LG Electronics, Inc.
% Do-Hyun Kim
CEO
BT Solutions, Inc.
904, Eonju-ro 86-gil 5,
Seoul, 06210 Kr

January 22, 2019

Re: K183671
Trade/Device Name: LG PRA.L Derma 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: December 21, 2018
Received: December 27, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R Ogden -S

Digitally signed by Neil R Ogden -S
Date: 2019.01.22 15:41:21 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
N/A K183671

Device Name
LG PRA.L DERMA LED MASK

Indications for Use *(Describe)*

The LG PRA.L DERMA 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.

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"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."

5. 510(k) Summary

Date: December 21, 2018

1. Applicant / Submitter:

LG Electronics, Inc.
222 LG-ro, Jinwi-myeon, Pyeongtaek-si,
Gyeonggi-do, 17709, Republic of Korea

2. Submission Correspondent:

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Tel: +82-2-538-9140 Fax: +82-2-539-9140
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3. Device Name and Code:

Device Name:	LG PRA.L DERMA LED MASK
Trade Name:	LG PRA.L DERMA 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)

4. Predicate Device:

- Primary Predicate Device: K170984 – LG BEAUTY LED MASK by LG Electronics, Inc.

5. Device Description:

The LG PRA.L DERMA 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. The LG PRA.L DERMA LED MASK includes 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 PRA.L DERMA 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 PRA.L DERMA LED MASK has protective eye-shield which blocks light energy from LEDs.

6. Indication for use:

The LG PRA.L DERMA LED MASK is an over the counter device that is intended for the use in the treatment of full face wrinkles.

7. Performance Data:

Non-clinical tests: Measurement of wavelength, average output power, and total irradiance (power density, in units of mW/cm2) 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 PRA.L DERMA 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. Substantial Equivalence:

The LG PRA.L DERMA LED MASK is an over the counter device that is intended for the use in the treatment of full face wrinkles. The subject device has the same device characteristics as the predicate (unmodified) device. They have the same intended use, material, and use concept and employ the same manufacturing processes. The differences are in shape, dimensions and LED total number. The performance test shown that there is no technical characteristic difference in the modified device. The external design changes do not raise any concerns regarding the device performance and safety. Therefore, LG PRA.L DERMA LED MASK is substantially equivalent to the legally marketed predicate/unmodified device.

	Predicate/Unmodified Device	Proposed/Modified Device	SE
Manufacturer	LG Electronics, Inc.	LG Electronics, Inc.	-
Device Name	LG BEAUTY LED MASK	LG PRA.L DERMA LED MASK	-
510(K) #	K170984	-	-
Class	2	2	YES
Product Code	OHS	OHS	YES
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.	The LG PRA.L DERMA LED MASK is an over the counter device that is intended for the use in the treatment of full face wrinkles.	YES
Materials	Mask frame: PC Eye frame: PP Eye shield: Silicone Viewing shield: ABS plastic Controller frame: PP Adaptor frame: PP Cradle frame: PP	Mask frame: PC Eye frame: PP Eye shield: Silicone Viewing shield: ABS plastic Controller frame: PP Adaptor frame: PP Cradle frame: PP	YES

Dimension (mm)	LED Mask: 180 x 214.5 x 92.4 Controller: 41 x 31 x 103 Adaptor: 87 x 44 x 28 Cradle: 190 x 222 x 156	LED Mask: 178.8 x 225 x 89 Controller: 40 x 30 x 110 Adaptor: 87x 44 x 28 Cradle: 180 x 229 x 167.8	YES
Net weight (g)	LED Mask: 207 g Controller: 82 g Adaptor: 75 g Cradle: 375 g	LED Mask: 225 g Controller: 84 g Adaptor: 75 g Cradle: 380 g	YES
LED Emission	RED (637 nm) and IR (854 nm)	RED (637 nm) and IR (854 nm)	YES
Number of LEDs	Total 120 LEDs (60 of them are for 637 nm and the rest 60 of them are for 854 nm)	Total 160 LEDs (80 of them are for 637 nm and the rest 80 of them are for 854 nm)	NO
LED power	25 mW/cm^2 total	25 mW/cm^2 total	YES
Electronic power	Input: AC 100V ~ 240V Frequency: 50Hz/60Hz Output: 5V 2A	Input: AC 100V ~ 240V Frequency: 50Hz/60Hz Output: 5V 2A	YES
Battery	Lithium-ion	Lithium-ion	YES
Treatment time	9 minutes daily 5 days per week for 8 weeks	9 minutes daily 5 days per week for 8 weeks	YES

9. Conclusion

On the basis of the information provided in this Summary, LG Electronics believes LG PRA.L DERMA LED MASK is substantially equivalent to the legally marketed predicate/unmodified device.