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

February 10, 2016

Nutra Luxe MD, LLC
Gloria Avendano
Regulatory Affairs Manager
12801 Commonwealth Dr. Units 2-6
Fort Myers, FL 33913

Re: K150826
Trade/Device Name: Nutra Face LIFT Model PE8050
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NFO
Dated: January 4, 2016
Received: January 13, 2016

Dear Gloria 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" (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,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K150826

Device Name
Nutra Face LIFT Model PE8050

Indications for Use *(Describe)*
The Nutra Face LIFT Model PE8050 device is intended for facial stimulation and indicated for over-the-counter cosmetic use.

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.

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FDA 510K Summary

The Nutra Face LIFT

1. General Information

Submitter:

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12801 Commonwealth Dr. Units 2-6
Fort Myers, FL 33913

Contact Person:

Gloria Avendano
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12801 Commonwealth Dr. Units 2-6
Fort Myers, FL 33913
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Summary Preparation Date: February 9, 2016.

2. Device Name

Trade Name: ***Nutra Face Lift Model PE8050***

Common Name: ***Facial Toning Device***

Classification Name: Transcutaneous electrical nerve stimulator 21 CFR 882.5890

Product Code: NFO

3. Predicate Device

The ***Nutra Face Lift*** is substantially equivalent to the NuFace Facial Toning Device K072260

4. Device Description

The ***Nutra Face Lift*** is a hand-held device intended to apply low level electrical impulses to strategic locations on the face. ***The Nutra Face Lift*** probes are designed for optimal contact with the face. The device continually alternates between the positive and negative probes and allows the user to adjust the settings from 0 to 400 microamps for personalized comfort level by pressing the up/down button. ***The Nutra Face Lift*** requires the use of a conductive derma gel.

The Nutra Face Lift unit contains a power supply and internal Ni-MH rechargeable battery. The enclosure is made of medical grade biocompatility plastics and the output contacts (Probes) consist of chrome-plated spheres. The on/off button on the unit directly allows the user to immediately remove all power from the unit.

5. **Intended Use and Indications:**

The Nutra Face Lift device is ntended for facial stimulation and is indicated for-over-the counter cosmetic use.

6. **Substantial Equivalency & Comparison of Technological Similarities and Differences**

The Nutra Face Lift is as safe and effective as the predicate device. ***The Nutra Face Lift*** has the same indications, as the predicate device.

The Nutra Face Lift is substantially equivalent in technological characteristics to the predicate device, including the positive and negative probes. The device powered by a 5V-500Ma AC/DC charger, produces microcurrent that is discharged through the two fixed, smooth probes.

The ***Nutra Face Lift*** has the following similarities to the NuFace

1. Has the same indicated use
2. Uses the same operating principle
3. Incorporates similar materials.
4. Utilizes a same treatment duration (i.e. 5 seconds per step, repeat each step 3 times)
5. Utilizes a similar treatment regimen (i.e. 5 times a week for 90 days)

One of the differences between the ***Nutra Face Lift*** and its predicate device is the predicate device uses a thumbwheel to adjust the desired intensity while the ***Nutra Face Lift*** uses an up/down button.

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

Section 1: Device Descriptions

Nutra Face Lift and NuFace Original Comparison Table

Elements of Comparison	Nutra Face Lift	Predicate Device
510(k) Number	K150826	K072260
Regulation Number	21 C.F.R 882.5890	21 C.F.R 882.5890
Regulation Name	Transcutaneous Electrical Nerve Stimulator	Transcutaneous Electrical Nerve Stimulator
Regulatory Class	Class II	Class II
Product Code	NFO	NFO
Intended use	Stimulate the face; skin toning	Stimulate the face; skin toning
Indications for Use	Intended for facial stimulation and is indicated for-over-the counter cosmetic use.	Intended for facial stimulation and is indicated for-over-the counter cosmetic use.
Technological Characteristics	The Nutra Face Lift is a hand-held device intended to apply low level electrical impulses to strategic locations on the face. The Nutra Face Lift probes are designed for optimal contact with the face.	NuFace® is a Facial Toning Device intended for facial stimulation. The device measures 7" L x 2.5" W x 1" D. Its outer case is injection molded of thermoplastic resin, ABS UL 94 HB, and the output contacts (probes) consist of chrome-plated spheres. The

	The device continually alternates between the positive and negative probes and allows the user to adjust the settings from 0 to 400 microamps for personalized comfort level by pressing the up/down button. The Nutra Face Lift requires the use of a conductive derma gel.	device, powered by a 9-volt battery, produces microcurrent that is Discharged through the two fixed, smooth spherical probes. To turn the device on, the thumbwheel is pushed upwards. A Green LED light will Then illuminate, indicating the unit is ready for use. Users then follow the instructions for use. The two probes gently glide over the skin to deliver low-level electrical impulses to strategic locations on the face.
Power Source	One 3.6 V battery	One 8V Battery
Number of output modules	1	1
Number of output channels	1 output channel	1 output channel
Regulated current or regulated Voltage?	Both	Both
Software/Firmware/Microprocessor Control?	Yes	Yes
Automatic Overload Trip?	No	No
Automatic Shut off?	No	No
Patient override control?	Yes	Yes
Indicator Display	Yes	No
Timer range	No Timer	No timer
Type of protection	Type BF	Type BF
Number of output modules	1	1
Number of output channels	1	1
Software/Firmware	No	No
On/off status	No	No
Standards Compliance	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-10
Biocompatibility	ISO 10993-5, -10	ISO 10993-5, -10
Waveform	Pulsed Monophasic	Pulsed Monophasic
Shape	Modulated Square	Rectangular Pulses
Maximum output voltage	50Vpp (No load condition) 8Vpp (10kΩ)	158 Mv @ 500Ω 780 Mv @ 2kΩ 2.6 V @ 10kΩ
Maximum output current	+/- 400µ (10kΩ)	223 µA @ 500 Ω
Output tolerance	+/- 10%	+/- 10%
Pulse Width	60ms	112 ms
Frequency (Hz)	8.34 Hz	8.39 Hz
Symmetrical phases	Not Multiphasic	Not Multiphasic
Phase duration	Not determined	Not determined
Net Charge (µC per pulsetrain)	0 µC per pulsetrain	0 µC per pulsetrain
Maximum Phase Charge (µC)	18.13 µC @ 500 Ω	18.13 µC @ 500 Ω

Maximum current Density (Ma/Cm²)	0.341mA/cm² @ 500 Ω	0.341mA/cm² @ 500 Ω
Maximum Power Density (μW/cm²)	3.02μW/cm² @ 500 Ω	3.02μW/cm² @ 500 Ω
Pulses per burst	20	20
Burst duration	2.4	2.3
ON Time (seconds)	Constant	Constant
OFF Time (Seconds)	None	None

Section 2: Basic Characteristics

510(k) Number	K150826	K072260
Device Name, Model	Nutra Face Lift	NuFace®
Manufacturer	NutraLuxe MD	Carol Cole Company
Power Source(s)	2.4	2.4
ON Time (seconds)	Constant	Constant
OFF Time (Seconds)	None	None

7. **Clinical Performance Data**

A Usability and Product Self Selection Study was conducted utilizing 80 participants: with the following four goals;

(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 Instruction Manual;
(4) To have consumers demonstrate their ability to adhere to what they had read in the Instruction Manual and actually operate and care for the device correctly. All four goals of the Study were met.

8. Nonclinical Performance Data

Based on the Risk Analysis, the verification and validation tests that were performed and the acceptance criteria applied for each are listed in Section 17.

The Nutra Face Lift device was tested and found to be in compliance with FDA's performance standards set forth in 21 C.F.R. §898.
The Nutra Face Lift was also 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 60601-1-11 Home healthcare medical equipment and IEC 60601-2-10:2012 2nd Edition "Medical Electrical equipment -- part 2-10: particular requirements for the basic safety and essential performance of nerve and muscle stimulators. (Neurology). 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,

Conclusion: Nutra Luxe MD, Inc. found ***The Nutra Face Lift*** device to be substantially equivalent to the legally marketed predicate devices.