DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 19, 2016

Nutra Luxe Md, LLC
Ms. Gloria Avendano
Regulatory Affairs Manager
12801 Commonwealth Dr., Unit 2-6
Fort Myers, Florida 33913

Re: K161941
Trade/Device Name: Pulsaderm Acne Device
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: September 14, 2016
Received: September 15, 2016

Dear Ms. Avendano:

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 and Part 809); 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 and Part 809), please contact the Division of Industry and Consumer Education 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 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 yours,

Jennifer R. Stevenson -A

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)*
K161941

Device Name
Pulsaderm Acne Device

Indications for Use *(Describe)*
Pulsaderm Acne Device 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.

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Section 5:

510(k) Summary

510(k) Summary
Pulsaderm Acne Device

1. General Information

Submitter: NutraLuxe MD, LLC
12801 Commonwealth Dr. Unit 5
Fort Myers, FL 33913

Contact Person:
Gloria Avendano
Regulatory Affairs Manager
Nutra Luxe MD
12801 Commonwealth Dr. Unit 5
Fort Myers, FL 33913
Gloria@nutraluxemd.com

Summary Preparation Date: July 12th, 2016

2. Device

Device Name:	Pulsaderm Acne Device
Common/Usual Name:	Acne Light Therapy System
Classification Name:	Over-the-counter powered light based laser for acne
Classification Regulation:	21CFR 878.4810
Classification Panel:	General and Plastic Surgery
Product Code:	OLP

3. Predicate Devices:

Pulsaderm acne device is substantially equivalent to the following predicate devices;

Device	510(k) Number	Manufacturer
Tanda Mini Skincare System	K124042	Syneron Beauty Inc.
illuMask Acne Light Therapy Mask	K123999	La Lumiere, LLC
Omnilux Clear-U	K081307	Photo Therapeutics Inc

4. Device Description:

The Pulsaderm Acne Device is a device that uses Blue and Red Light Emitting (LED) Diodes to provide LED Light therapy to the skin. A combination of red light and blue light is emitted for the treatment of mild to moderate acne.

5. Intended Use and Indications:

Pulsaderm Acne Device 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.

6. Technological Characteristics and substantial equivalence:

Pulsaderm Acne Device is substantially equivalent to other LED Light therapy devices currently in commercial distribution. Pulsaderm Acne Device has the same intended use as the predicate devices: Treat mild to moderate acne on the face. Pulsaderm Acne Device is as safe and (commensurate to number of diodes) effective as k124042 (Tanda mini Skin Care). Pulsaderm acne device uses a combination of red and blue light as k123999 (illumask acne light therapy) and k081307 (Omnilux Clear-U). Pulsaderm Acne Device has same treatment schedule as k124042 (Tanda mini Skin Care).

Any differences between the Pulsaderm Acne Device and its predicates does not affect the safety or efficacy of the product. Thus, Pulsaderm Acne Device is substantially equivalent to legally marketed medical devices.

Comparison table:

Device name	Pulsaderm Acne Device	Omnilux Clear-U	Tanda mini skin care system	Illumask acne light therapy
510(K)	Pending	K081307	K124042	K123999
Intended 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	Intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face	Indicated to treat dermatological conditions. Specifically, blue light modules are indicated to treat mild to moderate inflammatory acne.	Intended to emit energy in the red and blue region of the spectrum, specifically indicated to treat mild to moderate acne on the face
Energy type	Light Emitting diodes (LED's)	Light Emitting diodes (LED's)	Light Emitting diodes (LED's)	Light Emitting diodes (LED's)
OTC	Yes	Yes	Yes	Yes
Wavelength (nm)	Blue light 415 +/-5 nm Red light 630 +/-5 nm	Blue light 415 nm Red light 630 nm	Blue light 415 nm	Blue light 445 nm Red light 630 nm
Dose rate	Blue light: 20 mW cm² Red light 5 mW cm²	Blue: 40 mW cm² Red: 70 mW cm²	Blue light 22 mW/ cm²	Blue light 10.44 J/ cm² Red light 17.91 J/ cm²
Treatment Schedule	2 Minutes per spot	20 minutes-whole face	2 Minutes per spot	15 minutes- whole face

7. Performance Data:

Performance testing was conducted and confirm compliance to design specifications; similar wavelength, output power, energy type, treatment areas and energy delivery as FDA cleared predicate devices. Pulsaderm Acne Device has been tested and found in conformance with test standards: IEC 60601-1, IEC 60601-1-2, and IEC 62471. Biocompatibility testing to ISO 10993. Pulsaderm Acne Device was designed and developed under a quality management system conforming to ISO 14971.

8. Non clinical-testing

A lay-user study and self-selection study was conducted with Institutional Review Board (IRB) approval and oversight to determine if lay users could read the product labeling and then self-assess if the Pulsaderm acne device would be beneficial for them to use. Study data was collected and demonstrated that the intended users of the device could successfully follow the instructions and use the device as intended. The performance data supplied in this 510(k) demonstrated that 100% of lay users were able to properly self-select themselves using the box labeling and 98% of lay users were able to properly use the device by reading instructions in the user manual without any assistance.
In summary, the conclusion was that an average lay user can read and comprehend correctly the user manual and package labeling.

9. Summary of Clinical Data

A one-week clinical study with IRB approval was conducted with 26 male and female subjects, ranging in age from 13 to 36 years to assess the ability of the Pulsaderm acne device to decrease redness and diminish the size of a facial lesion following 24 hours, 48 hours and one week of use. All subjects underwent a one-week treatment. The subjects used the device for two minutes, three times a day.

Subjects were selected to participate in the evaluation of an acne blemish treatment, which consisted of VISIA digital photography, use of an electronic caliper to measure lesion size, expert clinical grading of facial lesion redness and consumer perception questionnaires.

In summary, the Pulsaderm acne device significantly decreased lesion size and redness when compared to baseline. Treated lesions significantly decreased in size after one week. Patients saw a significant reduction in redness after 24 hours, 48 hours and one week. Subjects had significant reduction in combined lesions (redness and size) after 48 hours and one week.

10. Conclusion

Based upon the analysis of the performance characteristics, safety characteristics and intended use for the pulsaderm acne device, Nutra Luxe MD, believes that no significant differences exist between this device and the predicates. Therefore, Substantial equivalency is requested.