K103472

NOV - 7 2011

Abbreviated 510(k) Summary
NūFACE® Plus Device

Prepared: November 11, 2010, updated December 22, 2010

CONTACT INFORMATION

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DEVICE NAME

Trade Name: NūFACE® Plus
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 NūFACE® device, cleared under K072260. This Abbreviated 510(k) submission is a new design based on the manufacturer's cleared device. Both devices are for transcutaneous electrical nerve stimulation for cosmetic use.

INDICATIONS FOR USE/INTENDED USE

The NūFACE® Plus Facial Toning 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 NūFACE® Plus is the face.

TECHNOLOGICAL CHARACTERISTICS

NūFace® Plus is a Facial Toning Device intended for facial stimulation. It produces microcurrent discharged through the two spherical probes. Microcurrent is an aesthetic modality providing electric current in millionths of an ampere and has the ability to increase facial contour and firm the skin and muscles by supplying 80 – 400 µA.

The device measures 3" W x 5.25" L x 1.25" D. Its outer case is injection molded of thermoplastic resin and the output contacts (probes) consist of chrome-plated spheres. The device is powered by 4 rechargeable batteries. The NūFACE® Plus comes with a rechargeable base, which measures 3.25" W x 4" L x 3.25" D.

To turn the device on, an ON/OFF button is pressed. 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 NūFACE® Plus probes are designed for optimal contact with the face. The NūFACE® Plus device continually alternates between the positive and negative probes, and allows the user to adjust settings from 0 to 400 microamps for a personalized comfort level. The NūFACE® Plus device requires the use of a conductive gel.

An ascending sequence of beeps informs the customer the NūFACE® Plus is ready for use. When the user turns off the device, a descending tone is emitted.

To promote proper use three alert beeps will sound if both probes are not touching the skin during treatment. Also to promote proper use, a single audio beep informs the user to relocate the device to treat a new location on the skin. User can also adjust output by pressing the + or – intensity buttons to increase or decrease microcurrent.

COMPLIANCE DATA

The NūFace® Plus Facial Toning Device was tested and found to be in compliance with FDA's performance standards set forth in 21 CFR §898.

The NūFace® Plus device was also tested and found to be in compliance with IEC 60601-1-2 for radiated and power line conducted emissions. The NūFace® Plus device was evaluated and found to be in compliance with IEC 60601-1 for Electrical Safety.

SUBSTANTIAL EQUIVALENCE

The NūFACE® Plus device has the same intended use and indications for use as the predicate device. The device also has similar 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.

Section 1: Device Descriptions

Device Descriptions
NuFACE® Plus and Original NuFace® Device Comparison Table

Section 1: Device Descriptions	NuFACE® Plus New Device	NuFace® Original Predicate Device
1. 510(k) Number	To Be Assigned	K072260
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® 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.	NuFace® is a facial toning device. Its outer case is injection molded thermoplastic resin, and the output contacts (probes) consist of chrome-plated spheres. The device, powered by a 9-volt battery, produces a micro-current 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. The NuFace® probes are designed for optimal contact with the face. The NuFace® device micro-current continually alternates between the positive and negative probes, and allows the user to adjust settings for a personalized comfort level. The NuFace® device requires the use of a conductive solution or gel.

Section 2: Basic Unit Characteristics

Basic Unit Characteristics
NuFACE® Plus and Original NuFace® Device Substantial Equivalence Comparison Table

Section 2: Basic Unit Characteristics	**NuFACE® Plus** New Device	**NuFace® Original** Predicate Device
1. 510(k) Number	To be assigned	K072260
2. Device Name, Model	NuFACE® Plus	NuFace®
3. Manufacturer	Carol Cole Company (CCC)	Carol Cole Company
4. Power Source(s)		
a. Method of Line Current Isolation	4 rechargeable AA NiMH batteries	One 9V Battery
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	No
9. Automatic Overload Trip?	Not required due to circuit design	No
10. Automatic No-Load Trip?	Yes	No
11. Automatic Shut Off?	Yes	No
12. Patient Override Control?	Yes	Yes
13. Indicator Display		
a. On/Off Status?	Yes	Yes
b. Low Battery?	Yes	No
c. Voltage/Current Level?	Yes	No
14. Timer Range (minutes)	Yes (21 minutes)	N/A - No Timer
15. Compliance with Voluntary Standards?	EN 60601-1-2	EN 60601-1
16. Compliance with 21 CFR 898?	Yes	Yes
17. Weight	9 oz without charging base	0.5 lbs
18. Dimensions of device(inch) [W x L x D]	3" x 5.25" x 1.25"	2.25" x 7" x 0.75"
19: Dimensions of charging Unit (inch) [W x L x	3.25" x 4" x 3.25"	NA
19. Housing Materials and Construction	Thermo Plastic	Thermo Plastic

Section 3: Output Specifications

Output Specifications
NuFACE® Plus and Original NuFace® Device Substantial Equivalence Comparison Table

Section 3: Output Specifications	**NuFACE® Plus** New Device	**NuFace® Original** 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)	137 mV @ 500 Ω	158 mV @ 500 Ω
	769 mV @ 2 kΩ	780 mV @ 2 kΩ
	3.82 V @ 10 kΩ	2.6 V @ 10 kΩ
Maximum Output Current (specify units)	274 µA @ 500 Ω	223 µA @ 500 Ω
	387 µA @ 2 kΩ	358 µA @ 2 kΩ
	383 µA @ 10 kΩ	263 µA @ 10 kΩ
Output Tolerance	+/- 2%	+/- 10%
Pulse Width (specify units)	119 ms	112 ms
Frequency (Hz)	8.40 Hz	8.39 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)	Not Determined	Not Determined
Net Charge (µC per pulse)	N/A - Battery Operated	N/A - Battery Operated
Maximum Phase Charge (µC)	23.06 µC @ 500 Ω	18.13 µC @ 500 Ω
Maximum Current Density (mA/cm²)	0.419 mA/cm² @ 500 Ω	0.341 mA/cm² @ 500 Ω
Maximum Power Density (µW/cm²)	3.22 µW/cm² @ 500 Ω	3.02 µW/cm² @ 500 Ω
Burst Mode (i.e., pulse trains)		
a. Pulses per burst	20	21
b. Pulses per second	8.4	9.1
c. Burst duration (seconds)	2.4	2.3
d. Duty Cycle [Line (b) x Line (c)]	20.2	20.9
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 Room –WO66-G609
Silver Spring, MD 20993-0002

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Carol Cole Company
c/o Mr. Bob Duffy
President
Bob Duffy Associates, Inc.
16405 Summer Sage Road
Poway, CA 92604

Re: K103472
Trade/Device Name: NuFace Plus
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: September 28, 2011
Received: October 3, 2011

Dear Mr. Duffy:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Abbreviated 510(k) for NūFACE® Plus Device

510(k) Number for original device to which Substantial Equivalence to a manufacturer's own device: K072260

Indications For Use:
The NūFACE® Plus Facial Toning Device is intended for facial stimulation and is indicated for over-the-counter cosmetic use (21 CFR 807 Subpart C).

Prescription Use _____ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K103472