DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 23, 2017

LG Electronics, Inc.
% Minusk Kim
BT Solutions, Inc.
Unit 502, 148 Yuksamro
Seoul, Gangnam-gu 06249
Republic of Korea

Re: K170984
Trade/Device Name: LG Beauty LED Mask
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHS
Dated: July 19, 2017
Received: July 21, 2017

Dear Minusk 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K170984

Device Name
LG BEAUTY LED MASK

Indications for Use *(Describe)*
The LG BEAUTY LED MASK is an over the counter device that is intended for the use in the treatment of full face wrinkles.

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."

6. 510(k) Summary

1. General Information

Date of preparation of 510(k) summary: July 16, 2017

Submitter: LG Electronics, Inc.
Address: 222 LG-ro Jinwi-myeon, Pyeongtaek-si,
Gyeonggi-do, 17709,
Rep. of Korea (South Korea)

Contact Person: Minsuk Kim, BT Solutions
Telephone: +82.2.538.9140
Email: cto@btsolutions.co.kr

2. Device Name and Code

Device Name:	LG BEAUTY LED MASK
Trade Name:	LG BEAUTY LED MASK
Classification Name:	Light Based Over The Counter Wrinkle Reduction
Product Code:	OHS
Regulation Number:	878.4810
Classification:	Class II
Review Panel:	General & Plastic Surgery (ODE) Division of Surgical Devices (DSD) General Surgery Devices Branch One - Light Based/Laser (GSDB1)

3. Predicate Devices

LG BEAUTY LED MASK is substantially equivalent to the following devices

Table 6.1 Predicate devices

Applicant	Device Name	510(k) Number
Pulsaderm LLC	Pulsaderm Wrinkle Mask 28 and Wrinkle Mask 72	K163329
Trophy Skin, Inc.	Rejuvalite MD	K133896

Table 6.2 Reference device

Applicant	Device Name	510(k) Number
Photo Therapeutics, Ltd	illuMask Acne Light Therapy Mask	K123999*

*This device is considered as reference device, of which only limited aspects are equivalent to those of the LG BEAUTY LED MASK.

4. Device Description

The LG BEAUTY LED MASK is a device which allows emission of LED light in the RED (637 nm) and IR (854 nm) spectrum on to the face, which induces photobiological effect to the face for reduction of wrinkle. The LG BEAUTY LED MASK include the mask that contains LEDs on the inner surface, the controller which turns on and off the device, and the

power supply unit that delivers electrical power to the controller for operation or for charging the battery contained in the controller.
Users place the lightweight mask over the face, and use the controller to operate the LG BEAUTY LED MASK. The device will automatically turn off after each treatment. Emitted light from LEDs are not intended for ocular or ophthalmic treatment. To prevent irradiation of LED lights to eyes during the treatment, LG BEAUTY LED MASK has protective eye-cup which blocks light energy from LEDs.

5. Indications / Intended Use
The LG BEAUTY LED MASK is an over the counter device that is intended for the use in the treatment of full face wrinkles.

6. Technical Characteristics in Comparison to Predicate Devices

LG BEAUTY LED MASK is substantially equivalent to the following devices

	Predicate Device	Predicate Device	Proposed Device
Applicant	Pulsaderm LLC	Trophy Skin, Inc.	LG Electronics
Device Name	Pulsaderm Wrinkle Mask 28 and Wrinkle Mask 72	Rejuvalite MD	LG BEAUTY LED MASK
510(k) number	K163329	K133896	N/A
Product Code	OHS	OHS	OHS
Intended Use	The Pulsaderm Wrinkle Masks 28 and 72 are intended for the use in the treatment of facial wrinkles and for people with Fitzpatrick Skin Types I, II and III	The Rejuvalite MD is an over-the-counter device intended for the use in the treatment of full-face wrinkles	The LG BEAUTY LED MASK is an over the counter device that is intended for the use in the treatment of full face wrinkles.
LED emission	Emission of red (620-630 nm) and IR (850 nm)	Emission of red (600, 622, 660 nm) and IR (820 nm)	RED (637 nm) and IR (854 nm)
LED power	21.18 - 25.35 mW/cm^2 total	62 mW/cm^2 total	25 mW/cm^2 total
Treatment time	15 minutes everyday	3 minutes daily 5 days per week for 8 weeks	9 minutes daily 5 days per week for 8 weeks

7. Performance Data
Non-clinical tests: Measurement of wavelength, average output power, and total irradiance (power density, in units of mW/cm^2) of treatment LEDs were performed. Other performance, such as optical hazard, electromagnetic compliance, etc, were tested using following consensus standards:

- Basic safety and essential performance of the LG BEAUTY LED MASK is tested and evaluated according to the FDA-recognized consensus standard, IEC 60601-1.

- Effect to the device by electromagnetic disturbances were tested and evaluated using IEC 60601-1-2.
- Optical hazard was evaluated using IEC 62471-1.
- Risk management was recorded by referring to ISO 14971.
- Usability was documented using IEC 62366-1.

The portion of the device that touches patient body is made of polypropylene, polycarbonate plastic, and silicone, which have been used for other medical devices without any biocompatibility risk.

8. Conclusion

On the basis of the information provided in this Summary, LG Electronics believes LG BEAUTY LED MASK is substantially equivalent to legally commercialized predicate devices.