December 17, 2018

Carol Cole Company dba NuFACE
Donald Ellis
Head - R&D Projects, Quality & Regulatory Affairs
1325 Sycamore Ave. Suite A
Vista, California 92081

Re: K182424
Trade/Device Name: NuFACE FIX Skin Toning Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: September 5, 2018
Received: September 6, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182424

Device Name
NuFACE FIX Device

Indications for Use *(Describe)*
The NuFACE FIX™ Device is intended for facial 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 FIX Device 510(k) Summary

DATE PREPARED: OCTOBER 2, 2018

510(K) SUBMITTER/OWNER

Carol Cole Company
1325 Sycamore Ave, Suite A
Vista, CA 92081, USA

CONTACT INFORMATION:

Donald Ellis, Regulatory Affairs/Quality Assurance
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DEVICE NAMES

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

PREDICATE DEVICES

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

510(k) Number:	K131251
Manufacturer:	Carol Cole Company dba NuFACE
Trade Name:	Trinity ELE
Product Code:	NFO

DEVICE DESCRIPTION

NuFACE FIX Skin Toning Device is intended for facial stimulation and is indicated for over-the-counter cosmetic use. Two (2) spherical electrodes, fixed on the NuFACE FIX device main face, deliver low level electrical impulses (aka. microcurrent) to targeted locations on the face.

INTENDED USE

NuFACE FIX Device is intended for facial stimulation and is indicated for over-the-counter cosmetic use.

TECHNOLOGICAL CHARACTERISTICS

The proposed NuFACE FIX device has the same, or similar, technological characteristics as the NuFACE Trinity ELE predicate device. The differences do not alter the clinical utility of our proposed NuFACE FIX device relative to the cleared NuFACE Trinity ELE predicate device listed below.

i) NuFACE FIX device is powered by a rechargeable, nonreplaceable, battery which uses a lithium ion chemistry.

ii) Microcurrent is discharged through two (2) smooth, chrome-plated, spherical electrodes.

iii) NuFACE FIX device generates continuous alternating microcurrent comparable to that of the NuFACE Trinity ELE predicate device.

PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY (EMC)

The following electrical safety and EMC tests have been performed:

- IEC 60601-1-2: 2014-02 -Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic Compatibility.
- IEC 60601-1-6: 2010 + AMD1:2013 TRF (Third Edition) - Medical electrical equipment – Part 1-6 General requirements for safety – Collateral Standard: Usability
- IEC 60601-2-10: 2012 (Second Edition), medical electrical equipment -- part 2-10: particular

requirements for the basic safety and essential performance of nerve and muscle stimulators. (Neurology)

- IEC 60601-1-11 - 2015/01/20 Ed. 2 - Medical Elec. Equip.- Part 1-11: Gen. Req. for Basic Safety & Essential Perf.- Collateral Standard - Req. for Medical Elec. Equip. & Medical Elec. Systems Used in the Home Healthcare Environment
- IEC 60601-1:2005Ed.3+A1 - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety & Essential Performance
    - Excluding: Clause 11.7 (Biocompatibility) referencing ISO 10993
- ANSI/AMI ES60601-1:2005/(R)2012,
    - Excluding; Clause 11.7 (Biocompatibility) referencing ISO 10993
- CAN/CSA-C22.2 No. 60601-1:2014-03 - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
    - Excluding; Clause 11.7 (Biocompatibility) referencing ISO 10993

INGRESS PROTECTION

- EC 60529 Degrees of protection provided by enclosures (IP Code)

USABILITY ENGINEERING

- IEC 62366:2007Ed.1+A1 - Medical Devices - Application Of Usability Engineering To Medical Devices

BATTERY TESTING

- IEC 62133 Edition 2.0 2012-12 and EN 62133: 2013

SOFTWARE VERIFICATION AND VALIDATION TESTING

Verification and validation testing of the device functionality including software was conducted in accordance with IEC 62304:2006 Ed.1 +A1 - Medical Device Software - Software Life Cycle Processes. A risk analysis was completed and risk controls were implemented in accordance with ISO 14971.
Human factors testing was conducted in accordance with IEC 60601-1-6, ISO 62366 and the FDA guidance on human factors engineering to demonstrate that the ergonomics of patient and user interfaces for the subject device are substantially equivalent to the predicate device. Usability of the device was assessed through a prospective Usability Study.

BIOCOMPATIBILITY TESTING

Biocompatibility testing is not needed for the NuFACE FIX device because the materials and manufacturing processes for the NuFACE FIX device are not significantly different to the NuFACE Trinity ELE predicate device and therefore did not raise questions of safety and effectiveness.

ANIMAL STUDY

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

CLINICAL STUDIES

Clinical testing was not required to demonstrate the safety and effectiveness of the Device.

PREDICATE COMPARISON

Table1: General Comparison Table

Device Descriptions	NUFACE® FIX DEVICE (NEW DEVICE)	NUFACE® TRINITY ELE DEVICE (PREDICATE)	SAME OR DIFFERENT TECHNOLOGICAL CHARACTERISTICS
1. 510(k) Number	K182424	K131251	
2. Regulation Number	21 C.F.R. § 882.5890	21 C.F.R. § 882.5890	Same
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 FIX Device is intended for facial stimulation and is indicated for over-the-counter cosmetic use.	NuFACE Trinity ELE is intended for facial stimulation and is indicated for over-the-counter cosmetic use	Same
9. Indications for Use	Over-the-Counter Cosmetic Use	Over-the-Counter Cosmetic Use	Same
10. Anatomic Sites	Face	Face	Same
11. Technological Characteristics	The NuFACE FIX is an over-the-counter facial stimulation device. Its outer case is injection molded thermoplastic resin. The output contacts consist of chrome-plated spherical	The NuFACE Trinity ELE is an over-the-counter facial stimulation device. Its outer case is injection molded thermoplastic resin. The output contacts consist of chrome-plated spheres. The	Same

Device Descriptions	NuFACE® FIX Device (New Device)	NuFACE® Trinity ELE Device (Predicate)	Same or Different Technological Characteristics
	electrodes. The NuFACE FIX device is powered by a rechargeable lithium ion battery. NuFACE FIX device produces microcurrent that is discharged through two fixed, smooth spherical electrodes. To turn the NuFACE FIX device on, the on/off button is pressed. The two spheres gently glide over the skin to deliver low-level electrical impulses to targeted locations on the face. The NuFACE FIX device spheres are designed for optimal contact with facial skin. The NuFACE FIX device delivers microcurrent as a constant biphasic square wave comprised of (10) positive pulses followed by (10) negative pulses. The microcurrent output continuously alternates between 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 on the face. NuFACE Trinity ELE spheres are designed for optimal contact with the face. The NuFACE Trinity ELE delivers microcurrent as a constant biphasic square wave comprising a (10) positive pulses	

Device Descriptions	NuFACE® FIX Device (New Device)	NuFACE® Trinity ELE Device (Predicate)	Same or Different Technological Characteristics
	positive and negative spherical electrodes. The NuFACE FIX device requires the use of a conductive gel. To promote proper use and provide feedback to the user, the NuFACE FIX Device increases tactile feedback to cue the user to relocate the NuFACE FIX device approximately every 5 seconds.	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 ELE requires the use of a conductive gel. To promote proper use and provide feedback to the user, the NuFACE Trinity ELE beeps to cue the user to relocate the device approximately every 5 seconds.	

Table 2: Basic Unit Characteristic Comparison

Basic Unit Characteristics	NuFACE® FIX Device (New Device)	NuFACE® Trinity ELE Device (Predicate)	Same or Different Technological Characteristic
1. 510(k) Number	K182424	K131251	
2. Device Name, Model	NuFACE FIX Device	NuFACE Trinity ELE Device	
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 (updated in K181008)	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	User supplied standard 5-volt USB port	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

Basic Unit Characteristics	NuFACE® FIX Device (New Device)	NuFACE® Trinity ELE Device (Predicate)	Same or Different Technological Characteristic
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 (3 minutes)	Yes (20 minutes)	Different
15. Compliance with Voluntary Standards	IEC 60601-1 IEC 60601-1-2 IEC 60529 IEC 60601-2-10 ISO 14971 IEC 60601-1-6 IEC 62366 IEC 60601-1-11 ANSI/AMI ES60601-1 CAN/CSA-C22.2 No. 60601-1 IEC 62133	IEC 60601-1 IEC 60601-1-2	Same
16. Compliance with 21 CFR 898	Yes	Yes	Same
17. Weight	Approximately 2 oz.	9 oz. without charging base	Different
18. Dimensions of device(inch) [WxLxD]	Approximately 5.7" x 0.82"	2.8" x 5.1" x 1.3"	Different
19. Housing Materials and Construction	Thermoplastic	Thermoplastic	Same

Table 3: Output Specification Comparison Table

Output Specifications	NuFACE FIX New Device	NuFACE Trinity + ELE Device (Predicate)	Same or Different Technological Characteristic
1. 510(k) Number	K182424	K131251	
2. Waveform (e.g., pulsed monophasic,	Pulsed Biphasic	Pulsed Biphasic	Same

OUTPUT SPECIFICATIONS	NUFACE FIX NEW DEVICE	NUFACE TRINITY + ELE DEVICE (PREDICATE)	SAME OR DIFFERENT TECHNOLOGICAL CHARACTERISTIC
biphasic)			
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	200 µA @ 500Ω	208 µA @ 500Ω	Same
6. Maximum Output Current Density	0.418 µA/cm^2	0.800 µA/cm^2	Same
7. Output Current when not stimulating	< 1 µA	< 1 µA	Same
8. Output Tolerance	+/- 10%	+/- 10%	Same
9. Pulse Width	60 ms	60 ms	Same
10. Frequency (Hz)	Approximately 8.3 Hz	Approximately 8.3 Hz	Same
11. For interferential modes, only			
a. Beat Frequency (Hz)	No Beat Frequency	No Beat Frequency	Same
12. For multiphasic waveforms, only			
a. Symmetrical phases	Not Multiphasic	Not Multiphasic	Same
b. Phase Duration (include units) c. (state range, if applicable) d. (both phases, if asymmetrical)	Not Multiphasic	Not Multiphasic	Same
13. Net Charge (µC per pulse)	N/A - Battery operated	N/A - Battery operated	Same
14. Burst Mode (i.e., pulse trains)			
a. Pulse ON time (msec)	60	60	Same
b. Pulse OFF time (msec)	60	60	Same
c. Pulses per burst	20	20	Same

OUTPUT SPECIFICATIONS	NUFACE FIX NEW DEVICE	NUFACE TRINITY + ELE DEVICE (PREDICATE)	SAME OR DIFFERENT TECHNOLOGICAL CHARACTERISTIC
d. Pulses per second	8.3	8.3	Same
e. Burst duration (sec)	2.4	2.4	Same
f. Duty Cycle	50%	50%	Same

CONCLUSION

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