510(k) Summary

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k) premarket notification was in accordance with 21 CFR 807.92.

Date prepared: May 20, 2009

1. **Applicant, Official Correspondent and Owner of 510(k)**

RS Medical
14001 S.E. First Street
Vancouver, WA 98684
Attn: Timothy J. Johnson, Director of Regulatory Affairs
Telephone: 360-823-4940
Fax: 866-210-6928

Official Correspondent: William Carroll

2. **Name of Device**

Trade/Proprietary Name: RS-LB™ Low Back Conductive Garment, RS-FBG™ Full Back Conductive Garment
Common/Usual Name: Conductive garments
Classification Name: Cutaneous electrode, 21 CFR 882.1320, product code GXY

3. **Legally Market Predicate Devices**

The RS-LB™ Low Back Conductive Garment and RS-FBG™ Full Back Conductive Garment are substantially equivalent to the Axelgaard Manufacturing Company, Ltd. UltraStim® Kit (K013532) which include UltraStim® Electrodes (K000947).

4. **Indications for Use**

The RS Medical Conductive Garments and associated accessories are indicated for use with RS Medical Stimulators to facilitate electrode placement and maintenance of electrode positioning for stimulation treatments of the lower, middle and upper back.

5. **Device Description and Substantial Equivalence**

The RS Medical Conductive Garments consist of the RS-LB™ Low Back Conductive Garment and RS-FBG™ Full Back Conductive Garment. The RS-LB™ Low Back Conductive Garment is a wrap designed for the low back that uses Velcro® closures to affix the garment around the waist and lower back. The garment contains eight conductive metal snaps onto which a snap cable can be connected to the outside of the garment. These snaps extend through the garment and an adhesive backed

electrode pad is affixed to the snap surface on the inner surface of the garment. The garment allows for easy electrode placement and stabilization of electrode locations on the back for repeated electrostimulation treatments to facilitate treatment compliance. The RS-FBG™ Full Back Conductive Garment is a similar vest type compliance accessory that has sixteen metal snaps spaced from the lower back on either side of the spinal column to the middle and upper back. The RS Medical Conductive Garments utilize the identical UltraStim® Electrode pads used with the predicate device. The RS Medical Conductive Garments share the same principle of operation and intended use with the predicate device, the design features of the conductive metal snaps are the same and the products utilize the identical UltraStim® Electrode pads (private labeled under RS Medical's name) used with the predicate device.

Based on the similarities, the RS Medical Conductive Garments and accessories are deemed to be substantially equivalent to the predicate device, the Axelgaard Manufacturing Company Ltd, UltraStim® Kit.

6. Non-Clinical Performance

The RS Medical Conductive Garments were tested for electrical continuity from stimulator through cable sets through the garments' metal snaps to the double sided cutaneous electrode. The results of continuity testing met applicable specifications. The garments metal snaps were tested for attachment and removal force of the associated cable sets and safety snap covers and met applicable specifications.

7. Conclusions

The non-clinical performance test results demonstrate that the RS Medical Conductive Garments are safe and effective in delivering electrical stimulation to the attached cutaneous electrodes. The devices perform in an equivalent manner as does the predicate device, the Axelgaard Manufacturing Company Ltd, UltraStim® Kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2009

RS Medical
c/o Marc M. Mouser
CAS Manager, Program Reviewer
Underwriters Laboratories, Inc.
2600 N.W. Lake Road
Camas, WA 98607-8542

Re: K090951
Trade/Device Name: RS-LB™ Low Back Conductive Garment, Rs-FGB™ Full Back Conductive Garment
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: May 22, 2009
Received: May 26, 2009

Dear Mr. Mouser:

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K090951

Device Name: RS Medical Conductive Garments

Indication for Use:

The RS Medical Conductive Garments and associated accessories are indicated for use with RS Medical Stimulators to facilitate electrode placement and maintenance of electrode positioning for stimulation treatments of the lower, middle and upper back.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-the-counter Use _____ (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)

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

510(k) Number K090951