K040871

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JUN 1 - 2005

510(k) SUMMARY

FaceMaster of Beverly Hills, Inc.
FaceMaster® Facial Toning System

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

FaceMaster of Beverly Hills, Inc.
23679 Calabasas Road, PMB 665
Calabasas, California 91302-1501

Telephone: (818) 222-2461
Facsimile: (818) 222-6534
E-Mail: J.Engco@Worldnet.Att.Net
Contact Person: Mr. Jim England

Date Prepared: April 1, 2004

Name of Device and Name/Address of Sponsor

FaceMaster Facial Toning System

FaceMaster of Beverly Hills, Inc.
23679 Calabasas Road, PMB 665
Calabasas, CA 91302-1501

Common or Usual Name

FaceMaster Facial Toning System

Classification Name

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

Predicate Devices

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

Intended Use / Indications for Use

The FaceMaster Facial Toning System ("FaceMaster System") is intended to stimulate the face. The device is indicated for cosmetic use.

Technological Characteristics

The FaceMaster System is a transcutaneous electrical stimulator that incorporates a control module and two electrodes on separate, handheld probes to deliver electrical stimulation to the face muscles. The device is prepared for use by laying it flat on a table, opening the control module cover and removing the probes from their cradles inside the control module. Conductive solution is dispensed into a basin within the control module and, after placing the foam pads over the distal end of each probe the pads are soaked in the solution until they are moist. The user then pushes the power (ON/OFF) button to turn the device on and follows the instructions for use and the LCD and audible prompts from the control module to complete the three cosmetic stimulation modes, *i.e.*, the eye cycle, the facial cycle, and the feathering cycle.

Performance Data

The FaceMaster Facial Toning System complies with FDA's performance standard for electrode lead wires and patient cables set forth in 21 C.F.R. § 898.12. A clinical study of the FaceMaster System, which included testing both with trained observers and self-assessments, was completed to demonstrate the substantial equivalence of the FaceMaster System to other transcutaneous electrical nerve stimulator devices for OTC cosmetic use.

Substantial Equivalence

The FaceMaster System is substantially equivalent to other legally marketed transcutaneous electrical nerve stimulator devices for cosmetic use. Specifically, the FaceMaster System is substantially equivalent to Salton, Inc.'s Rejuvenique® Facial Toning System ("Rejuvenique" or the "predicate device"). The FaceMaster System has the same intended use and the same indication for use as the Rejuvenique. The device also has similar technological characteristics as its predicate device. Minor differences in the technological characteristics of the FaceMaster System and the Rejuvenique do not raise any new issues of safety or effectiveness. Thus, the FaceMaster System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 - 2005

FaceMaster of Beverly Hills, Inc.
c/o C. Stephen Lawrence
Hogan & Hartson, L.L.P.
2603 Main Street, Suite 1170
Irvine, California 92614

Re: K040871
Trade/Device Name: FaceMaster Facial Toning System
Regulation Number: 21 CFR 882.5850
Regulation Name: Transcutaneous Electrical Stimulator for Cosmetic Use
Regulatory Class: Class II
Product Code: NFO
Dated: March 1, 2005
Received: March 3, 2005

Dear Mr. Lawrence:

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.

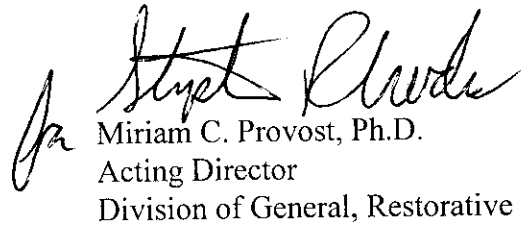
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):_____

Device Name: **FaceMaster® Facial Toning System**

Indications for Use:

The FaceMaster® Facial Toning System is intended to stimulate the face. The device is indicated for cosmetic use.

Prescription Use ____ OR Over-The-Counter Use__X__
(Per 21 C.F.R. 801.109)

(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

510(k) Number K040871