Touchbeauty Beauty & Health (Shenzhen) Co., Ltd.
% Jet Li
Regulation Manager
Guangzhou KEDA Testing Tech Co., Ltd.
6F, No.1 TianTai road, Science City, LuoGang District
GuangZhou, CN

February 15, 2019

Re: K183217
Trade/Device Name: IPL 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 ONF
Dated: November 10, 2018
Received: November 19, 2018

Dear Jet Li:

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,

Neil R Ogden -S

Digitally signed by Neil R Ogden -S
Date: 2019.02.15 08:56:30 -05'00'

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)*

K183217

Device Name

IPL Hair Removal Device (Model: TB-1755)

Indications for Use *(Describe)*

The IPL Hair Removal Device (Model: TB-1755) is an Over the Counter device intended for the removal of unwanted body 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K183217 **510(k) Summary**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 878.4810.

1. Submitter Information

- Company Name: Touchbeauty Beauty & Health (Shenzhen) Co., Ltd.
- Establishment Registration Number: Applying
- Address: 7/F, Marina Bay Centre A, South of Xinhua Road, Bao'an Centre Area, Xin'an Street Bao'an District, Shenzhen, China.
- Phone: +86 755-3366 2222
- FAX: +86 755-3366 8880
- Contact Person (including title): Aaron Zhai (Engineer)
- E-mail: bz@touchbeauty.com

2. Application Correspondent

- Company Name: Guangzhou KEDA Testing Tech Co., Ltd.
- Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhou City, China
- Contact Person: Mr. Jet Li
- Title: Regulation Manager
- Tel: +86-20-22325619
- Email: med-jl@foxmail.com

3. Subject Device Information

- Type of 510(k) submission: Traditional
- Common Name: Light Based Over-The-Counter Hair Removal
- Trade Name: IPL Hair Removal Device
- Classification Name: Laser surgical instrument for use in general and plastic surgery and in

dermatology

- Review Panel: General & Plastic Surgery
- Product Code: OHT
- Regulation Number: 21 CFR 878.4810
- Regulation Class: 2

4. Predicate Device Information

Sponsor	Trade Name	510(k) number	Product Code	Approval Date
CyDen Limited	iPulse SmoothSkin Gold Hair Removal System	K160968	OHT	April 14, 2016
Shen Zhen CosBeauty Co., Ltd	Perfectsmooth	K161428	OHT	March 23, 2017

5. Device Description

IPL Hair Removal Device Model: TB-1755, a small over-the-counter 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, an adaptor and goggles. The size of the device is about 185 x 72.4 x 69.2mm (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.

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 triggered a pulse emitting.

6. Intended Use

The IPL Hair Removal Device (Model: TB-1755) is an Over the Counter device intended for the removal of unwanted body hair.

7. Test Summary

IPL Hair Removal Device has been evaluated the safety and performance by lab bench testing according to the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 2005+A1:2012

- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -Requirements and tests, 2014

- 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

- 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.

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff

8. Comparison to Predicate Device

Compare with predicate devices, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate devices do not raise any new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Primary Predicate Device 1	Predicate Device 2	Verdict
Manufacturer	Touchbeauty Beauty & Health (Shenzhen) Co., Ltd.	CyDen Limited.	Shen Zhen CosBeauty Co., Ltd	--
Product Name	IPL Hair Removal Device	iPulse SmoothSkin Gold Hair Removal System	Perfectsmooth	--
510(K) No.	Applying	K160968	K161428	_

Elements of Comparison	Subject Device	Primary Predicate Device 1	Predicate Device 2	Verdict
Indications for Use	The IPL Hair Removal Device (Model: TB-1755) is an Over the Counter device intended for the removal of unwanted body 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 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 Note 1
IFU Type	Over-The-Counter	Over-The-Counter	Over-The-Counter	SE
Classification Product Code	OHT	OHT	OHT	SE
Device Type	Intense Pulsed Light	Intense Pulsed Light	Intense Pulsed Light	SE
Device Design				
Power source	an external power supply	AC Mains	an external power supply	SE Note 2
Light source	Xenon Arc Flashlamp	Xenon Arc Flashlamp	Xenon Arc Flashlamp	SE
Wavelength	510nm~1100nm	510nm~1100nm	475nm~1200nm	SE Note 2
Spot Size	3.1 cm^2	3 cm^2	4.5 cm^2	SE Note 2
Max. Fluence (J/cm^2)	3.8-5.2 J/cm^2	3-6 J/cm^2	4.7 J/cm^2	SE Note 2
Pulse duration	3 milliseconds	2-10 milliseconds	11-13 milliseconds	SE Note 2
Output energy	12-16 J	9-18 J	< 22 J	SE Note 2
Pulsing Control	Finger switch	Finger switch	Finger switch	SE
Output Channel	One channel	One channel	One channel	SE
Delivery	Direct Illumination to	Direct Illumination to Tissue	Direct Illumination to	SE

Elementsof Comparison	Subject Device	Primary Predicate Device 1	Predicate Device 2	Verdict
Device	Tissue		Tissue	
Software Control	Yes	Yes	Yes	SE
Dimensions	182*72.4*69.2mm	132*35*65mm	-	SE Note 2
FDA-Recognized Standards				
Electrical safety, EMC, Biological Evaluation	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 IEC 62471 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 IEC 62471 ISO 10993-5 ISO 10993-10 ISO 10993-12	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-57 IEC 62471 ISO 10993-5 ISO 10993-10	SE Note3

Note 1

Although there is little difference about the indication for use, the application of the subject device is only the removal unwanted hair, such as back, legs &arms, armpits and bikini areas, except the face and other delicate areas. Besides, the subject device isn't applied to long-term, stable reduction. This difference does not affect the safety and effectiveness.

Note 2

Although the device design between the predicate devices and subject device are mainly equivalent, the specifications of subject device are not completely same. Even so the key specifications of subject device is similar to the predict devices', or under their ranges. After all, the safety and effectiveness of the subject device is verified via tests, so the differences do not affect the safety and effectiveness.

Note 3

Although the subject takes more applicable FDA-recognized standards for reference, so the differences do not affect the safety and effectiveness.

9. Conclusion

The subject device, IPL Hair Removal Device (Model: TB-1755), is substantially equivalent to the predicate devices.

10. Summary Prepared Date

14 Feb 2019