May 23, 2023

Hubei YJT Technology Co.,Ltd
% Gamma Zhang
RA Manager
Tacro Guangzhou Branch
Rm. 501, No.55 West Tiyu Rd., Tianhe Dist., Guangzhou
Guangdong
Guangzhou, Guangdong 510000
China

Re: K230134
Trade/Device Name: Laser Therapy Hair Growth Comb, Model: Lasercomb-001 & Lasercomb-002
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: April 7, 2023
Received: April 7, 2023

Dear Gamma Zhang:

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/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 -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K230134

Device Name
Laser Therapy Hair Growth Comb

Indications for Use *(Describe)*
Laser Therapy Hair Growth Comb is indicated to treat Androgenetic Alopecia, and promote hair growth in females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss and in males who have Norwood Hamilton Classifications of IIa to V and who both have Fitzpatrick Skin Types I to 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

K230134

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

Date: 2023-05-23

I. Submitter

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III. Device

Type of 510(k): Traditional
Common Name: Laser therapy hair growth comb
Trade Name: Laser Therapy Hair Growth Comb
Model: Lasercomb-001 & Lasercomb-002
Classification Name: Laser, Comb, Hair
Regulation Number: 21 CFR 890.5500
Review Panel: General & Plastic Surgery
Regulatory Class: II
Product Code: OAP

IV. Predicate Device

Applicant	Predicate Device	510(k) Number
Lexington International, LLC	HairMax LaserComb Advanced 7, HairMax LaserComb Lux 9, Hairmax lasercomb professional 12	K103368

Lexington International, LLC	HairMax LaserComb (Model: HairMax Advanced 7)	K112524
Lexington International, LLC	HairMax LaserComb (Model: HairMax Lux 9)	K110233

V. Device Description

Laser Therapy Hair Growth Comb is a hand-held comb-shaped low level laser therapy device that emits laser light designed to promote hair growth in women and men. The device provides distributed laser light to the scalp while the comb teeth simultaneously part the user's hair to ensure the laser light reaches the user's scalp. Lasercomb-001 contains 7 laser diodes, and MT Lasercomb-002 contains 9 laser diodes.

VI. Indications for Use

Laser Therapy Hair Growth Comb is indicated to treat Androgenetic Alopecia, and promote hair growth in females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss and in males who have Norwood Hamilton Classifications of IIa to V and who both have Fitzpatrick Skin Types I to IV..

VII.Comparison of Technological Characteristics With the Predicate Device

Laser Therapy Hair Growth Comb raises no safety or efficacy concerns when compared to the predicate devices.

A technical comparison to the predicate is provided below:

For Model: Lasercomb-001

Comparison Elements	Subject Device	Predicate Device I	Predicate Device II
K Number	K230134	K103368	K112524
Trade name	HairMax L Laser Therapy Hair Growth Comb aserComb	HairMax LaserComb Advanced 7	HairMax LaserComb Advanced 7
Model	Lasercomb-001	HairMax LaserComb Advanced 7	HairMax LaserComb Advanced 7
Classification name	Infrared Lamp	Infrared Lamp	Infrared Lamp
Product code	OAP	OAP	OAP
Intended use/Indications for Use	Laser Therapy Hair Growth Comb is indicated to treat Androgenetic Alopecia, and promote hair growth in females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss and in males who have Norwood Hamilton Classifications of IIa to V and who both have Fitzpatrick Skin Types I to IV.	The HairMax LaserComb Advanced 7, Lux9, and the Professional 12 models are indicated to treat androgenetic alopecia, promote hair growth and help prevent further hair loss in males who have Norwood Hamilton Classifications of IIa to V and who both have Fitzpatrick Skin Types I to IV.	The HairMax LaserComb Advanced 7 is indicated to treat androgenetic alopecia and promote hair growth in females who have Ludwig (Savin) Scale I-4, II-1, II-2, or frontal and Fitzpatrick Skin Types I to IV.
Location for use	OTC application	OTC application	OTC application
Type of laser	Visible red light-emitting diodes	Visible red light-emitting diodes	Visible red light-emitting diodes
Wavelength	650nm±10nm	650nm±10nm	650nm±10nm
Amount of laser diodes	7	7	7
Energy of per laser diode	4.63 mW, 4.56 mW, 4.66 mW, 4.78 mW, 4.86 mW, 4.78 mW, 4.89 mW＜5mW	4.71mW, 4.68mW, 4.77mW, 4.73mW, 4.89mW, 4.88mW, 4.90mW＜5mW	4.71mW, 4.68mW, 4.77mW, 4.73mW, 4.89mW, 4.88mW, 4.90mW＜5mW
Classification according to IEC60825-1	Class 3R	Class 3R	Class 3R
Treatment time	15 min per treatment	15 min per treatment	15 min per treatment

Comparison Elements	Subject Device	Predicate Device I	Predicate Device II
Treatment frequency	3 times per week, spaced out every other day, as little as 16 weeks	3 times per week, spaced out every other day, as little as 16 weeks	3 times per week, spaced out every other day, as little as 16 weeks
Applicable people	Norwood-Hamilton IIa~V (males) Ludwig-Savin I~II (females)	Norwood-Hamilton IIa~V (males)	Ludwig-Savin I~II (females)
Applicable skin	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV
Shape design	Comb	Comb	Comb
Safety feature	Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1 Complied with IEC 62133 (Battery pack)	Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1 Complied with IEC62133 (Battery pack)	Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1 Complied with IEC62133 (Battery pack)
Biocompatibility	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10, ISO 10993-23.	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10, ISO 10993-23.	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10, ISO 10993-23.

For Model: Lasercomb-002

Comparison Elements	Subject Device	Predicate Device I	Predicate Device II
K Number	K230134	K103368	K110233
Trade name	Laser Therapy Hair Growth Comb	HairMax LaserComb Lux 9	HairMax LaserComb Lux 9
Model	Lasercomb-002	HairMax LaserComb Lux 9	HairMax LaserComb Lux 9

Comparison Elements	Subject Device	Predicate Device I	Predicate Device II
Classification name	Laser, Comb, Hair	Laser, Comb, Hair	Laser, Comb, Hair
Product code	OAP	OAP	OAP
Intended use/Indications for Use	Laser Therapy Hair Growth Comb is indicated to treat Androgenetic Alopecia, and promote hair growth in females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss and in males who have Norwood Hamilton Classifications of IIa to V and who both have Fitzpatrick Skin Types I to IV.	The HairMax LaserComb Advanced 7, Lux9, and the Professional 12 models are indicated to treat androgenetic alopecia, promote hair growth and help prevent further hair loss in males who have Norwood Hamilton Classifications of IIa to V and who both have Fitzpatrick Skin Types I to IV.	The HairMax LaserComb Lux 9 is indicated to treat androgenetic alopecia and promote hair growth in females who have Ludwig (Savin) Scale I-4, II-1, II-2, or frontal and Fitzpatrick Skin Types I to IV.
Location for use	OTC application	OTC application	OTC application
Type of laser	Visible red light-emitting diodes	Visible red light-emitting diodes	Visible red light-emitting diodes
Wavelength	650nm±10nm	650nm±10nm	650nm±10nm
Amount of laser diodes	9	9	9
Energy of per laser diode	4.59 mW, 4.67 mW, 4.67 mW, 4.77 mW, 4.78 mW, 4.81 mW, 4.84 mW, 4.86 mW, 4.91 mW＜5mW	4.53mW, 4.82mW, 4.66mW, 4.68mW, 4.87mW, 4.70mW, 4.66mW, 4.59mW, 4.70mW＜5mW	4.53mW, 4.82mW, 4.66mW, 4.68mW, 4.87mW, 4.70mW, 4.66mW, 4.59mW, 4.70mW＜5mW
Classification according to IEC60825-1	Class 3R	Class 3R	Class 3R
Treatment time	11 min per treatment	11 min per treatment	11 min per treatment
Treatment frequency	3 times per week, spaced out every other day, as little as 16 weeks	3 times per week, spaced out every other day, as little as 16 weeks	3 times per week, spaced out every other day, as little as 16 weeks
Applicable people	Norwood-Hamilton IIa~V (males) Ludwig-Savin I~II (females)	Norwood-Hamilton IIa~V (males)	Ludwig-Savin I~II (females)
Applicable skin	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV
Shape design	Comb	Comb	Comb

Comparison Elements	Subject Device	Predicate Device I	Predicate Device II
Safety feature	Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1 Complied with IEC62133 (Battery pack)	Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1 Complied with IEC62133 (Battery pack)	Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1 Complied with IEC62133 (Battery pack)
Biocompatibility	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10, ISO 10993-23.	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10, ISO 10993-23.	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10, ISO 10993-23.

VIII. 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 Laser Therapy Hair Growth Comb 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 testing was performed to, and passed, including:

- 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
- ISO 10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation

2)**Electrical and EMC Safety**

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

- IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Medical electrical equipment –Part 1-11: 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 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility – Requirements and tests

In addition, testing to IEC 60825-1 certifies the laser system to classification 3R, which is the same as the predicate devices.
The battery conforms to IEC 62133.

Summary

Based on the above performance as documented in this application, Laser Therapy Hair Growth Comb was found to have a safety and effectiveness profile that is same as 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, Laser Therapy Hair Growth Comb is to be concluded same to its predicate devices.