November 18, 2022

Dongguan Lescolton Medical Equipment Co., Ltd
% Shanfeng Jiang
Quality Manager
Guangzhou Junyi Information Technology Co., Ltd.
Room 304, Building A, No. 62 Nanyun 2nd Road, Science Town
Huangpu District, Guangzhou City, Guangdong 510663
China

Re: K222477
Trade/Device Name: Hair Growth Device
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: August 16, 2022
Received: August 16, 2022

Dear Shanfeng Jiang:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222477

Device Name
Hair Growth Device

Indications for Use *(Describe)*
The Hair Growth Device is indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of IIa-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I to IV. All users should also 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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Section 5 - 510(k) Summary

K222477

Date of Summary Preparation: July 16, 2022

Date of Modification: September 04, 2022

Date of Modification: October 01, 2022

Date of Modification: October 26, 2022

1. Submitter's Identifications

Submitter's Name: Dongguan Lescolton Medical Equipment Co., Ltd.

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2. Correspondent's Identifications

Correspondent's Name: Guangzhou Junyi Information Technology Co., Ltd.

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Contact Person: Shanfeng Jiang

Contact Title: Regulation Control Manager

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3. Name of the Device

Trade Name: Hair Growth Device

Model: LS-D620, LS-D630

Regulation Number: 21 CFR 890.5500

Regulation Name: Infrared Lamp

Common Name: Laser, Comb, Hair

Regulatory Class: Class II

Product Code: OAP

Review Panel: General & Plastic Surgery

4. The Predicate Devices

Primary Predicate: K210169 Hair Growth Device

Secondary Predicate: K200464 LG Pra.L Derma LD Scalp Care

5. Device Description

5.1 Device Description for LS-D620:

The Hair Growth Device LS-D620 is composed of 80 laser diodes (wavelength: 650-660nm, power<5mW) configured within an outer helmet and protective inner liner. The combined light is absorbed by the scalp.

The use of diode lasers provides for a full coverage of the upper 1/3 of the head; i.e., the area commonly covered with stylized hair. The helmet system designed to automatically pause to therapy if the subject's head is moved outside of the zone of radiation and will resume therapy when the correct head position is re-established. At the end of the therapy cycle, the system signals that therapy is complete and ready to be powered down, by emitting an audible beep pattern.

The Hair Growth Device LS-D620may produce 20% maximum output deviation in different treatment sites.

The device uses a non detachable polymer lithium battery for power supply, and the continuous use time for the battery is 180 minutes. Which meets the requirements of IEC 62133-2 safety standard..

5.2 Device Description for LS-D630:

The Hair Growth Device LS-D630 is composed of 162 laser diodes (wavelength: 650-660nm, power<5mW) configured within an outer helmet and protective inner liner. The combined light is absorbed by the scalp.

The use of diode lasers provides for a full coverage of the upper 1/3 of the head; i.e., the area commonly covered with stylized hair. The helmet system designed to automatically pause to therapy if the subject's head is moved outside of the zone of radiation and will resume therapy when the correct head position is re-established. At the end of the therapy cycle, the system signals that therapy is complete and ready to be powered down, by emitting an audible beep pattern.

The Hair Growth Device LS-D630 may produce 20% maximum output deviation in different treatment sites.

The device uses a non detachable polymer lithium battery for power supply, and the continuous use time for the battery is 80 minutes. Which meets the requirements of IEC 62133-2 safety standard.

6. Intended Use of Device

The Hair Growth Device is indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of IIa-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I to IV. All users should have Fitzpatrick Skin Types I to IV.

7. Summary of Substantial Equivalence

Table 1 Technical Characteristic in Comparison to Predicate Devices

	Proposed Device	Primary Predicate	Secondary Predicate	Comparison
510k number	K 222477	K210169	K200464	------
Proprietary name	Hair Growth Device	Hair Growth Device	LG Pra.L Derma LD Scalp Care	------
Model	LS-D620, LS-D630	LS-D601	HGN1	------
Manufacturer	Dongguan Lescolton Medical Equipment Co., Ltd.	Dongguan Lescolton Intelligent Electrical Appliance Co., Ltd.	LG Electronics, Inc.	------
Regulation number	890.5500	890.5500	890.5500	Same
Regulation name	Infrared Lamp	Infrared Lamp	Infrared Lamp	Same
Regulatory Class	Class II	Class II	Class II	Same
Product code	OAP	OAP	OAP	Same
Common name	Laser, Comb, Hair	Laser, Comb, Hair	Lamp, non-heating, for promotion of hair growth	Same The device common name for Product Code OAP has been changed to Laser, Comb, Hair
Review panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery	Same
Indications for use	The Hair Growth Device is indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood	The Hair Growth Device is indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood	The LG Pra.L Derma LD Scalp Care is indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood	Same

	Classifications of IIa-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I to IV. All users should have Fitzpatrick Skin Types I to IV.	Classifications of Ila-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of l-II and Fitzpatrick Classification of Skin Phototypes I to IV.	Classifications of IIa-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I to IV.	
Intended user	Females & Males	Females & Males	Both sex	Same
Type of use	OTC	OTC	OTC	Same
Mode of operation	Low-level laser diodes	Low-level laser diodes and light emitting diodes	Low-level laser diodes and light emitting diodes	Substantially equivalent The Hair Growth Device LS-D620 is composed of 80 2 class laser diodes. The Hair Growth Device LS-D630 is composed of 162 2 class laser diodes.
Wavelength	Laser: 650-660nm	Laser: 650-660nm Red light LED: 640-660nm	LD: 650~667nm LED: 645nm~665nm	Substantially equivalent The Hair Growth Device LS-D620 is composed of 80 2 class laser diodes. The Hair Growth Device LS-D630 is composed of 162 2 class laser diodes.
No. of light source	LS-D620 Laser diodes: 80 LS-D630 Laser diodes: 162	Laser diodes: 26 LED diodes: 30	250	Different[1]

Power output	<5mW per light output point	<5mW per light output point	5mW per light output point	Same
Treatment duration	LS-D620：20 minutes each time for 16 weeks LS-D630：12 minutes each time for 16 weeks	25 minutes each time for 16 weeks	18 minutes or 27 minutes	Different[2]
Way to get power	Rechargeable battery	Power adapter	Rechargeable battery	Same as K200464
Bluetooth	No	No	Yes	Same as K210169
Weight	LS-D620：993g±2% LS-D630：836g±2%	625g	790g	Different[3]
Sterilization requirements	Non-sterile	Non-sterile	Non-sterile	Same
Materials	LS-D620,LS-D630 Laser dome housing：ABS	Laser dome housing：ABS	Shell：ABS	Same
	LS-D620 Light source contactless safety limit pad ：Silicone Pad/Leather mat.	Light source contactless safety limit pad： Silicone Pad	Safety limit pad : Silicone Pad	Different[4]
	LS-D630 Light source contactless safety limit pad ：Silicone Pad	Light source contactless safety limit pad： Silicone Pad	Safety limit pad : Silicone Pad	Same
Laser window power value	4.5wm±10%	4.5wm±10%	5wm	Same
Maximum output irradiance	LS-D620/ LS-D630 ：40mW/cm^2	40mW/cm^2	Don't know	Same as K210169

8. Substantial Equivalence discussion:

Note 1: Number of light source of proposed device is more than that of primary predicate K210169.This difference does not raise safety and effectiveness of proposed device.

Note 2: The treatment time of the proposed device is different from the subject predicate k200464. The proposed device has passed the safety and EMC compatibility tests. This difference does not improve the safety and effectiveness of the proposed device.
Note 3: The weight of the proposed device is different from the subject predicate k210169. The proposed device has passed the safety test. This difference does not improve the safety and effectiveness of the proposed device.
Note 4: The proposed device Ls-D620 light source contactless safety limit pad is different from the subject predicate. The proposed equipment and materials have passed the biocompatibility test. This difference does not improve the safety and effectiveness of the proposed device.
Note 5: The proposed device Ls-D620 light source contactless safety limit pad is different from the subject predicate. The proposed equipment and materials have passed the biocompatibility test. This difference does not improve the safety and effectiveness of the proposed device.

Most technical specifications of the Hair Growth Device LS-D620, LS-D630 are either the same or substantially equivalent as compared to the predicate devices. There are no technological differences that raise new or different questions of safety or effectiveness.

9. Non-Clinical Tests Performed:

The following non-clinical testing was provided in this 510(k):

Biocompatibility Testing – The skin contacting materials of the device were subjected to biocompatibility testing per ISO 10993-1:2018, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" for devices in contact with intact skin, including in vitro cytotoxicity, skin sensitization, and skin irritation. All tests passed. The tests comply with the applicable requirements of the following standards:

ISO10993-5:2009, Biological evaluation of medical devices-Part 5: tests for in vitro cytotoxicity.

ISO10993-10:2010, Biological evaluation of medical devices-Part10: tests for irritation and skin sensitization.

Electrical Safety and Electromagnetic Compatibility Testing –The Hair Growth Device LS-D620, LS-D630 has been tested and complied with the applicable requirements of the following standards for medical devices used in the home environment:

● ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance

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

● IEC 60601-1-11:2015 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 60825-1:2007 Safety of laser products - Part 1: Equipment classification, and requirements

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.

10. Usability Study:

The Hair Growth Device LS-D620 was performed usability study separately by similar methods. Testing of 15 participants was conducted showing that the participants were able to understand the user manual and box labeling and were able to safely and effectively use the device.

The Hair Growth Device LS-D630 was performed usability study separately by similar methods. Testing of 15 participants was conducted showing that the participants were able to understand the user manual and box labeling and were able to safely and effectively use the device.

11. Conclusion:

The proposed device uses similar or identical technology as the predicate devices and has the same intended use. Based upon the predicted overall performance characteristics for Hair Growth Device LS-D620, LS-D630, Dongguan Lescolton Medical Equipment Co., Ltd., believes that the technological characteristics of Hair Growth Device LS-D620, LS-D630 does not raise new types of questions regarding its safety and efficacy for its intended use compared with the predicate devices. On the basis of the information provided in this 510(k), Dongguan Lescolton Medical Equipment Co., Ltd., Ltd. believes that the Hair Growth Device LS-D620, LS-D630 is substantially equivalent to the predicate devices.