K011935

AUG - 8 2001

510(k) SUMMARY
REJUVENIQUE® FACIAL TONING SYSTEM

Applicant/Address

- Salton, Inc., 1955 W. Field Court, Lake Forest, IL 60045

Contact Person/Telephone

- Leon Dreimann, Chief Executive Officer, (PH) 847-803-4600 ext. 1200; (FAX) 847-803-1211

Preparation Date

- August 7, 2001

Device Trade Name

- Rejuvenique®

Classification Name

- TENS Device(21 CFR 882.5890)

Legally Marketed Predicate Devices

- TENS devices.

Device Description

- The Rejuvenique facial toning system consists of three connected components - a face mask, connecting cable and control unit. The mask is a PBC mask that is shaped to fit over the user's face. It is held on the user's face by an adjustable headband. It contains 26 fixed-position, gold plated, brass electrodes. The connecting cable is an 8-conducter cable in a PVC jacket. It connects the face mask to the control unit by modular, phone jack-style plugs on each end. The Control Unit contains the power-source (a nine-volt battery), and the microprocessor control.
- When the Rejuvenique® system is activated, it provides a stimulus to the first pair of electrodes for 20 seconds, and then the microprocessor automatically switches to the next pair of electrodes in the sequence. The Facial Point Location Display indicates which pair of electrodes are currently activated (1-12). A full cycle through the 12 pairs of electrodes requires approximately 4 minutes. Unless stopped by the user the product will go through four complete cycles (approximately 20 minutes), and then automatically shuts off.

Intended Use

- Rejuvenique® is indicated for cosmetic use.

Substantial Equivalence Summary

- Rejuvenique® is substantially equivalent to legally marketed TENS devices.

Technological Characteristics

Basic Unit Characteristics

1. Power Source(s):	Single 9V Battery
2. Number of Output Modes:	1
3. Number of Output Channels:	1 channel
- Synchronous or Alternating?	Alternating into 12 electrode groups
- Method of Channel Isolation	Electrode group selected by relays
4. Regulated Current or Voltage?	Regulated Voltage
5. Software/Firmware/Microprocessor Control?	Yes
6. Automatic Overload Trip?	No
7. Automatic No-Load Trip?	No
8. Automatic Shut Off?	Yes
9. Patient Override Control?	Yes
10. Indicator Display:	
- On/Off Status?	Yes
- Low Battery?	Yes
- Voltage/Current Level?	Yes, Uncalibrated Knob
11. Timer Range (minutes)	Fixed 16 minutes
12. Compliance with 21 CFR 898	Yes
13. Weight	80 grams
15. Dimensions (in.) [WxHxD]	4-1/2" x 3" x 1-1/4
16. Housing Materials and Construction	ABS Plastic, snap latch assembly

Output Specifications

1. Waveform:	Pulsed Biphasic
2. Shape:	Rectangular (+ phase), Spike (- phase)
3. Maximum Output Voltage:	18.8V @ 500 Ohms
4. (+/- 10 %)	24.8V @ 2k Ohms
5.	28.0V @ 10k Ohms
6. Maximum Output Current:	37.6mA @ 500 Ohms
7. (+/- 10 %)	12.4mA @ 2k Ohms
8.	2.8mA @ 10k Ohms
9. Pulse Width	300 microseconds fixed
10. Frequency (Hz)	8 Hz fixed
11. Beat Frequency (Hz)	N/A
12. Symmetrical Phases	No

13.	Phase Duration: (both phases, if asymmetrical)	300 microseconds (+ phase) 124.7 milliseconds (- phase, exponential)
14.	Net Charge (microC per pulse) (if zero, state method to achieve)	0 @ 500 Ohms Transformer Coupling
15.	Maximum Phase Charge, (microC)	11.3 microCoulombs @ 500 Ohms
16.	Maximum Current Density	46.4 mA/cm^2 @ 500 Ohms

Sample Calculation:

Jmax = Imax/(pi * $D^2/4$) = 37.6 mA/(3.1416 * (1.016 cm)^2 / 4) = 46.4 mA/cm^2
Assumes only one electrode pair contacting. If both pairs make contact, Jmax is 23.2 mA/cm^2

17.	Maximum Power Density, (W/cm2)	2.31 mW/cm2

Sample Calculation:

Pmax = Jmax * Vmax * 0.3 ms/125 ms + V- * J- * 2.8 ms/125 ms
Pmax = 46.4 mA/cm^2 * 18.8 * 0.0024 + 2.0V * 4.93 mA/cm^2 * 0.0224
Pmax = 2.093 mW/cm^2 + 0.221 mW/cm^2 = 2.31 mW/cm^2
First portion is positive phase, second is negative phase. Assumes negative Phase is square shaped with constant amplitude equal to initial negative spike. This slightly overestimates the power density of the negative phase.

18.	Burst Mode:	
	a. Pulses per burst	160 pulses
	b. Bursts per second	1/240 (per electrode group)
	c. Burst duration	20 seconds
	d. Duty Cycle	1/12
19.	On Time (Seconds)	20 seconds/electrode group

Testing

- Clinical efficacy and safety data was submitted in the application.

Conclusion

- Based on the foregoing, Salton believes the Rejuvenique® facial toning system is substantially equivalent to legally marketed predicate TENS devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Georgia C. Ravitz
Counsel for Salton, Inc.
Arent Fox Kinter Plotkin & Kahn, PLLC
1050 Connecticut Avenue, NW
Washington, DC 20036-5339

AUG - 8 2001

Re: 510(k) Number K011935
Trade/Device Name: Rejuvenique® System, Model RJV-10
Regulation Numbers: 21 CFR 882.5890 and 21 CFR 882.1275
Regulatory Class: II
Product Codes: NFO and GYB
Dated: June 20, 2001
Received: June 21, 2001

Dear Ms. Ravitz:

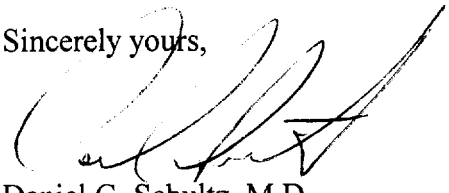
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html".

Sincerely yours,



Daniel G. Schultz, M.D.
Deputy Director for Clinical
and Review Policy
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011935

Device Name: Rejuvenique® System, Model RJV-10

Indications For Use:

The Rejuvenique System is indicated for cosmetic use.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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