K133823

APR 17 2014

510(k) Summary
NuFACE® Mini Device

CONTACT INFORMATION

Rand Daoud, Compliance Specialist
Carol Cole Company
1325 Sycamore Ave, Suite A
Vista, California 92081

Phone: (760) 734-4545 x126
Facsimile: (760) 650-3667
Email: rdaoud@mynuface.com

DEVICE NAME

Trade Name: NuFACE® Mini Device
Common Name: Facial Toning Device
Classification Name: Transcutaneous Electrical Nerve Stimulator (21 CFR 882.5890)
Product Code: NFO

PREDICATE DEVICE

The Carol Cole Company is claiming substantial equivalence with its own device, the NuFACE® Trinity device, cleared as the NuFACE® Plus under 510(k) K103472. This Abbreviated 510(k) submission is a new design based on the manufacturer's cleared device. The electrical output of the NuFACE® Mini is identical to the previously cleared NuFACE® Trinity Facial Toning Device. Both devices are for transcutaneous electrical nerve stimulation for cosmetic use.

INDICATIONS FOR USE/INTENDED USE

The NuFACE® Mini Device is intended for facial stimulation and is indicated for over-the-counter cosmetic use. (21 CFR 801 Subpart C).

The anatomical site for application of the NuFACE® Mini Device is the face.

TECHNOLOGICAL CHARACTERISTICS

The NuFACE® Mini Device is a non-invasive at home, over-the-counter facial toning device. The dual spheres of the NuFACE® Mini Device are designed for optimal contact with the face and are identical in size to the predicate device. The NuFACE® Mini Device is extremely responsive as it delivers soft wave micro-current in the millionths of an ampere and has the ability to increase facial contour and firm the skin and muscles.

The NuFACE® Mini device measures 2.5" W x 4.2" L x 1.2" D. Its outer case is injection molded of thermoplastic resin. The device comes with an external Power Supply to charge the internal batteries of the device when not in use. The external Power Supply provides DC power from a pre-approved wall adapter. All charging circuitry is contained within the device itself. The microcurrent output is disabled when the device is connected to the external Power Supply.

An ascending sequence of beeps informs the customer the NuFACE® Mini is ready for use. When the user turns the device OFF, a descending tone is emitted. A

single control button is used to turn the device on and off and to change the device's output intensity. A long press of the control button toggles the device between on and off.

To promote proper use, a single audio beep informs the user to relocate the device to treat a new location on the skin. The user can also adjust the output intensity by briefly pressing the control button to step between multiple micro-current output level selections. When the device is set to the maximum output and the control button is pressed, the device sequences to the minimum output.

COMPLIANCE DATA

The NuFACE® Mini Device is in conformance to the FDA's performance Standards set forth in 21 CFR §898. Additionally, there are no electrode lead wires or patient cables with this device.

The NuFACE® Mini Device will be tested for compliance with IEC 60601-1-2:2010 for radiated and power line conducted emissions and IEC 60601-1:2005 (3rd edition) for Electrical Safety.

SUBSTANTIAL EQUIVALENCE

The NuFACE® Mini device has the same intended use and indications for use as the predicate device. The device also has nearly identical technological characteristics. During design and development, a Risk Analysis of the device was used to identify potential Hazards that could occur in use of the device, or in the event of Failure Modes of device components. The Risk Analysis was used to identify risk reduction measures which have been incorporated in the device design and labeling.

The determination of substantial equivalence for the NuFACE® Mini is based on an assessment of non-clinical performance. This assessment included a comparison of the output of the NuFACE® Mini to that of the predicate. The output performance testing included:

1. Waveform Type
2. Waveform Shape
3. Maximum Output Voltage
4. Maximum Output Current
5. Output Tolerance
6. Pulse Width
7. Output Frequency
8. Maximum Phase Charge
9. Maximum Current Density
10. Maximum Power Density
11. Burst Mode (i.e., pulse trains)
    a. Pulses per burst
    b. Pulses per second
    c. Burst duration
    d. Duty Cycle
12. ON Time

The results are provided in Section 3 (Output Specifications) below. As shown in the Substantial Equivalence Comparison Table:

1. Waveform type is identical to the predicate

2. Waveform Shape is identical to the predicate
3. Maximum Output Voltage is identical to the predicate
4. Maximum Output Current is identical to the predicate
5. Output Tolerance is identical to the predicate
6. Pulse Width is identical to the predicate
7. Output Frequency is identical to the predicate
8. Maximum Phase Charge is identical to the predicate
9. Maximum Current Density is identical to the predicate
10. Maximum Power Density is identical to the predicate
11. Burst Mode (i.e., pulse trains)
    a. Pulses per burst is identical to the predicate
    b. Pulses per second is identical to the predicate
    c. Burst duration is identical to the predicate
    d. Duty Cycle is identical to the predicate
12. ON Time is identical to the predicate

The main body of the NuFACE® Mini Device is smaller in size than the predicate; however the functionality remains the same. The NuFACE® Mini does not use a charging cradle, but instead is charged from DC power supplied by an external power supply. The interchangeable head feature of the predicate NuFACE® Trinity device has also been eliminated on the NuFACE® Mini Device. The NuFACE® Mini Device will only function as a microcurrent emitting device.

The results support a determination of substantial equivalence in that the NuFACE® Mini provides the same functionality and microcurrent output as the predicate.

Section 1: Device Descriptions

NuFACE® Mini and NuFACE® Trinity Device Comparison Table

Section 1: Device Descriptions	NuFACE® Mini New Device	NuFACE® Trinity (Cleared as the NuFACE® Plus) Predicate Device
1. 510(k) Number	K133823	K103472
2. Regulation Number	21 C.F.R. § 882.5890	21 C.F.R. § 882.5890
3. Regulation Name	Transcutaneous Electrical Nerve Stimulator	Transcutaneous Electrical Nerve Stimulator
4. Regulatory Class	Class II	Class II
5. Product Code	NFO	NFO
6. Intended Use	Stimulate the face; skin toning	Stimulate the face; skin toning
7. Indications for Use	Over-the-Counter Cosmetic Use	Over-the-Counter Cosmetic Use
8. Technological Characteristics	The NuFACE® Mini is a facial toning device. The chrome plated dual electrode 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. 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 for a personalized comfort level. The outer case of the NuFACE® Mini is injection molded of thermoplastic resin. The device comes with an external Power Supply to charge the internal batteries of the device, when the device is 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, the control button is pressed. An ascending sequence of beeps and one to five 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 control button to shift between multiple microcurrent output levels. When the device is set to the maximum output and the control button is pressed, the device sequences to the minimum output. 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® Plus is a facial toning device. Its outer case is injection molded thermoplastic resin. The output contacts (probes) consist of chrome-plated spheres. The device, powered by four rechargeable AA nickel-metal hydride batteries, produces a micro-current that is discharged through the two fixed, smooth spherical probes. To turn the device on, the on/off button is pressed. An ascending tone sounds, indicating the device on. One to five red LED lights 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. The NuFACE® Plus probes are designed for optimal contact with the face. The NuFACE® Plus micro-current continually alternates between the positive and negative probes, and allows the user to adjust settings for a personalized comfort level. The NuFACE® Plus device requires the use of a conductive solution or gel. To promote proper use and feedback to the user, the NuFACE® Plus beeps to cue the user to relocate the device approximately every 5 seconds. The beep also informs the user that the two spheres are making contact with the skin surface. An alert tone sounds to indicate that both probes are not touching the skin during treatment.

Section 2: Basic Unit Characteristics
NuFACE® Mini and NuFACE® Trinity Device Substantial Equivalence Comparison Table

Section 2: Basic Unit Characteristics	NuFACE® Mini Device New Device	NuFACE® Trinity (Cleared as the NuFACE® Plus) Predicate Device
1. 510(k) Number	K133823	K103472
2. Device Name, Model	NuFACE® Mini Device	NuFACE® Trinity
3. Manufacturer	Carol Cole Company (CCC)	Carol Cole Company (CCC)
4. Power Source(s)		
a. Method of Line Current Isolation	2 rechargeable AA NiMH batteries	4 rechargeable AA NiMH batteries
b. Patient Leakage Current		
1. Normal condition	N/A - Battery Operated	N/A - Battery Operated
2. Single fault condition	N/A - Battery Operated	N/A - Battery Operated
5. Number of Output Modules	1	1
6. Number of Output Channels	1	1
a. Synchronous or Alternating	N/A - 1 Output Channel	N/A - 1 Output Channel
b. Method of Channel Isolation	N/A - 1 Output Channel	N/A - 1 Output Channel
7. Regulated Current or Regulated Voltage?	Both	Both
8. Software/Firmware/ Microprocessor Control?	Yes	Yes
9. Automatic Overload Trip?	Not required due to circuit design	Not required due to circuit design
10. Automatic No-Load Trip?	Yes	Yes
11. Automatic Shut Off?	Yes	Yes
12. Patient Override Control?	Yes	Yes
13. Indicator Display		
a. On/Off Status?	Yes	Yes
b. Low Battery?	Yes	Yes
c. Voltage/Current Level?	Yes	Yes
14. Timer Range (minutes)	Yes (21 minutes)	Yes (21 minutes)
15. Compliance with Voluntary Standards?	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2
16. Compliance with 21 CFR 898?	Yes	Yes
17. Weight	6 oz	9 oz without charging base
18. Dimensions of device(inch) [W x L x D]	2.5" W x 4.2" L x 1.2" D	3" W x 5.2" L x 1.25" D
19: Dimensions of charging Unit (inch) [W x L x D]	None	3.25" W x 4.0" L x 3.25" D
20. Housing Materials and Construction	Thermo Plastic	Thermo Plastic

Section 3: Output Specifications
NuFACE® Mini and NuFACE® Trinity Device Substantial Equivalence Comparison Table

Section 3: Output Specifications	NuFACE® Mini Device New Device	NuFACE® Trinity (Cleared as the NuFACE® Plus) Predicate Device
Waveform (e.g., pulsed monophasic, biphasic)	Pulsed Monophasic	Pulsed Monophasic
Shape (e.g., rectangular, spike, rectified sinusoidal)	Modulated Square	Modulated Square
Maximum Output Voltage (specify units)	222 mV @ 500 Ω	137 mV @ 500 Ω
	781 mV @ 2 kΩ	769 mV @ 2 kΩ
	3.90 V @ 10 kΩ	3.82 V @ 10 kΩ
Maximum Output Current (specify units)	396 µA @ 500 Ω	274 µA @ 500 Ω
	395 µA @ 2 kΩ	387 µA @ 2 kΩ
	391 µA @ 10 kΩ	383µA @ 10 kΩ
Output Current When On, But Not Stimulating (Charging is the only case where this occurs)	1.53 µA @ 10 kΩ	27.8 µA @ 10 kΩ
Output Tolerance	+/- 2%	+/- 2%
Pulse Width (specify units)	ON phase: 60.4 ms OFF phase: 60.4 ms Total Pulse Width: 120.8 ms	119 ms
Frequency (Hz)	8.28 Hz	8.40 Hz
For interferential modes only		
Beat Frequency (Hz)	No Beat Frequency	No Beat Frequency
For multiphasic waveforms only		
Symmetrical phases?	Not Multiphasic	Not Multiphasic
Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	Not Multiphasic	Not Determined
Net Charge (µC per pulse)	1.43 µC @ 500 Ω	1.40 µC @ 500 Ω
Maximum Phase Charge (µC)	23.7 µC @ 500 Ω	23.6 µC @ 500 Ω
Maximum Current Density (mA/cm²)	0.514 mA/cm² @ 500 Ω	0.512 mA/cm² @ 500 Ω
Maximum Power Density (µW/cm²) (using smallest electrode conductive surface area)	1981 µW/cm² @ 10k Ω	1991 µW/cm² @ 10k Ω
Patient Leakage Current During Charging With Normal Mains Polarity	0.5 µA RMS	0.4 µA RMS
Patient Leakage Current During Charging With Reversed Mains Polarity	0.5 µA RMS	0.6 µA RMS
Burst Mode (i.e., pulse trains)		
a. Pulses per burst	20	20
b. Pulses per second	8.28	8.40
c. Burst duration (seconds)	2.42	2.40
d. Duty Cycle [Line (b) x Line (c)] (on time per burst)	20	20.2
ON Time (seconds)	Constant	Constant
OFF Time (seconds)	None	None

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

April 17, 2014

Carol Cole Company
Rand Daoud
Compliance Specialist
1325 Sycamore Ave, Suite A
Vista, California 92081

Re: K133823
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: March 18, 2014
Received: March 19, 2014

Dear Ms. Daoud:

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 Small Manufacturers, International and Consumer Assistance 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,

Felipe Aguel -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 on last page.

510(k) Number *(if known)*
K133823

Device Name
NuFACE® Mini Device

Indications for Use *(Describe)*
The NuFACE® Mini Facial Toning device is intended for facial stimulation and is indicated for over-the-counter cosmetic use (21 CFR 807 Subpart C).

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)*

Felipe Aguel -S Date: 2014.04.17 18:46:47 -04'00'

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."