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

August 20, 2014

Nutra Luxe MD, LLC
Ms. Jill Creasy
Regulatory & ISO Consulting
5575 Santa Rosa Court
Sparks, Nevada 89436

Re: K141308
Trade/Device Name: Nutra Light Red
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: June 9, 2014
Received: June 13, 2014

Dear Ms. Creasy:

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,

David Krause -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

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)*
K141308

Device Name
Nutra Light Red

Indications for Use *(Describe)*

The Nutra Light Red is a non-invasive LED light device is intended/indicated for over- the –counter use for the treatment of periorbital wrinkles, and rhytides

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510K Summary of Safety and Effectiveness for *Nutra Light Red*

1. General Information

Submitter:
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Contact Person: C/O Jill Creasy
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Sparks, NV 89436
775-622-9591
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Summary Preparation Date: May 15, 2014

2. Device Name

Device Name: ***Nutra Light Red*** (Model: NL-2212)
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: OHS

3. Predicate Device

The ***Nutra Light Red*** is substantially equivalent to the Tanda Max OTC (K110735)), Light for Wrinkles (K101190).

4. Device Description

The ***NutraLuxe Red,*** Model NL-2212 is a device that utilizes Light Emitting Diodes to provide LED light to the body. The ***NutraLuxe Red*** is a visible light source of high spectral purity. They provide uniform or "hot-spot" free illumination. The output is pre-tuned to one wavelength with a narrow spectral bandwidth. The output wavelength of Red is 650 +/- 5 at 80 mW. The ***NutraLuxe Red*** unit contains the power supply, internal NI-MH rechargeable battery and the control unit. The enclosure and LED lens are made of medical grade biocompatibility plastics via injection molding. It has the capabilities to deliver the light to the skin as the unit is moved over the skin surface. The STOP button directly on the unit allows the user to immediately remove all power to the unit. The ***Nutra Light Red*** does not use any software.

5. Intended Use and Indications:

The ***Nutra Light Red*** is a non-invasive LED light device is intended/indicated for over- the –counter use for the treatment of periorbital wrinkles, and rhytides

6. Substantial Equivalency & Comparison of Technological Similarities and Differences

The intended use and technological characteristics of the ***Nutra Light Red*** are equivalent to the listed predicates.
1. Has the same intended use as the predicates (i.e., Treatment of periorbital wrinkles, and rhytides
2. Has a similar output (i.e., 80 mW/cm^2) as the predicates
3. Utilizes a similar wavelength (i.e., 650 nm) as the predicates
4. Utilizes a same treatment duration (i.e., 3 minutes per target area) as the predicates

5. Utilizes a similar treatment regimen (i.e., 2 treatments per week for 6 weeks)

Any differences between the ***Nutra Light Red*** and the predicates device are not significant to its safety or effectiveness for its intended use.

7. **Clinical Performance Data**

An OTC Usability Study was conducted with the following four goals in mind with 80 participants;
1. To attract participants that represented the “intended users” of the device;
2. To determine if consumers could correctly self-select using the packaging labeling only
3. To test consumer knowledge of the packaging labeling and user manual and actually assembly, operate and care for the device correctly. All four goal of the study were met.

8. Nonclinical Performance Data

The ***NutraLight Red*** device was tested and complies with Electrical Safety and EMC testing, which include the requirements of IEC 60601-1:2012 3rd Edition “Medical Electrical Equipment Part 1 – General Requirements for Safety” IEC 60601-1-2 “Medical Electrical Equipment Part 1-2, General Requirements for Safety – Collateral Standard Electromagnetic Compatibility Requirements and Tests. IEC 60601-2-57, Medical Electrical Equip. - Part 2-57 Basic Safety and Performance of Non-Laser Light Cosmetic/Aesthetic use. IEC 62471 Photobiological Safety of lamps and lamp systems. In addition, testing and analysis have demonstrated compliance of the plastic within ISO 10993 (Biocompatibility).

9. Regulatory Requirements

NutraLuxe MD manufactures under strict quality assurance guidelines and US FDA Good Manufacturing Practice (GMP)
Nutra Luxe 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,

10. Substantial Equivalence

Based upon an analysis of the overall performance characteristics the ***Nutra Light Red*** device was found to have the same intended use and indication for use as the predicate devices. The device also has similar technological characteristics to its predicate devices. The minor technological differences between the ***Nutra Light Red*** and predicate devices do not raise any issues of safety or effectiveness. Therefore, Nutra Luxe MD, Inc. found the ***Nutra Light Red*** device to be substantially equivalent to the legally marketed predicate devices.