October 15, 2019

Carol Cole Company dba NuFACE
Nadia Miller
Regulatory Affairs Specialist
1325 Sycamore Avenue, Suite A
Vista, California 92081

Re: K191672
Trade/Device Name: NuFACE Mini Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: August 16, 2019
Received: August 16, 2019

Dear Nadia Miller:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Vivek Pinto
Division Director (Acting)
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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)*
K191672

Device Name

NuFACE Mini Device

Indications for Use *(Describe)*

The NuFACE Mini Device 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.

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NUFACE

NuFACE Mini Device 510(K) Summary

Date Prepared: June 20, 2019

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 Mini Facial and Neck Skin Toning Device
Device Common or Usual Name:	NuFACEMini 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:	K181008
Manufacturer:	Carol Cole Company dba NuFACE
Trade Name:	NuFACE Trinity Device
Product Code:	NFO

Device Description

The NuFACE® Mini Device is an over-the- counter facial and neck toning device. The chrome plated dual spheres of the NuFACE® Mini are designed to gently glide over the skin to deliver low-level electrical impulses to strategic locations on the face and neck. The NuFACE® Mini electrodes are designed for optimal contact with the face.

The NuFACE® Mini microcurrent continually alternates between the positive and negative electrodes and allows the user to adjust settings.

The NuFACE® Mini Device measures approximately 2.5" W x 4.2" L x 1.2" D. Its outer case is injection mold thermoplastic resin. The device comes with an external Power Supply to recharge the lithium ion battery of the device when not in use. The external Power Supply is a pre- approved wall adapter. All charging circuitry is contained within the device itself.

To turn the device on/off, the power/control button is pressed. An ascending sequence of beeps and one to five blue LED lights illuminate indicating the unit is ready for use.

Users then follow the instructions for use. The NuFACE® Mini Device requires the use of a conductive gel or medium during treatment. The user can also adjust the output level by briefly pressing the power/control button to rotate between three microcurrent output levels. A long press of this button toggles the device on and off.

To promote proper use and feedback to the user, the NuFACE® Mini beeps to cue the user to relocate the device after approximately 5 seconds of treatment. When the user turns off the device, a descending tone is emitted.

Intended Use

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

Technological Characteristics

The NuFACE Mini Device (proposed) is substantially equivalent to that of its NuFACE Trinity (predicate) and its technological characteristics are virtually identical/ equivalent. It produces microcurrent discharged through the two spherical electrodes.

Biocompatability

User contacting materials for NuFACE Mini are identical and manufactured identically to those of the predicate device. All materials were previously tested and shown to be biocompatible.

Performance Standards

The NuFACE Mini Device (proposed) is substantially equivalent to that of its NuFACE Trinity (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
3. IEC 60601-2-10
4. IEC 60601-1-11

Table 1. Device Description Comparison

Device Description	NUFACE Mini (Proposed)	NUFACE Trinity (Predicate)	Same or Different Technological Characteristics
1. 510(k) Number	TBD	K181008	-
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 Mini Device is intended for facial and neck stimulation and is indicated for over-the- counter cosmetic use.	NuFACE Trinity Device is intended for facial and neck 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 and Neck	Face and Neck	Same

11. Technological Characteristics	The NuFACE® Mini Device is an over-the-counter facial and neck toning device. The chrome plated dual spheres of the NuFACE® Mini are designed to gently glide over the skin to deliver low-level electrical impulses to strategic locations on the face and neck. The NuFACE® Mini electrodes are designed for optimal contact with the face. The NuFACE® Mini microcurrent continually alternates between the positive and negative electrodes and allows the user to adjust settings. The NuFACE® Mini device measures approximately 2.5" W x 4.2" L x 1.2" D. Its outer case is injection mold thermoplastic resin. The device comes with an external Power Supply to recharge the lithium ion battery of the device when not in use. The external Power Supply is a pre- approved wall adapter. All charging circuitry is contained within the device itself. To turn the device on/off, the power/control button is pressed. An ascending sequence of beeps and one to five blue LED lights illuminate indicating the unit is ready for use. Users then follow the instructions for use. The NuFACE® Mini Device requires the use of a conductive gel or medium during treatment. The user can also adjust the output level by briefly pressing the power/control button to rotate between three microcurrent output levels. A long press of this button toggles the device on and off. To promote proper use and feedback to the user, the NuFACE® Mini beeps to cue the user to relocate the device after approximately 5 seconds of treatment. When the user turns off the device, a descending tone is emitted.	The NuFACE® Trinity Device is an over-the-counter facial and neck 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 Trinity spheres are designed for optimal contact with the skin. The NuFACE Trinity 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 Trinity requires the use of a conductive gel. To promote proper use and provide feedback to the user, the NuFACE Trinity beeps to cue the user to relocate the device approximately every 5 seconds.	Same

Table 2. Basic Unit Characteristics Comparison

Basic Unit Characteristics	NUFACE Mini (Proposed)	NUFACE Trinity (Predicate)	Same or Different Technological Characteristics
1. 510(k) Number	TBD	K181008	-
2. Device Name, Model	NuFACE Mini	NuFACE Trinity	-
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 5-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 or 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 (5 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	6 oz.	9 oz. without charging base	Same
18. Dimensions of device(inch) [W x L x D]	2.5" x 4.2" x 1.2"	2.8" x 5.1" x 1.3"	Same
19. Housing Materials and Construction	Thermoplastic	Thermoplastic	Same

Table 3. Output Specifications Comparison

Output Specifications	NUFACE Mini (Proposed)	NUFACE Trinity (Predicate)	Same or Different Technological Characteristics
1. 510(k) Number	TBD	K181008	-
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	28VDC	28 VDC	Same
5. Maximum Output Current	348 µA at 500 Ω	400 µA at 500 Ω	Same
6. Maximum Output Current Density	0.452 mA/cm²	0.419 mA/cm²	Same
7. Output Current when not stimulating	< 1 µA	< 1 µA	Same
8. Output Tolerance	+/- 5%	+/- 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	50%	50%	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 Mini Device is substantially equivalent to the NuFACE Trinity Device with regards to safety and effectiveness.