April 16, 2021

Dongguan Lescolton Intelligent Electrical Appliance Co., Ltd.
% Jinghua Zhou
Regulation Control 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: K210169
Trade/Device Name: Hair Growth Device
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: January 22, 2021
Received: January 22, 2021

Dear Jinghua Zhou:

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,

Purva U. Pandya -S

Purva Pandya
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K210169

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 Ila-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of l-II and Fitzpatrick Classification of Skin Phototypes 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Dongguan Lescolton Intelligent Electrical Appliance Co., Ltd.

Section 5 - 510(k) Summary

Date of Summary Preparation: March 31, 2021

1. Submitter's Identifications

Submitter's Name: Dongguan Lescolton Intelligent Electrical Appliance Co., Ltd.
Address: 401, Building 1, # 3, Xinxing 3rd Road, jiaoshe, Dongkeng Town, Dongguan City, Guangdong Province, China
ZIP Code: 523586
Contact Person: Liu Jianwen
Contact Title: General Manager
Contact E-mail Address: lescolton2012@outlook.com
Telephone: +86-755-33141373

2. Correspondent's Identifications

Correspondent's Name: Guangzhou Junyi Information Technology Co., Ltd.
Address: Room 304, Building A, No. 62 Nanyun 2nd Road, Science Town, Huangpu District, Guangzhou City, Guangdong, 510663, China
ZIP Code: 510663
Contact Person: Jinghua Zhou
Contact Title: Regulation Control Manager
Contact E-mail Address: admanzhou@126.com
Telephone: +86-20-82329549
Fax: +86-20-82329549

3. Name of the Device

Trade Name: Hair Growth Device
Model: LS-D601
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:	K200464	LG Pra.L Derma LD Scalp Care
Secondary Predicate:	K151662	iRestore Hair Growth System

5. Device Description

Dongguan Lescolton Intelligent Electrical Appliance Co., Ltd.

The Hair Growth Device LS-D601 is composed of 26 3R class laser diodes (wavelength: 650-660nm, power<5mW) and 30 red light diodes (wavelength: 640nm-660nm) configured within an outer helmet and protective inner liner.

The use of diode lasers and non-laser LEDs 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 will 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.

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.

7. Comparison with Predicate Device

Table 1 Technical Characteristic in Comparison to Predicate Devices

	Proposed Device	Primary Predicate	Secondary Predicate
510k number	------	K200464	K151662
Proprietary name	Hair Growth Device	LG Pra.L Derma LD Scalp Care	iRestore Hair Growth System
Model	LS-D601	HGN1	ID-500
Manufacturer	Dongguan Lescolton Intelligent Electrical Appliance Co., Ltd.	LG Electronics, Inc.	Freedom Laser Therapy, Inc.
Regulation number	890.5500	890.5500	890.5500
Regulation name	Infrared Lamp	Infrared Lamp	Infrared Lamp
Regulatory Class	Class II	Class II	Class II
Product code	OAP	OAP	OAP
Common name	Laser, Comb, Hair	Lamp, non-heating, for promotion of hair growth	Lamp, non-heating, for promotion of hair growth
Review panel	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery
Indications for use	The Hair Growth Device is indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood 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.	The LG Pra.L Derma LD Scalp Care 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.	The iRestore Hair Growth System is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of I – II, males who have Norwood-Hamilton Classifications of IIa – V and for both, Fitzpatrick Classification of Skin Phototypes I to IV.
Intended user	Females & Males	Both sex	Females & Males
Type of use	OTC	OTC	OTC

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Mode of operation	Low-level laser diodes and light emitting diodes	Low-level laser diodes and light emitting diodes	LLLT Device Type
Wavelength[1]	Laser: 650-660nm Red light LED: 640-660nm	LD: 650~667nm LED: 645nm~665nm	—
No. of light source[2]	Laser diodes: 26 LED diodes: 30	250	21 red visible light diode lasers 30 red light super-luminescent diodes
Power output	<5mW per light output point	5mW per light output point	—
Treatment duration	25 minutes every other day for 16 weeks	—	25 minutes every other day for 16 weeks
Way to get power	Power adapter	Rechargeable battery	—
Bluetooth[3]	No	Yes	—

Note 1: The wavelengths are all within the range of red light wavelengths. The proposed device emits wavelengths that are similar to predicate device. Differences between the devices do not raise new questions regarding the safety and effectiveness of proposed device and the performance testing done demonstrates that the proposed device can be used safety and effectively.

Note 2: Number of light source of proposed device is less than that of primary predicate K200464, close to secondary predicate K151662. Differences between the devices do not raise new questions regarding the safety and effectiveness of proposed device and the performance testing done demonstrates that the proposed device can be used safety and effectively.

Note 3: The proposed device does not have bluetooth capability. This difference between the devices does not raise new questions regarding the safety and effectiveness of proposed device.

Dongguan Lescolton Intelligent Electrical Appliance Co., Ltd.

8. 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 conform 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-Part 10: tests for irritation and skin sensitization.

Electrical Safety and Electromagnetic Compatibility Testing – The Hair Growth Device LS-D601 has been tested and conformed 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 60601-2-57:2011 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests
- 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.

9. Usability Study:

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.

10. Conclusion:

The proposed device uses similar or identical technology as the predicate devices and has the same intended use. Based upon the overall performance characteristics for Hair Growth Device LS-D601, Dongguan Lescolton Intelligent Electrical Appliance Co., Ltd. believes that the technological characteristics of Hair Growth Device LS-D601 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 Intelligent Electrical Appliance Co., Ltd. believes that the Hair Growth Device LS-D601 is substantially equivalent to the predicate devices.