510(k): k112351

Traditional 510(k)

MAR 30 2012

Summary
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Date of Summary Submission	: August 05, 2011
Resubmitting on.	: N.A.

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NEW DEVICE FOR WHICH SUBMITTING

Trade Name : **Ultra Beauty**

Common Name : **Transcutaneous Electrical Nerve Stimulator**

Classification Name : **Stimulator, Nerve, Transcutaneous, Aesthetic Purposes**

Device's Classification Panel : **Neurology (As Per 21 CFR Section 882.5890)**

Regulatory Class : **Class II**

Product Code : **NFO**

LEGALLY MARKETING DEVICE

Rejuvenique	:	Transcutaneous Electrical Nerve Stimulator
Manufacturer	:	Salton Inc
Address	:	1955 W. Field Court Lake Forest, IL 60045
NuFACE	:	Transcutaneous Electrical Nerve Stimulator
Manufacturer	:	Carol Cole Company
Address	:	147 Basil Street Encinitas, California 92024
FaceMaster	:	Transcutaneous Electrical Nerve Stimulator
Manufacturer	:	FaceMaster of Beverly Hills Inc
Address	:	2603 Main Street 1170 Irvine, California 92614

DESCRIPTION OF NEW DEVICE ULTRA BEAUTY

Ultra Beauty is a microcurrent device that provides facial stimulation for cosmetic purposes. Ultra Beauty provides a suite of treatment options, combining the different modes and applications from various devices available in the market. The device provides three easy to use pre-programmed modes and the device manual illustrates in detail the suggested treatment protocols for the desired results. The unit features a portable battery powered base module that features a large LCD display and various buttons for easy navigation through the different treatment settings. Ultra Beauty utilizes two different types of probes and to enhance the ease of use and the maneuverability, each probe is attached to the two separate hand pieces. Stimulations generated by the base unit are delivered to the hand pieces through conductive cables.

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Features:

- Sleek and Modular Design
- Two separate hand pieces for maneuverability and ease of use
- LED indicators on the hand pieces and a conductivity bar on the display screen that shows the micro-current is working
- Two different types of probes
- Large LCD display
- Battery life indicator

Accessories:

S. No.	Particulars	Qty.
1.	Hand pieces wire cable(Hand piece size 13.9 cm × 2.5 cm, Cable: 4 core 1.25 meter)	02 Nos.
2.	T Bar(Cylindrical size: Diameter: 0.62 cm, Length: 5 cm)	02 Nos.
3.	Two Prong Applicator(Diameter size: 2× 0.508 cm=1.016 cm)	04 Nos.
4.	5 Volt Battery Charger	01 No.
5.	Conductive Gel	250gram

INDICATION FOR USE

- **Ultra Beauty** device is intended for facial stimulation and is indicated for over-the-counter cosmetic use

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3. DISPLAY

ULTRA BEAUTY comes with LCD display to show parameter of selected step, Phase, Time and Output intensity, all parameter can be modified by using MKB panel on top of the unit.

NuFACE uses LED of power on/off indication and power intensity can be controlled by potentiometer.

Face master uses LCD display to show treatment time and power intensity and can be controlled by using buttons on the unit.

Rejuvenique uses LCD display to show treatment time and power intensity and can be controlled by using button on unit.

4. POWER

ULTRA BEAUTY use 3.7V /1200MA rechargeable Lithium ion battery and all predicated devices use +9V battery.

5. KEY PADS

In **ULTRA BEAUTY** all parameter can be modified by using MKB panel on top of the unit.

In **NuFACE** power intensity can be controlled by potentiometer.
In **Face master** power intensity can be controlled by using button on unit.
In **Rejuvenique** power intensity can be controlled by potentiometer.

6. CASING

ULTRA BEAUTY is packaged in an attractive ABS body enclosure. It is strong and sturdy. It is ergonomically designed.

FaceMaster Rejuvenique and NuFACE is fitted in ABS enclosures.

SAFETY:

1. In **ULTRA BEAUTY** the micro-current parameter is controlled by feedback signals, any component failure system gets off.
2. Since **ULTRA BEAUTY** operates only on battery, it makes it safe.
3. A reliable high speed controller used to get interface between all parameters.
4. Circuitry efficiency is high and reliable.

ULTRA BEAUTY functions normally after open and short circuited conditions between output jacks, with the device operating for maximum of 15 minutes, in each condition at the maximum available setting of pulse width, pulse rate and pulse amplitude. A concise detailed design control activities, verification and validation activities are described in next section.

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NON-CLINICAL TESTS PERFORMED:

Ultra Beauty complies with international standards for electrical safety and electromagnetic compatibility. Compliance to applicable voluntary standards includes IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, and ISO 14971: 2007. Comprehensive risk analysis has been carried out for the device with regards to safety and effectiveness.

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

SUBSTANTIAL EQUIVALENCE:

Based on the foregoing, the Ultra Beauty 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 Ultra Beauty device and the predicate devices do not raise any issues of safety or effectiveness. Thus Ultra Beauty device is found to be substantially equivalent to the legally marketed predicate devices labeled for over-the-counter cosmetic use

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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c/o Ms. Pooja Johari
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Rajasthan, India

Re: K112351
Trade/Device Name: Ultra Beauty
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NFO
Dated: March 6, 2012
Received: March 12, 2012

Dear Ms. Johari:

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,

for Kesia Alexander

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

- **Ultra Beauty** device is intended for facial stimulation and is indicated for over-the-counter cosmetic use.

Prescription Use _____ AND/OR Over-The-Counter Use _____√_____
(Part 21 CFR 801 Subpart D) (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)
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(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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