June 19, 2018

Johnson & Johnson Consumer, Inc.
Cindy Abraham
Associate Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, Pennsylvania 19034

Re: K180856
Trade/Device Name: Neutrogena Light Therapy Aging 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: March 21, 2018
Received: April 2, 2018

Dear Cindy Abraham:

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.

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,

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)*
K180856

Device Name
Neutrogena Light Therapy Aging Mask+

Indications for Use *(Describe)*
The Neutrogena Light Therapy Aging Mask+ is an over the counter device that is indicated for 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.

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5. 510(k) SUMMARY

510(k) NUMBER:	K180856
510(k) SUBMITTER:	Johnson & Johnson Consumer, Inc. 7050 Camp Hill Road Fort Washington, PA 19034
CONTACT:	Cindy R. Abraham Associate Director, Regulatory Affairs cabraha3@its.jnj.com
DATE PREPARED:	March 21, 2018
PROPRIETARY NAME:	Neutrogena® Light Therapy Aging Mask+
PANEL:	General & Plastic Surgery
REGULATION NUMBER:	CFR Title 21, 878.4810
CLASSIFICATION:	Class II
PRODUCT CODES:	OHS
COMMON NAME:	Light-based Over The Counter Wrinkle Reduction

5.1 Predicate Devices [807.92(a)(3)]

- LG Beauty LED MASK, K170984
- Rejuvalite MD, K133896
- Pro X OTC 5 Light Therapy, K140471

5.2 Device Description [807.92(a)(4)]

The Neutrogena Light Therapy Aging Mask+ uses known LED light therapy technology for the treatment of facial wrinkles. The device emits a combination of red light and infrared light. Users place the lightweight mask over the face and press the “On” button on the controller module to start treatment. The device will automatically turn off after each 10-minute treatment.

5.3 Intended Use and Indications for Use [807.92(a)(5)]

The Neutrogena Light Therapy Aging Mask+ is an over the counter device that is indicated for the treatment of full face wrinkles.

5.4 Comparison of Technological Characteristics with the Predicate Devices [807.92(a)(6)]

The Neutrogena Light Therapy Aging Mask+ is substantially equivalent to the predicate devices in that it has the same intended use and technological characteristics, as demonstrated in **Table 5.1**. Performance testing performed on the Neutrogena Light Therapy Aging Mask+ is sufficient to demonstrate that the subject device is as safe and effective as the legally marketed predicate devices. The technological and labeling differences do not raise new or different questions about safety or effectiveness. The Neutrogena Light Therapy Aging Mask+ is substantially equivalent to the predicate devices.

Table 5.1 Technological Characteristics

Device Feature	Johnson & Johnson **Neutrogena Light Therapy Aging Mask+** Subject Device	LG Electronics **LG Beauty LED Mask** Predicate 1	Trophy **Rejuvalite MD** Predicate 2	La Lumiere, LLC **Pro X OTC 5 Light Therapy** Predicate 3
510(k) Number	Not yet assigned	K170984	K133896	K140471
Classification	21 CFR 878.4810			
Common Name	Light-based over-the-counter wrinkle reduction			
Intended Use	Light-based treatment to reduce wrinkles on the body in general or specific anatomical area			
Product Code	OHS			
Rx and/or OTC	OTC			
Use Environment	Home-Use			
Anatomical Location	Full face			
Indications for Use	The Neutrogena Light Therapy Aging Mask+ is an over the counter device that is indicated for 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.	The Rejuvalite MD is an Over the Counter device that is intended for the use in the treatment of full face wrinkles.	The Pro X OTC 5 is an Over-The-Counter device intended for use in the treatment of facial wrinkles. It is for people with wrinkles on their face and who have Fitzpatrick skin types I, II and/or III.
Power Source	Nickel-Metal Hydride rechargeable batteries	Li-Ion rechargeable batteries	AC to DC	AA alkaline batteries
Energy Source	Light-emitting diodes			
Wavelength (nm)	Red 620-640nm	Red 637nm	Red 600, 622, 660nm	Red 620-640nm
	IR 820-880nm	IR 854nm	IR 860nm	IR 820-880nm
Intensity (mW/cm^2)	1.32 mW/cm^2	4.08 mW/cm^2	2.35 mW/cm^2	0.76 mW/cm^2
Treatment Regimen	10 minutes/day for 60 sessions	9 minutes/day, 5 days a week for 8 weeks	3 minutes/day, 5 days a week for 8 weeks	15 minutes/day for 60 sessions
Total Energy Dose (J/cm^2)	47.58 J/cm^2	88.21 J/cm^2	16.94 J/cm^2	41.23 J/cm^2

5.5 Performance Data [807.92(b)(1), (b)(2)]

Performance bench and safety testing include

- Performance verification
- Human Factors Evaluation
- Biocompatibility testing in accordance with requirements put forth in ISO 10993-1
- Electrical Safety and Electromagnetic Compatibility testing

The verification, electrical safety testing, electromagnetic compatibility testing, and human factors data presented in this 510(k) submission demonstrate the Neutrogena Light Therapy Aging Mask+ device met the established specifications for its intended use and environment of use In addition, the testing demonstrated that the subject device does not raise new or different questions of safety or effectiveness when compared to the legally-marketed predicate devices.

5.6 Conclusion [807.92(b)(3)]

The basis for substantial equivalence for the Neutrogena Light Therapy Aging Mask+ device and the predicate devices is performance data and conformity with recognized standards. Performance bench verification and validation demonstrate that the subject device performs comparably to the predicate devices that are marketed for the same intended use. Based on the performance testing and the similarities of the indications for use and the technological characteristics, it can be concluded that the Neutrogena Light Therapy Aging Mask+ device is substantially equivalent to the predicate devices.