200nm Level 2: 14.12J@ 510nm~1200nm Level 3: 17.12J@ 510nm~1200nm Level 4: 19.95J@ 510nm~1200nm Level 5: 22,21J@ 510nm~1200nm	9- 18J @ 510nm~1100nm	Level 1: 11.5J @ 475nm~1200nm Level 2: 15.0J @ 475nm~1200nm Level 3: 17.0J@ 475nm~1200nm Level 4: 20.0J@ 475nm~1200nm Level 5: 22,0J@ 475nm~1200nm	SE Note 5
	facial lamp cartridge	Level 1: 3.65J@ 512nm~1197nm Level 2: 4.59J@ 512nm~1197nm Level 3: 5.33J@ 512nm~1197nm Level 4: 6.16J@ 512nm~1197nm Level 5: 7.04J@ 512nm~1197nm			
	bikini lamp cartridge	Level 1: 3.84J@ 511nm~1200nm Level 2: 4.92J@ 511nm~1200nm Level 3: 5.43J@ 511nm~1200nm Level 4: 6.23J@ 511nm~1200nm Level 5: 7.22J @ 511nm~1200nm			
Software/Firmware/Microprocessor Control?	Yes		Yes	Yes	SE
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	SE

Elements of Comparison	Subject Device	Predicate Device I	Predicate Device II	Remark
Compliance* with 21 CFR 898	No	No	No	SE
Weight	402g	1Kg	--	SE Note 1
Dimensions	126*78*200mm	132*35*65mm (H*W*D)	--	SE Note 1
Standards				
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	SE
Electrical Safety	Comply with IEC60601-1 and IEC60601-2-57	Comply with IEC 60601-1 and IEC 60601-2-57	Comply with IEC 60601-1 and IEC 60601-2-57	SE

Comparison in Detail(s):

Note 1:

"Power Source(s)", "Weight", "Dimensions" is belong to basic characteristics. Although it is a little different from the predicate devices, it will not affect the main function and the intended use of the device. They all also comply with IEC 60601-1 requirements. So the differences will not raise any safety or effectiveness issue.

Note 2:

Although the Max. Fluence of subject device is a little larger than the one of the predicate device II, but comparing to Predicate device II, the energy density of subject device is less than 10 Joules/cm². And they all comply with IEC 60601-1, IEC 60601-2-57 requirement.

So the differences of function specification will not raise any safety or effectiveness issue.

Note 3:

Although the wavelength of subject device is a little different from the predicate devices, but they all comply with IEC 60601-1, IEC 60601-2-57 requirement.

And the wavelength of subject device is in the range of the one of predicted devices "PerfectSmooth"

So the differences of function specification will not raise any safety or effectiveness issue.

Note 4:

There are three types of “Spot Size (cm2)” of subject device, and there is minor difference between the subject device and the predicate device I, but in predicate device II, there is similar spot size to the size of bikini area /face lamp cartridge in subject device. And they all comply with IEC 60601-1,IEC60601-2-57 requirement.

So the differences of Spot size will not raise any safety or effectiveness issue.

Note 5:

For IPL light, the energy spectrum is Continuous wavelength range. So even there is minor value difference on the energy spectrum between subject device and predicate devices, but the total energy output density (Max. Fluence value) is similar; and they comply with IEC60601-2-57 Requirement. So the differences of energy spectrum will not raise any safety or effectiveness issue.

And for facial lamp cartridge and bikini lamp cartridge, even the max output energy is lower than the data of predicate devices of K161428/K160968 due to the difference of spot size, but the total energy output density (Max. Fluence value) is similar; and the maximum output energy density of subject device for facial lamp cartridge is about 3.52 J/cm2; and 3.61 J/cm2 for bikini lamp cartridge. Comparing with the predicate device of K 160968, the value range of energy density of predicate device of K160968 is 3-6 J/cm2, which can cover the maximum output energy density of subject device for facial lamp cartridge and bikini lamp cartridge. The phototherapy effectiveness is crucially related to the output energy density and wavelength parameters for IPL, and the output energy of one pulse is minor different to predicate devices because of its spot window size. The spot size of device only affect the treatment target skin area per each pulse flashing, it do not raise any safety or effectiveness issue.

So the differences of output energy for facial lamp cartridge and bikini lamp cartridge will not raise any safety or effectiveness issue.

Finial Conclusion:

The subject device “ IPL Hair Removal Device Joy Version, Model: CB-027” is substantial Equivalence to all predicate devices.