NOV 10 2011 K103031

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This 510k Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Contact Details

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Prepared:	November 8, 2011

2. Device Name

Trade Name of Device:	BMR Face, Type 371 & Type 372*
Common Name:	Facial Stimulator
Regulation Number:	21 CFR 882.5890
Regulation Description:	Transcutaneous electrical nerve stimulator for pain relief.
Product Code:	NFO
Device Class:	2

3. Identification of Equivalent Legally Marketed Device

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

4. Description of Device

BMR Face, Type 371/372* (* Type 372 is simply a black version of Type 371) is a two-channel, battery operated cosmetic device which is intended for use on the face. The device consists of a rechargeable electronic device which connects to an applicator. Each side

paddle of the applicator contains a set of replaceable twin conductive gel pads which deliver electrical impulses to the face.

The BMR Face device operates by applying Transcutaneous Electrical Nerve Stimulation (TENS) to the facial area. Low-level electrical impulses are sent from the stimulator unit via an applicator to gel pads that are positioned anterior to each ear and strategically over the cranial nerve #7 of the face.

3 programs are available to the user and these vary in treatment times from 10 to 20 minutes. Power is derived from a 3.6V NiMH rechargeable battery pack that is pre-installed in the unit and there is no capability for charging the unit whilst any treatment is ongoing. All internal connections of the unit are over molded to prevent moisture ingress.

5. Statement of Intended Use/Indications for Use

BMR Face is intended for facial stimulation and is indicated for over the counter cosmetic use

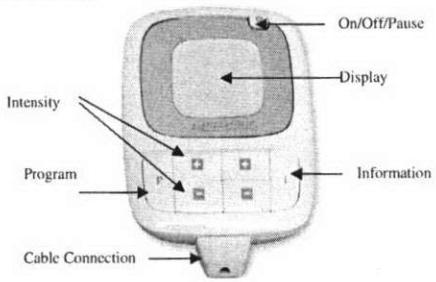
6. Summary of Technological Characteristics

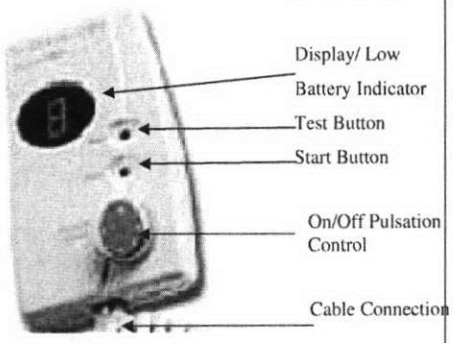
There are no new technological characteristics that could affect safety or effectiveness of the BMR Face device. Substantial Equivalence has been demonstrated as part of this 510k submission. Table 5.1 provides a summary comparison of technological characteristics of BMR Face versus that of the predicate "Rejuvenique® System".

Table 5.1 Summary Comparison of Technological Characteristics of BMR Face Versus Rejuvenique® System (Predicate)

Table 5.1	**BMR Face, Type 371 (New Device)**	**Rejuvenique System (Predicate)**
Intended Use	Same	Stimulation of the Face
Indications for Use	BMR Face is intended for facial stimulation and is indicated for over the counter cosmetic use.	Cosmetic Use (OTC)
Target Population	Healthy adults	Healthy adults
Anatomical Site	Same	Face
Where Used	Same	Portable, may be used at home
Energy Used/Delivered	3.6V (rechargeable battery). Symmetric, Pulsed, Biphasic	9V battery (standard or rechargeable)
Human Factors	Validation Testing conducted in accordance with the Draft Guidance Document Applying Human Factors and Usability Engineering to Optimize Medical Device Design, and the AAMI's HE75 Human factors engineering–design of medical devices	Ref: K011935
Materials	Same for unit. Applicator constructed of PC-141R, 2 applicator paddles contain carbon impregnated silicone rubber. The pads are manufactured by Axelgaard Manufacturing Company, Fallbrook, California and are composed of a skin conductive adhesive hydrogel layer (Axelgaard MultiStick® MG-1500) which contains glycerin, water and a polyacrylate co-polymer. Each gel pad is supplied with protective liners for both skin and the paddle adhesive faces. The charger is constructed of PC/ABS.	Unit constructed of ABS Plastic, Face Mask is a PBC mask with 26 fixed-position, gold-plated brass electrodes.
Biocompatibility	Gel pads comply to ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity & ISO 10993-10	Ref: K011935

Table 5.1	BMR Face, Type 371 (New Device)	Rejuvenique System (Predicate)
	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity	
Compatibility with the environment/other devices	Complies to IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	Ref: K011935
Sterility	N/A	N/A
Electrical Safety	Complies to IEC 60601-1 Medical electrical equipment - Part 1: General requirements for safety & IEC 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators	Ref: K011935
Mechanical Safety	Complies to IEC 60601-1 & IEC 60601-2-10	Ref: K011935
Chemical Safety	MSDS Sheet provided for conductive gel pads	Ref: K011935
Design	Device contains a control unit, applicator, gel pads, charger and instructions for use. - The unit may be recharged (charger supplied). - 12 twin conductive gel pads used - Applicator used to apply stimulation (gel pads placed on two paddles of applicator)	Device contains a control unit, facial mask, adjustable headband, connecting cable, toning gel, and instructions for use. - Device may not be charged, rechargeable batteries may be used however. - Toning gel supplied - Facial mask used to apply stimulation (toning gel used on the gold-plated brass contact points).
User Interface	The user interfaces with the control unit, applicator and gel pads. The user attaches the gel pads to the two paddles of the applicator	The user interfaces with the control unit, face mask and conductive gel. The user applies a pea sized amount of the

<table>
<tr><th>Table 5.1</th><th>BMR Face, Type 371 (New Device)</th><th>Rejuvenique System (Predicate)</th></tr>
<tr><td>Modes of Operation</td><td>and fits the applicator per the instructions for use. The user interacts with the control unit – On/off/pause button, increase or decrease intensity on the left and right hand sides of the applicator, information button, program button and display. Display icons are explained in the instructions for use.
<u>Control Unit</u>
 

3 programs delivered
<table>
<tr><th>Treat Time (min)</th><th>Freq. (HZ)</th><th>Pulse Width (µS)</th><th>Ramp-up (Sec)</th><th>Contr (sec)</th><th>Ramp-down (sec)</th><th>Relax (sec)</th></tr>
<tr><td>20</td><td>70</td><td>100</td><td>1</td><td>0</td><td>1</td><td>1</td></tr>
<tr><td>10</td><td>80</td><td>80</td><td>2.5</td><td>0.5</td><td>1.5</td><td>0.5</td></tr>
<tr><td>15</td><td>70</td><td>80</td><td>0.5</td><td>0.5</td><td>0.5</td><td>0.5</td></tr>
</table></td><td>toning gel to the surface of each facial contact point before the face mask is fitted. The user interacts with the control unit - start button and the pulsation, on/off knob and display.
<u>Control Unit</u>
 

1 program only, intensity may be adjusted on the control unit.</td></tr>
</table>

Table 5.1	BMR Face, Type 371 (New Device)	Rejuvenique System (Predicate)
Performance Testing	Comparison basic unit characteristics and output specifications tables, using the "Guidance Document on Powered Muscle Stimulator 510(k)s. 1999"and the draft guidance document "Class II Special Controls Guidance Document: Transcutaneous Electrical Stimulator with Limited Output for Aesthetic Purposes" April 5, 2010, have been included as part of this submission.	Ref: K011935
Thermal Safety	Complies to IEC 60601-1 & IEC 60601-2-10	Ref: K011935
Radiation Safety	N/A	N/A
Standards Met	IEC 60601-1:1988 +A1:91, A2:95, Corrigendum 95 EN 60601-1-2:2007 EN 60601-2-10:2000 + A1:2001 (IEC 60601-2-10:1987/A1:2001) Charger: UL 60950 & CSA-C22.2 No. 60950-00 ISO 14971:2007	Ref: K011935
Software	Completed based on the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" 2005.	Ref: K011935

7. Clinical and Non-Clinical Tests

Clinical Tests: No new clinical studies have been submitted as part of this Premarket Notification.

Non-Clinical Tests: BMR Face has been designed and independently tested to the following requirements:

- EN 60601-1: 1990 + A1: 93 + A11: 93 ++ A12: 93, A2:95, A13: 96, Corrigendum 94 Medical Electrical Equipment - Part 1: General Requirements for Safety.
- IEC 60601-1:1988 +A1:91, A2:95, Corrigendum 95 Medical Electrical Equipment - Part 1: General Requirements for Safety
- EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007 Modified)
- EN 60601-2-10:2000 + A1:2001 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators (IEC 60601-2-10:1987/A1:2001

In addition, the power supply unit complies with the following:

- UL 60950 - Information Technology Equipment Safety - Part 1: General Requirements
- CSA-C22.2 No. 60950-00 - Information Technology Equipment Safety – Part 1: General Requirements

8. Safety and Effectiveness

Bio-Medical Research Ltd. ("BMR") has over 30 years experience in the research, design, manufacture and marketing of medical grade products for both muscle strengthening and pain relief. BMR has two divisions – Slendertone, which develops and markets a range of consumer health and fitness products and Neurotech, which provides a range of neuromuscular stimulators for pain management and rehabilitation.

Bio-Medical Research Ltd. complies with 21 CFR 820 and is registered to I.S. EN ISO 13485:2003 Medical Device Quality Management System for the design, manufacture and distribution of electro-medical devices.

- A risk management plan was carried out to EN ISO 14971:2007.

- Independent EMC and Electrical Safety testing has been carried out.
- In Europe (EU), Slendertone Face has been CE marked and complies with the Medical Device Directive 93/42/EEC.

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

Bio-Medical Research Ltd.
c/o Ms. Anne-Marie Keenan
Quality and Regulatory Engineer
Parkmore Business Park West
Galway
Ireland El

NOV 10 2011

Re: K103031
Trade/Device Name: BMR Face
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: October 27, 2011
Received: October 31, 2011

Dear Ms. Keenan:

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,

Kesia Alexander

for 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

510(k) Number (if known): K103031

Device Name: BMR Face, Type 371 & Type 372

Indications for Use:

BMR Face is intended for facial stimulation and is 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K103031