DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Nutra Luxe MD, LLC
Ms. Gloria Avendano
Regulatory Affairs Manager
6835 International Center Boulevard Unit 4-5
Fort Myers, Florida 33912

July 22, 2015

Re: K150370
Trade/Device Name: Nutra Light Advanced
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, OHS
Dated: May 14, 2015
Received: June 22, 2015

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,

Joshua C. Nipper -S

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 K150370

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

Device Name: *Nutra Light Advanced*

Indications for Use:

Nutra Light Advanced is intended/indicated for over the counter use for the treatment of mild to moderate acne and for the treatment of periorbital wrinkles and rythides.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA 510(k) Summary of Safety and Effectiveness for Nutra Light Advanced

1. General Information

Submitter:
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Summary Preparation Date: 02-05-2015

2. Device

Device Name:	**Nutra Light Advanced**
Classification Name:	Laser Surgical Instrument, for use in General and Plastic Surgery and in Dermatology
Regulation Numbers:	21 CFR 878.4810
Regulatory Class:	II
Product Codes:	OLP and OHS
Common name:	LED Light device

3. Predicate Device:

Nutra Light Advanced is substantially equivalent to the following predicate devices;

	DEVICE	510(k)	MANUFACTURER
1.	Nutra Light Blue	K132838	NutraLuxe MD, LLC
2.	Nutra Light Red	K141308	NutraLuxe MD, LLC

4. Device Description

Nutra Light Advanced is a visible light and/or heat source with high spectral purity. The device is made of Lustran ABS 348 with clear cover lenses covering the LED light sources. The device has two exchangeable heads; with one head emitting narrow band blue light at 410nm for the treatment of mild to moderate acne vulgaris, the other head emits red light at 650nm for the treatment of periorbital wrinkles and rhytides. The device consists of a basic-hand-held, battery operated control unit and two optional (Blue and Red LED) interchangeable heads, which allows the operator to select either the blue or red operation. The STOP button directly on the unit allows the user to immediately remove all power to the unit. The device does not allow the operator to select the red and blue light simultaneously.

5. Intended Use and Indications:

Nutra Light Advanced is intended/indicated for over the counter use for the treatment of mild to moderate inflammatory acne and for the treatment of periorbital wrinkles and rhytides.

6. Substantial Equivalency & Comparison of Technological Similarities and Differences

NutraLuxe MD wishes to use the following devices as predicates;

Device	**510(k)**	**Manufacturer**
Nutra Light Red	K141308	Nutra Luxe MD
Nutra Light Blue	K132838	Nutra Luxe MD

- Nutra Light Advanced has the same intended use as predicate devices: Nutra Light Red and Nutra Light Blue for the treatment of mild to moderate inflammatory acne and treatment of periorbital wrinkles and rhytides.
- Nutra Light advanced has 410nm wavelength and 650nm wavelength as the predicate devices have a 410nm wavelength and 650nm wavelength.
- Nutra Light Advanced utilizes the same treatment duration as predicate devices.
- Nutra Light Advanced utilizes similar treatment regimen as predicate devices.

The only difference between the Nutra Light Advanced and its predicates is the interchangeable heads feature. This feature raises no new issues of safety and effectiveness. Thus, Nutra Light Advanced is substantially equivalent.

7. Nonclinical Performance Data:

- Nutra Light Advanced has been tested and found in compliance with performance standards that have been established for such devices under section 878 of the Federal Food, Drug and Cosmetics Act. The device has been tested and is in conformity with the following requirements:

- IEC 60601-1:2005; ANSI/AAMI ES60601-1: 2005 + CORR. 1 (2009) + A2 (2010); CAN/CSA C22.2 No.60601-1-08 incorporates Corrigendum 2; June 2011.

- EMC 60601-1-2:2014 Medical Electrical Equipment- Part 1-2: General Requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances-Requirements and tests.

- IEC 60601-2-57, 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.

- ISO 10993-5, Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity, 1999.

- ISO 10993-10, Biological Evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity, 1996.

8. Regulatory Requirements

NutraLuxe MD manufactures under strict quality assurance guidelines and US FDA Good Manufacturing Practice (GMP). NutraLuxe MD is fully compliant with 21 CFR Part 820, US FDA Quality Systems Regulations (QSR), Risk Analysis and Risk Management files (RMF) conforms to ISO 14971.

Conclusion:

Based upon the indications for use and data provided in this pre-market notification, all functional modes of the Nutra Light Advanced have been shown to be substantially equivalent to current marketed predicate devices. Nutra Light Advanced emits red and blue light at the same wavelength as the predicate devices. NutraLuxe MD believes that no significant differences exist between the device and the predicates listed in section 6. Therefore Substantial equivalency is requested. The minor differences between Nutra Light Advanced and the predicate devices raise no new issues of safety and effectiveness as its predicates. Thus, Nutra Light Advanced is substantially equivalent.