DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 15, 2016

Nutra Luxe MD, LLC
Ms. Gloria Avendano
Regulatory Affairs Manager
12801 Commonwealth Dr., Unit 5
Fort Myers, FL 33913

Re: K162371
Trade/Device Name: Pulsader ACE-All Blue
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: October 31, 2016
Received: November 16, 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); 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 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" (21CFR 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

Indications for Use

510(k) Number (if known): *pending* K162371

Device Name: *Pulsaderm ACE-All Blue*

Indications for Use:

Pulsaderm ACE-All Blue is indicated to treat mild to moderate acne on the face.

Prescription Use _____ AND/OR Over-The-Counter Use __X_____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
Pulsaderm ACE - All Blue

1. General Information

Submitter: NutraLuxe MD, LLC
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Contact Person:
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Summary Preparation Date: August 20th, 2016

2. Device

Device Name:	Pulsaderm ACE - All Blue
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 ACE-All Blue is substantially equivalent to the following predicate devices;

Device	510(k) Number	Manufacturer
Nutra Light Blue	K132838	Nutra Luxe MD, LLC
Tanda Mini Skincare System	K124042	Syneron Beauty Inc.

4. Device Description:
The Pulsaderm ACE-All Blue is a device that uses Blue Light Emitting Diodes to provide LED Light therapy to the skin. Blue light is emitted for the treatment of mild to moderate acne.

5. Indications for use:
Pulsaderm ACE-All Blue is indicated to treat mild to moderate acne on the face.

6. Technological Characteristics and substantial equivalence:
Pulsaderm ACE-All Blue is substantially equivalent to Nutra Light Blue (k132838) and Tanda Mini Skin Care System (k124042). Pulsaderm ACE-All Blue is a smaller version of the predicate device Nutra Light Blue (k132838) and shares the same features and characteristics as the predicate. Pulsaderm ACE-All Blue uses the same technology to deliver blue light and same indications for use as the predicates. Pulsaderm ACE-All Blue uses the same dose rate and treatment regimen as Tanda Mini Skin Care System (k124042). Any minor technological differences between the Pulsaderm ACE-All Blue and the predicate devices raise no new issues of safety or effectiveness.

Comparison table:

Device name	Pulsaderm ACE-All Blue	Nutra Light Blue	Tanda mini skin care system
510(K)	Pending	K132838	K124042
Intended use	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.	Indicated for over the counter use for the treatment of mild to moderate acne
Energy type	Light Emitting diodes (LED's)	Light Emitting diodes (LED's)	Light Emitting diodes (LED's)
OTC	Yes	Yes	Yes
Wavelength (nm)	Blue light 415 +/-5 nm	Blue light 415 +/- 5 nm	Blue light 415+/- 5 nm
Dose Rate mW cm²	Blue light: 25 mW cm²	Blue light: 75 mW cm²	Blue light 22 .4 mW cm²
Dose J/cm2	12 J/cm2	14 J/cm2	12 J/cm2

7. Performance Data:

Performance testing was conducted and confirm compliance to design specifications; similar wavelength, output power and energy type as FDA cleared predicate devices. Pulsaderm ACE-All Blue has been tested and found in conformance with test standards: IEC 60601-1:2012, 60601-1-2:2014, and IEC 62471:2006. Biocompatibility testing to ISO 10993. Pulsaderm ACE-All Blue was designed and developed under a Risk Management System conforming to ISO 14971:2007.

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 ACE-ALL Blue 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 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. Conclusion

Based upon the analysis of the performance characteristics, safety characteristics and intended use for the Pulsaderm ACE-All Blue, Nutra Luxe MD, believes that no significant differences exist between this device and the predicates. Therefore, Substantial equivalence is requested.