

K072260



CAROLCOLE

510(k) Summary
NuFace® Device

Date Prepared: August 10, 2007

CONTACT INFORMATION

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NOV 27 2007

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Contact Person: Carol Cole, President & CEO

DEVICE NAMES

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

PREDICATE DEVICES

The legally marketed predicate devices to which the Carol Cole Company is claiming equivalence include the following transcutaneous electrical nerve stimulator devices for cosmetic use:

510(k) Number: K040871
Manufacturer: FaceMaster of Beverly Hills, Inc.
Trade Name: FaceMaster Facial Toning System
Product Code: NFO

510(k) Number: K011935
Manufacturer: Salton, Inc.
Trade Name: Rejuvenique
Product Codes: NFO and GYB

INDICATIONS FOR USE/INTENDED USE

The NuFace® Facial Toning Device is intended for facial stimulation and is indicated for over-the-counter cosmetic use. (21 CFR 807 Subpart C).

The anatomical site for application of the NuFace is the face.

TECHNOLOGICAL CHARACTERISTICS

NuFace[®] is a Facial Toning Device intended for facial stimulation. The device measures 7" L x 2.5" W x 1" D. Its outer case is injection molded of thermoplastic resin, ABS UL 94 HB, and the output contacts (probes) consist of chrome-plated spheres. The device, powered by a 9-volt battery, produces microcurrent 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 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 NuFace[®] device requires the use of a conductive derma gel.

The NuFace[®] device is quite different from both Electrical Nerve Stimulation Devices and Electro-Muscle Stimulation Devices, which use a much stronger current to cause muscular contraction or nerve stimulation.

PERFORMANCE DATA

The NuFace[®] Facial Toning Device was tested and found to be in compliance with FDA's performance standards set forth in 21 C.F.R. §898.

The NuFace[®] device was also tested and found to be in compliance with the EU Declaration of Conformity under the EMC and Safety Standards IEC 60601-1 and IEC 60601-1-2. Accordingly, NuFace[®] has received a CE Mark under the Medical Device Directive 93/42/EEC.

The non-clinical performance data from the comparative analyses of the NuFace[®] device and the two 510(k) approved predicate devices demonstrated the NuFace[®] device is as safe and effective as, and performs similarly to, the predicate 510(k) approved transcutaneous electrical nerve stimulator devices for OTC cosmetic use. Several other devices on the U.S. market that are not 510(k) approved yet have their device listed on the FDA website were not included in the comparative analysis (e.g., Arasys and Bio-Dermology).

SUBSTANTIAL EQUIVALENCE

Based on the foregoing, the NuFace[®] device was found to have the same intended use and indication for use as the predicate devices. The device also has similar technological characteristics to its predicate devices. Minor differences in the technological characteristics of the NuFace[®] device and the predicate devices do not raise any issues of safety or effectiveness. Thus, the Carol Cole Company found the NuFace[®] device to be substantially equivalent to the legally marketed predicate devices labeled for over-the-counter cosmetic facial toning.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Carole Cole Company
% Global Life Sciences, Inc.
Mr. Howard Asher
President and CEO
3366 N. Torrey Pines Ct
Suite 130
La Jolla, CA 92037

NOV 27 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Re: K072260
Trade/Device Name: NuFace®
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NFO
Dated: October 30, 2007
Received: October 31, 2007

Dear Mr. Asher:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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.

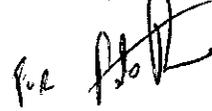
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

Page 2 – Mr. Howard Asher

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Mark N. Melkerson *11/26/07*

Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



CAROLCOLE

Indications for Use
NuFace® Device

510(k) Number: K072260

Indications For Use:

The NuFace® Facial Toning Device is intended for facial stimulation and indicated for over-the-counter cosmetic use.

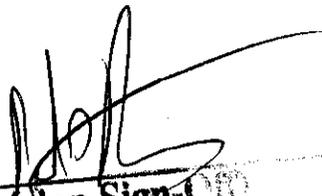
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

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 General, Restorative,
and Neurological Devices**
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