June 24, 2022

Yibin Yingtong Intelligent Technology Co.,Ltd.
% Iris Fung
Official Correspondent
SGS-CSTC Standards Technical Services Co., Ltd.
198 Kezhu Road, Scientech Park Guangzhou Economic &
Technology Development District
Guangzhou, Guangdong 510000
China

Re: K213789
Trade/Device Name: Intelligence LaserComb
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: May 10, 2022
Received: May 11, 2022

Dear 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 and Part 809 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)*
K213789

Device Name
Intelligence Laser Comb (Model: YTLC001-W)

Indications for Use *(Describe)*
The Intelligence Laser Comb (Model: YTLC001-W) is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V or females with androgenic alopecia who have Ludwig-Savin Classifications of I-4, II-1, II-2, or frontal and both with Fitzpatrick Skin Phototypes 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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Date of the summary prepared: June 17, 2022

510(k) Summary

510K number: K213789

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92. This is a traditional 510(K) submission with no previous application.

1. Submitter's Information

Sponsor

- Company Name: YIBIN YINGTONG INTELLIGENT TECHNOLOGY CO.,LTD.
- Address: 3F, Building 1, Area A, Intelligent terminal industrial park,Yibin economic development zone, Sichuan province, China
- Phone: +86 0831-2020866
- Contact Person (including title): Pengcheng Pan (Manager)
- E-mail: tony@interthings.cn

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; jianda-lee@foxmail.com

2. Subject Device Information

- Type of 510(k) submission: Traditional
- Common Name: Lamp, non-heating, for promotion of hair growth
- Trade Name: Intelligence Laser Comb
- Model: YTLC001-W
- 510(K) Number: K213789
- Classification Name: Laser, Comb, Hair
- Review Panel: General & Plastic Surgery
- Product Code: OAP
- Regulation Number: 890.5500
- Regulation Class: II

3. Predicate Device Information

	Predicate Device
Sponsor	OMM IMPORTS INC DBA ZERO GRAVITY
Device Name	Laser Hair Therapy
Model	Recreo 200
510(k) Number	K183329
Product Code	OAP
Regulation Number	890.5500
Regulation Class	II

2. Device Description

The Intelligence Laser Comb (Model: YTLC001-W) is a home-use comb-shaped low level laser therapy (LLLT) device that emits laser light with the intention to promote hair growth in men and women. The device provides distributed laser to the scalp at 655+/-10nm while the comb teeth simultaneously part the user's hair to ensure the laser light reaches the user's scalp. The Laser Comb is an over-the-counter (OTC) device intended for home-use.

The Laser Comb works by providing laser energy to stimulate hair follicles. For optimal results, the laser must not be blocked by the hair and must have an unobstructed path to the scalp. The Laser Comb has teeth that part the hair and allow the maximum amount of laser energy to reach the scalp.

The Laser Hair Growth Comb design with plastic Mainframe, it is composed of PCB circuit board, Power Button, Indicator Light, Red Laser Light, Teeth, USB charging port. And the device is equipped with one internal rechargeable lithium battery (3.7 V d.c. 500mA) that can be charged directly by external adapter. The device uses beep and vibrate to alert the user to the next step during treatment.

3. Intended Use / Indications for Use

The Intelligence Laser Comb (Model: YTLC001-W) is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V or females with androgenic alopecia who have Ludwig-Savin Classifications of I-4, II-1, II-2, or frontal and both with Fitzpatrick Skin Phototypes I-IV.

4. Test Summary

The Intelligence LaserComb (Model: YTLC001-W) was evaluated for conformance to recognized international standards. The following is a list of these evaluations and tests that were found to be in conformance:

- **Electrical safety test**

  IEC 60601-1:2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

  IEC60601-1-11:2015 medical electrical equipment - part 1-11: 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 60825:2014 Safety of laser products - Part 1: Equipment classification and requirements
- **Electromagnetic compatibility test**

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

  ISO 10993-5:2009, 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
- **Software verification and validation test**

  FDA "Guidance for Premarket Submissions and for Software Contained in Medical Devices"
- **Software Life Cycle Processes**

  IEC 62304:2006+AMD1:2015 Medical Device Software

5. Comparison to predicate device and conclusion

The subject device Intelligence LaserComb (Model: YTLC001-W) is substantially equivalent to the predicated device based on intended use, design, specifications and performance. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness. Information for predicate device was obtained from publicly available sources. A technical comparison to the predicate is provided below.

Elements of Comparison	Subject Device	Predicate Device	Reference Device
510(k) Number	K213789	K183329	K193008
Device Name	Intelligence LaserComb (YTLC001-W)	Laser Hair Therapy /(Model: Recreo 200)	Tricoglam Home USE
Product Code	OAP	OAP	OAP
Regulation Number	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500
Regulation Class	II	II	II
Prescription	OTC	OTC	Not disclosed

Elements of Comparison	Subject Device	Predicate Device	Reference Device
Intended Use	The Intelligence LaserComb (Model: YTLC001-W) is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V or females with androgenic alopecia who have Ludwig-Savin Classifications of I-4, II-1, II-2, or frontal and both with Fitzpatrick Skin Phototypes I-IV.	Laser Hair Therapy is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V or females with androgenic alopecia who have Ludwig-Savin Classifications of I-4, II-1, II-2, or frontal and both with Fitzpatrick Skin Phototypes I-IV.	Tricoglam Home Use is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications I - II, in males with androgenetic alopecia who have Norwood Hamilton Classifications IIa - V and for both, Fitzpatrick Classification of Skin Phototypes of I - IV
Type of Laser	Visible red light-emitting diodes	Visible red light-emitting diodes	Visible red LED diodes
Wavelength	655nm±10nm	655nm±5nm	650 nm +/- 10 nm
Amounts of laser diode	10	12	105
Energy of Per Laser Diode	≤5mW	≤5mW	5mW
Power intensity	2.5 mW/cm^2	Not disclosed	Not disclosed
Dosage intensity	1.2 J/cm^2	Not disclosed	1.2 J/cm^2
Classification according to IEC60825-1	Class 3R	Class 3R	Not disclosed
Treatment Time	8 minutes per treatment	8 minutes per treatment	20 minutes
Treatment Frequency	3 times per week(every other day)	3 times per week(every other day)	Continuous every day
Applicable People	Norwood Hamilton IIa-V (males) Ludwig-Savin I-4, II-1, II-2, or frontal (females)	Norwood Hamilton IIa-V (males) Ludwig-Savin I-4, II-1, II-2, or frontal (females)	Ludwig-Savin Classifications I - II(females); Norwood Hamilton Classifications IIa - V (males).
Applicable Skin	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV
Appearance Design	Comb	Comb	Helmet
Safety and Performance Feature	Complied with IEC 60601-1, IEC 60601-1-2, IEC60601-1- 11 ,IEC 60825-1	Complied with IEC 60601-1, IEC 60601-1-2, IEC 60825-1, IEC 60601-1-11	Complied with IEC 60601-1, IEC 60601-1-2, IEC 62471, IEC 60601-2-57, IEC 60601-1-11
Biocompatibility	All patient contacting materials are complied with ISO 10993-5, ISO 10993-10	All patient contacting materials are complied with ISO 10993-1, ISO 10993-5	All patient contacting materials are complied with ISO 10993-1, ISO 10993-5

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 Intelligence LaserComb (Model: YTLC001-W) was conducted in accordance with the ISO 10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, as recognized by FDA.

The battery of testing was performed to, and passed, including:

ISO 10993-5:2009, 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

2) Electrical and EMC Safety

Electrical safety and EMC safety testing was performed to, and passed, the following standards:

IEC 60601-1:2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC60601-1-11:2015 medical electrical equipment - part 1-11: 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 60825:2014 Safety of laser products - Part 1: Equipment classification and requirements

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

Summary for clinical test

Clinical performance is not deemed necessary.

Conclusion

Based on the above performance as documented in this application, Intelligence Laser Comb (Model: YTLC001-W) was found to have a safety and effectiveness profile that is similar to the predicate devices. Thus, the subject device is substantially equivalent to the predicate devices.