July 23, 2020

LG Electronics, Inc.
% Do-Hyun Kim
CEO
BT Solutions, Inc.
904-ho, Eonju-ro 86-gil 5 Gangnam-gu
Seoul, 06210
Korea, Republic Of

Re: K200464
Trade/Device Name: LG Pra. L Derma LD Scalp Care
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: February 24, 2020
Received: February 26, 2020

Dear Do-Hyun Kim:

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,

Colin Kejing Chen
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)*
K200464

Device Name
LG Pra.L Derma LD Scalp Care

Indications for Use *(Describe)*
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.

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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6. 510(k) Summary

6.1 General Information

Applicant/Submitter:	LG Electronics, Inc.
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Contact Person:	Do Hyun Kim, BT Solutions, Inc.
Address:	Unit 904, Eonju-ro 86gil 5, Gangnam-gu, Seoul 06210, Korea. Tel: +82-2-538-9140 Email: smanager@btsolutions.co.kr
Preparation Date:	February 24, 2020

6.2 Device Name and Code

Device Trade Name:	LG Pra.L Derma LD Scalp Care
Model Name:	HGN1
Common Name:	Lamp, non-heating, for promotion of hair growth
Classification Name:	Infrared Lamp
Product Code:	OAP
Regulation Number:	890.5500
Classification:	Class II
Review Panel:	General & Plastic Surgery (ODE)

6.3 Technical Characteristics in Comparison to Predicate Devices

	Proposed Device	K162071
Company	LG Electronics Inc.	EGlobal, LLC
Product name	LG Pra.L Derma LD Scalp Care	IllumiFlow Laser Cap
Product code	OAP	OAP
Regulation number	890.5500	890.5500
Classification	Class II	Class II
Intended Use	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	IllumiFlow is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa to V or females with androgenic alopecia who have Ludwig-Savin Classification of I-II and both with

	I-II and Fitzpatrick Classification of Skin Phototypes I to IV.	Fitzpatrick Skin Phototypes I to IV.
Intended user	Both sex	Both sex
Type of use	OTC	OTC
Technological characteristics		
Mode of operation	Low-level laser diodes and light emitting diodes	Low-level laser diodes
Wavelength	LD: 650 ~ 667nm LED: 645 ~ 665nm	650 nm
No. of light source	250	272
Power output	5 mW per light output point	5 mW per light output point
Usage duration		
Treatment duration	18 minutes or 27 minutes	30 minutes

Reference Device: Apira Science, Inc's iGrow II Hair Growth System (K140931).

6.4 Device Description

The LG Pra.L Derma LD Scalp Care utilizes a combination of laser diodes and light-emitting diodes (LEDs). 5-milliwatt laser diodes emit light from a range of wavelengths of about 650 nm to 667 nm, which is combined with light from 5 milliwatt LEDs emitting wavelengths from about 645nm to 665 nm. The combined light is absorbed by the scalp.

The LG Pra.L Derma LD Scalp Care is a dome shaped helmet with laser diodes and LEDs on the inside surface. By connecting a controller, the user can power the device on and off, start and pause treatment, and change the care mode. In addition, there is a charging cradle to place the controller in to charge the battery, and the status of the battery is displayed on the controller's indicator. The device can also be connected wirelessly via Bluetooth to a Smartphone App in order to manage treatment. After a treatment is completed, the LG Pra.L Derma LD Scalp Care device can automatically power off the laser, LEDs and controllers.

6.5 Indications / Intended Use

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.

6.6 Performance Data

Non-clinical tests: Measurement of wavelength, average output power, and total irradiance (power density, in units of J/cm2) of treatment LEDs and LDs were performed. Other performance, such as safety of laser product, electromagnetic compatibility and electrical safety, etc, were tested using following consensus standards:

- Basic safety and essential performance of the LG Pra.L Derma LD Scalp Care is tested and evaluated according to the FDA-recognized consensus standard, ES 60601-1.
- Effect to the device by electromagnetic disturbances were tested and evaluated according to the FDA-recognized consensus standard IEC 60601-1-2.
- Safety of laser product is evaluated in accordance with IEC 60825-1: 2014.
- Risk management was recorded by referring to ISO 14971.
- Usability was documented by referring to ISO 62366-1.

Testing of 34 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.

6.7 Conclusions

The proposed device uses similar or identical technology as the predicate device and has the same intended use. Based upon the predicted overall performance characteristics for LG Pra.L Derma LD Scalp Care, LG Electronics, Inc. believes that the technological characteristics of LG Pra.L Derma LD Scalp Care do not raise new types of questions regarding its safety and efficacy for its intended use compared with the predicate device. On the basis of the information provided in this 510(k), LG Electronics, Inc. believes that the LG Pra.L Derma LD Scalp Care is substantially equivalent to the predicate device.