K071573

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510(k) SUMMARY

DEC 0 9 2008

Rugalift

Submitter

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Date Prepared: 09/26/2008

Device Trade Name

Rugalift

Classification Name

Transcutaneous Electrical Nerve Stimulator (21 C.F.R. 882.5890)

Predicate Devices

Salton, Inc.'s Rejuvenique® Facial Toning System, Model RJV-10 (K011935)

Intended Use

Rugalift is indicated for cosmetic use.

Technological Characteristics

Rugalift works by delivering electrical microcurrents to stimulate the skin of the face in a non invasive way. The body of the device includes the electronics for the control of the device, and the power switch for the activation of the device by the user and a detachable applicator with 5 microelectrodes.
Rugalift is switched on when the microelectrodes are on the skin and pressing the finger on the power switch.
The output of the device increases linearly over the first 10 seconds of stimulation, then it remains constant for 13 seconds and stops. The output cannot be changed by the user. During the treatment, an acoustic signal is activated. The frequency of the acoustic signal increases as the output current increases. When the user removes the device from the face, it automatically resets and turns itself off.
Rugalift is powered by a 12V power adapter which is supplied with the device.

Performance Data

Rugalift is in conformity with the requirements as set forth in the following standards:

- EN 60601-1-2 ED. 2 (2001): Medical electrical equipment. Part 1-2: General Requirements for safety.
- IEC 60601-1-2 (2001-09): Medical electrical equipment. Part 1-2: General Requirements for safety. Collateral standard: EMC Requirements and tests.
- EN 60601-2-10 (2001-11): Medical electrical equipment. Part 2-10: Particular requirements for the safety of nerve and muscle stimulators

- EN 60601-2-10 (1990-08): Medical electrical equipment. Part 1: General Requirements for safety and its amendments: EN60601-1/Ec (1994-07) + A1 (1993) + A1/Ec (1994-07) + A2 (1995-06) + A13 (1996-01).
- CEI 62-39 (1992-10): Electrical equipment for aesthetic use.

Rugalift operation is based on the principle of stimulating the skin with microcurrents delivered through microelectrodes.

The microelectrodes are positioned on the face skin, after the skin has been cleansed and dried. The effects on the stimulated region of the face can vary based on individual sensitivity and the duration of treatment. Many people notice a softening effect which can enhance the results of make-up and works against the effects of skin ageing.

The results are not permanent but can last several months following the appropriate maintenance program.

An usability study has been performed to evaluate Rugalift usability and safety after self-training. The study provided evidence that the documentation included is sufficient for self-selection and safety of the device.

Rugalift is a device that can be used easily, is reliable and safe.

Substantial Equivalence

Rugalift is substantially equivalent to other legally marketed transcutaneous electrical nerve stimulator devices for cosmetic use. Specifically, Rugalift is substantially equivalent to Salton, Inc.'s Rejuvenique® Facial Toning System.

The Rejuvenique system delivers electric stimulation through 26 fixed position electrodes which are contained in a face mask shaped to fit over the user's face, and held into position by an adjustable headband. The electrodes are activated in sequence: each pair of electrodes delivers the stimulus for 20 seconds (similar to the Rugalift recommended stimulation time), then a microprocessor located in the device control unit automatically switches to the next pair of electrodes. A full cycle requires approximately 4 minutes. Unless stopped by the user, the product will repeat the cycle four times (approximately 20 minutes) and then automatically shuts off.

Although the mechanism of action of the two devices is the same (i.e. stimulation of the face using microcurrents), there are some differences, which are related to the specific principle of operation of the two devices.

- The Rugalift is a handheld device which allows delivery of the stimulation precisely on the selected area. This is not possible with the Rejuvenique device because the mask shape and electrodes position are fixed, whereas face anatomy is variable form subject to subject. Therefore, in order to obtain the same effect, the current density delivered by Rejuvenique and/or stimulation time may need to be greater than that of the Rugalift.
- With Rejuvenique the user may be forced to interrupt the treatment cycle if stimulation of a certain area is not tolerated, and this may prevent completion of the treatment. With Rugalift, selective application on each face area and the possibility to interrupt and resume treatment easily may allow completion of stimulation even in the most sensitive areas. The ability to interrupt the stimulation easily by lifting the device from the skin is an important advantage in terms of patient safety.
- Rugalift is a simpler device as it does not require a control unit and does not have a display; therefore, it is more user-friendly.

The above mentioned differences in the principle of operation result in some differences in the technological characteristics of the two devices, but do not cause substantial differences in terms of performance and safety features. Rugalift has the same intended use as the Rejuvenique®. The device also has similar technological characteristics as its predicate device. Both devices provide local stimulation of the face using low intensity currents.

Minor differences in the technological characteristics of Rugalift and the Rejuvenique® do not raise any new issues of safety or effectiveness. Thus, Rugalift is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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DEC 0 9 2008

Re: K071573
Trade Name: RUGALIFT version 2.1
Regulation Number: 21 CFR 882.5890
Regulation Names: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NFO
Dated: September 5, 2008
Received: September 10, 2008

Dear Dr. Peluso:

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.

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 Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indication for Use

510(k) Number (if known): K071573

Device Name: RUGALIFT version 2.1

Indication For Use: The RUGALIFT is indicated for cosmetic use.

Prescription Use _____ And/Or Over the Counter Use X .
(21 CFR Part 801 Subpart D) (21 CFR Part 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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