June 19, 2018

Johnson & Johnson Consumer Inc.
Timothy Kline
Associate Manager, Regulatory Affairs
7050 Camp Hill Rd
Fort Washington, Pennsylvania 19034

Re: K180847
Trade/Device Name: Neutrogena Light Therapy Acne 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: OLP
Dated: March 30, 2018
Received: April 2, 2018

Dear Timothy Kline:

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)*
K180847

Device Name
Neutrogena Light Therapy Acne Mask+

Indications for Use *(Describe)*
The Neutrogena Light Therapy Acne Mask+ is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.

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."*

# 5. 510(K) SUMMARY

## 510(k) Summary

**General Information**
JOHNSON & JOHNSON CONSUMER INC.
Skillman, NJ 08558
Contact Person: Timothy Kline
Email: tkline3@its.jnj.com
Telephone: 215-273-7241
FAX: 215-273-4123
Summary Preparation Date: March 16, 2018

**Device**
Common Name: Acne Light Therapy System
Classification Name: Over the Counter powered Light Based Laser for Acne
Classification Regulation: 21 CFR 878.4810
Classification Panel: General and Plastic Surgery
Product Code: OLP

**Predicate Devices:**
Predicate Device(s): Pulsaderm Acne Mask 28 (K170111)
Reference Device(s): Illumask Acne Light Therapy (K123999)

**Device Description:**

The Light Therapy Acne Mask + uses a known light emitting diode (LED) therapy, non-coherent light, in the red and blue range to treat mild to moderate acne bearing similar methods of operation, treatment regimen, and the ability to be recharged as the predicate K170111. The reference device bears the same technological characteristics including anatomical design and biocompatible materials as the Light Therapy Acne Mask +.

Consistent with the intended use of the predicate and reference device, the Light Therapy Acne Mask + uses blue light to kill acne causing bacteria and the red light to decrease inflammation. The user wears the mask over their face, like a pair of glasses, and presses the button on the integrated module – holding for one second – to initiate the treatment. The device has a continuous working time of 10 minutes and shuts off automatically. Each use counts as a single dose. The module contains rechargeable batteries. The module is then recharged prior to the next treatment via a micro USB cable.

**Indications for Use:**
The Light Therapy Acne Mask + is intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face.

**Technological Characteristics and substantial equivalence:**
The Light Therapy Acne Mask+ share the same methods of operation, a similar treatment regimen, and the ability to be recharged as the predicate (K170111). The reference device

(K123999) is included because the Light Therapy Acne Mask+ shares the same anatomical position to support the scientific methodology of the Light Therapy Acne Mask+.

**Table 1** shows that the subject device and the predicate device share similar output and technology characteristics

**Table 1. Device Comparison Table**

| Feature | Subject Device | Primary Predicate (K170111) |
|---|---|---|
| Classification- Regulation | 21 CFR 878.4810 | 21 CFR 878.4810 |
| Classification- Product Code | Primary: OLP - Laser surgical instrument for use in general and plastic surgery and in dermatology. | Primary: OLP - Laser surgical instrument for use in general and plastic surgery and in dermatology. |
| Indications for Use | Intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face | Intend for over the counter use for the treatment of mild to moderate acne |
| Environment of Use | Home | Home |
| Wavelength (nm) | Blue 425-450nm | Blue: 440+/-5nm |
| | Red 620-640nm | Red: 630+/-5nm |
| Total 30-day Energy Dose ($J/cm^2$) | 38.38 $J/cm^2$ | 23.76 $J/cm^2$ |
| Treatment Regimen | 10 minutes/day | 10 minutes/day |
| Power Source(s) | Ni-MH Batteries | Ni-MH / AA Batteries |

**Performance Data:**
The bench performance tests demonstrated that the Light Therapy Acne Mask + is as safe, and as effective as the predicate device. Applicable recognized consensus standards included the following:

- IEC 60601-1: 2005 + A1: 2012 – Medical Electrical Equipment part 1: General requirements for basic safety and essential performance

- IEC 60601-1-11 Edition 2.0 2015-01 – 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 60601-1-2 Edition 4.0 2014-02 – Medical Electrical Equipment – Part 1-2: General Requirements For Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
- IEC 60601-1-6 Edition 3.1 2013-10 - Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability
- IEC 60601-2-57 Edition 1.0 2011-01 – Medical Electrical Equipment - Part 2-57: Particular Requirements For The Basic Safety And Essential Performance Of Non-Laser Light Source Equipment Intended For Therapeutic, Diagnostic, Monitoring And Cosmetic/Aesthetic Use
- The photobiological safety of lamps and lamp systems was evaluated according to IEC 62471 first edition 2006-07. The safety requirements for portable sealed secondary cells and for batteries made from them, for use in portable applications was tested in accordance with IEC 62133-1:2012. The applied part is made from a common medical grade plastic commonly used in the OLP product code amongst other medical devices. The applied part components were assessed & evaluated for biocompatibility risk in accordance with ISO 10993-1.

A Human Factors (HF) evaluation was conducted to support the safe and effective development of the Light Therapy Acne Mask+ in accordance with “Applying Human Factors and Usability Engineering to Medical Devices” (April 2016).

**Conclusion**

Based upon the analysis of the performance data, the characteristics, and the intended use of the subject and predicate device, the Light Therapy Acne Mask+ does not have any differences in the safety or efficacy as the predicate device (K170111), and therefore the subject and predicate devices are substantially equivalent.