October 11, 2018

Carol Cole Company dba NuFACE
Donald Ellis
Head - Regulatory Affairs/ Quality Assurance
1325 Sycamore Ave. Suite A
Vista, California 92081

Re: K181008
Trade/Device Name: NuFACE Trinity
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: August 14, 2018
Received: August 16, 2018

Dear Donald Ellis:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vivek J. Pinto -S

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)*
K181008

Device Name
NuFACE Trinity

Indications for Use *(Describe)*
The NuFACE Trinity is intended for facial and neck stimulation and is 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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NUFACE TRINITY DEVICE 510(K) SUMMARY

DATE PREPARED: AUGUST 14, 2018

510(K) SUBMITTER/OWNER
Carol Cole Company dba NuFACE
1325 Sycamore Ave, Suite A
Vista, CA 92081, USA

CONTACT INFORMATION:
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DEVICE NAMES

Device Trade/ Proprietary Name:	NuFACE Trinity Facial and Neck Skin Toning Device
Device Common or Usual Name:	NuFACE Trinity Device
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief
Regulation Number:	21 CFR 882.5890
Product Code:	NFO

PREDICATE DEVICE
The legally marketed predicate device to which the Carol Cole Company is claiming equivalence for over-the-counter use:

510(k) Number:	K103472
Manufacturer:	Carol Cole Company dba NuFACE
Trade Name:	NuFACE Plus
Product Code:	NFO

DEVICE DESCRIPTION
The NuFACE Trinity Device(proposed) is intended for facial and neck skin stimulation and is indicated for over-the-counter cosmetic use. It is identical to that of its NuFACE Plus (predicate) and its technological characteristics remain unchanged.

INTENDED USE
The NuFACE Trinity Device is intended for facial and neck stimulation and is indicated for over-the-counter cosmetic use.

TECHNOLOGICAL CHARACTERISTICS

The NuFACE Trinity Device (proposed) is identical to that of its NuFACE Plus (predicate) and its technological characteristics remain unchanged. It produces microcurrent discharged through the two spherical probes.

NON-CLINICAL TESTING

The NuFACE Trinity device is identical to the predicate which was tested to the applicable standards for electrical safety, EMC, and biocompatibility. Literature provided and usability studies conducted demonstrate that the device is substantially equivalent to the predicate given the new indications.

PERFORMANCE STANDARDS

The NuFACE Trinity Device (proposed) is identical to that of its NuFACE Plus (predicate) and both comply to FDA performance standards set forth in 21 CFR §898.

Product Safety and EMC performance testing was conducted for the following aspects:

1. Electrical and Constructional Safety in accordance with IEC 60601-1
2. Electromagnetic Compatibility (EMC) in accordance with IEC 60601-1-2

Thus, with respect to Safety and EMC, the NuFACE Trinity Device (proposed) is substantially equivalent to the NuFACE Plus (predicate).

Table 1: Substantial Equivalence Comparison Table

DEVICE DESCRIPTIONS	NUFACE TRINITY DEVICE (PROPOSED)	NUFACE PLUS (PREDICATE)	SAME OR DIFFERENT
1. 510(k) Number	K181008	K103472	
2. Regulation Number	21 C.F.R. § 882.5890	21 C.F.R. § 882.5890	21 C.F.R. § 882.5890
3. Regulation Name	Transcutaneous electrical nerve stimulator for pain relief	Transcutaneous electrical nerve stimulator for pain relief	Same
4. Regulatory Class	Class II	Class II	Same
5. Device Classification Name	Stimulator, Transcutaneous Electrical, Aesthetic Purposes	Stimulator, Transcutaneous Electrical, Aesthetic Purposes	Same
6. Product Code	NFO	NFO	Same
7. Regulation Medical Specialty	Neurology	Neurology	Same

8. Intended Use	NuFACE Trinity Device is intended for facial and neck skin stimulation and is indicated for over-the-counter cosmetic use.	NuFACE Plus is intended for facial stimulation and is indicated for over-the-counter cosmetic use.	Different
9. Indications for Use	Over-the-Counter Cosmetic Use	Over-the-Counter Cosmetic Use	Same
10. Anatomic Sites	Face and Neck	Face	Different
11. Technological Characteristics	The NuFACE Trinity Device. Its outer case is injection molded thermoplastic resin. The output contacts consist of chrome-plated spheres. The device is powered by a rechargeable lithium ion battery and produces a microcurrent that is discharged through two fixed, smooth electrode spheres. To turn the device on, the on/off button is pressed. Ascending tonal beeps indicate the device is on. One to five red LED lights illuminate indicating the output intensity level and the unit is ready for use. Users then follow the instructions for use. The two spheres gently glide over the skin to deliver low-level electrical impulses to targeted locations. The NuFACE Trinity spheres are designed for optimal contact with the skin. The NuFACE Trinity Device delivers microcurrent as a constant biphasic	The NuFACE Plus is a facial toning device. Its outer case is injection molded thermoplastic resin. The output contacts consist of chrome-plated spheres. The device is powered by a rechargeable lithium ion battery and produces a microcurrent that is discharged through two fixed, smooth electrode spheres. To turn the device on, the on/off button is pressed. Ascending tonal beeps indicate the device is on. One to five red LED lights illuminate indicating the output intensity level and the unit is ready for use. Users then follow the instructions for use. The two spheres gently glide over the skin to deliver low-level electrical impulses to targeted locations. The NuFACE Plus spheres are designed for optimal contact with	Same

	square wave comprising a (10) positive pulses followed by (10) negative pulses. The microcurrent output continuously alternates between the positive and negative electrode spheres, and allows the user to adjust the output for a personalized comfort level. The NuFACE Trinity Device requires the use of a conductive gel. To promote proper use and provide feedback to the user, the NuFACE Trinity Device beeps to cue the user to relocate the device approximately every 5 seconds.	the skin. The NuFACE Plus device delivers microcurrent as a constant biphasic square wave comprising a (10) positive pulses followed by (10) negative pulses. The microcurrent output continuously alternates between the positive and negative electrode spheres, and allows the user to adjust the output for a personalized comfort level. The NuFACE Plus device requires the use of a conductive gel. To promote proper use and provide feedback to the user, the NuFACE Plus beeps to cue the user to relocate the device approximately every 5 seconds.	
BASIC UNIT CHARACTERISTICS			
1. 510(k) Number	K181008	K103472	Different
2. Device Name, Model	NuFACE Trinity Device	NuFACE Plus	Same
3. Manufacturer	Carol Cole Company (dba NuFACE)	Carol Cole Company (dba NuFACE)	Same
4. Power Source(s)	Internal rechargeable Lithium ion battery	Internal rechargeable Lithium ion battery	Same
a. Method of Line Current Isolation	Type BF	Type BF	Same

b. Patient Leakage Current			
1). Normal condition	N/A - Battery operated	N/A - Battery operated	Same
2). Single fault condition	N/A - Battery operated	N/A - Battery operated	Same
5. External power adapter	NuFACE 7-volt power adapter	NuFACE 7-volt power adapter	Same
6. Number of Output Channels	1	1	Same
a. Synchronous or Alternating	N/A - 1 Output channel	N/A - 1 Output channel	Same
b. Method of Channel Isolation	N/A - 1 Output channel	N/A - 1 Output channel	Same
7. Regulated Current or Regulated Voltage	Both	Both	Same
8. Software/Firmware/Microprocessor Control	Yes	Yes	Same
9. Automatic Overload Trip	Not required due to circuit design	Not required due to circuit design	Same
10. Automatic No-Load Trip	Yes	Yes	Same
11. Automatic Shut Off	Yes	Yes	Same
12. Patient Override Control	Yes	Yes	Same
13. Indicator Display			
a. On/Off Status	Yes	Yes	Same
b. Low Battery	Yes	Yes	Same

c. Voltage/Current Level	Yes	Yes	Same
14. Automatic Shut-Off (minutes)	Yes (20 minutes)	Yes (20 minutes)	Same
15. Compliance with Voluntary Standards	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Same
16. Compliance with 21 CFR 898	Yes	Yes	Same
17. Weight	9 oz. without charging base	9 oz. without charging base	Same
18. Dimensions of device(inch) [W x L x D]	2.8" x 5.1" x 1.3"	2.8" x 5.1" x 1.3"	Same
19. Housing Materials and Construction	Thermoplastic	Thermoplastic	Same
OUTPUT SPECIFICATIONS			
1. 510(k) Number		K103472	Unknown
2. Waveform (e.g., pulsed monophasic, biphasic)	Pulsed Biphasic	Pulsed Biphasic	Same
3. Shape (e.g., rectangular, spike, rectified sinusoidal)	Modulated Square	Modulated Square	Same
4. Maximum Output Voltage	28 VDC	28 VDC	Same
5. Maximum Output Current	400 µA @ 500Ω	400 µA @ 500Ω	Same
6. Maximum Output Current Density	0.419 mA/cm2	0.419 mA/cm2	Same
7. Output Current when not stimulating	< 1 µA	< 1 µA	Same

8. Output Tolerance	+/- 10%	+/- 10%	Same
9. Pulse Width (specify units)	60 msec	60 msec	Same
10. Frequency (Hz)	Approximately 8.3 Hz	Approximately 8.3 Hz	Same
11. For interferential modes, only			
12. Beat Frequency (Hz)	No Beat Frequency	No Beat Frequency	Same
13. For multiphasic waveforms, only			
14. Symmetrical phases	Not Multiphasic	Not Multiphasic	Same
15. Phase Duration (include units)	Not Multiphasic	Not Multiphasic	Same
16. Net Charge (µC per pulse)	N/A - Battery operated	N/A - Battery operated	Same
17. Burst Mode (i.e., pulse trains)			
a. Pulses per burst	20	20	Same
b. Pulses per second	8.3	8.3	Same
c. Burst duration (seconds)	2.4 s	2.4 s	Same
d. Duty Cycle [Line (b) x Line (c)] (on time per burst)	20.2 s	20.2 s	Same
18. ON Time (seconds)	60 msec	60 msec	Same
19. OFF Time (seconds)	60 msec	60 msec	Same

CONCLUSION

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR part 807 and based on the relative information provided in this premarket notification, we conclude the NuFACE Trinity Device is substantially equivalent to the NuFACE Plus with regards to safety and effectiveness.