K032652 1/2

SEP 12 2003

510(k) SUMMARY
RS-4i family
July 15, 2003

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 807.87.

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

RS Medical
14401 SE First St.
Vancouver, WA 98684

Attn: Mike McGraw, Vice President, Product Development
Telephone: (360) 896-2503
Fax: (306) 896-2566

Submitter of 510(k) and Consultants

Underwriters Laboratories Inc.
2600 NW Lake Road
Camas, WA 98607-8542
Telephone: (360) 817-5515
Fax: (360) 817-6133

2. **Name of Device**

Trade/Proprietary Name: RS-4i Muscle Stimulator family

Common/Usual Name: Muscle and Interferential Current Stimulator

Classification Name: 21 CFR 890.5850 "Powered Muscle Stimulator", Class II.

3. **Legally Market Predicate Devices**

The RS-4i family is substantially equivalent to its legally marketed predecessor the RS-4M+ (K000114) muscle stimulator.

4. Indications for Use

Muscle Stimulation, Interferential and Non-Interferential Modality

- Relax muscle spasms
- Prevent or retard disuse atrophy
- Maintain or increase range of motion
- Increase local blood circulation
- Re-educate muscle
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

Pain Relief, Interferential Current Modality

- Relieve acute pain
- Relieve and manage chronic pain

5. Device Description and Substantial Equivalence

The RS-4i device family consists of a hardware/software system that is identical to its predicate device (the RS-4M+ device family K100114). The RS-4i device family manufacturing process has been changed to a Surface Mount process and components. The RS-4i device family includes a 'Pattern Stimulation' modality that allows sequential 'pattern' output of the standard muscle stimulation pulses.

The RS-4i device family incorporates traditional muscle stimulation and interferential current stimulation modalities into one unit. Only one modality may be operated at a time. The RS-4i is housed in a plastic enclosure. The front of the enclosure houses the LCD patient display and the operator keypad. The accessories provided with the RS-4i include the output cables, the electrode pads, and the AC Charging Adapter.

The RS-4i pulse mode muscle stimulation modality operates at a specified 57.5 volts peak (+/-10% into a 500 ohm load) and 115 mA peak (+/-10% into a 500 ohm load) with a maximum pulse width of 415 μSec. (+/-10%) and a cycle frequency of 71 Hz (+/-5%). The pulses are bi-phasic. Intensity levels are controlled via pulse width while maintaining the pulse voltage within the specified peak. The waveform includes an on/off ramp, which slowly increases the pulse width to the desired setting.

The RS-4i interferential modality operates at a specified maximum of 100 mA peak (+/-10% into a 500 ohm load). The carrier and interferential signals are simulated sine wave symmetric, balanced outputs with zero net charge. The interferential modality can operate in a true interferential mode (4 pad mode) or the signals can be pre-mixed and only the pre-mixed signals sent to the patient (2 pad mode). The interference signal frequency can be fixed (Continuous) or varied based on three selections (Variable).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2003

RS Medical
c/o Mr. Marc M. Mouser
Project Engineer/Program Reviewer
Underwriters Laboratories, Inc.
2600 NW Lake Road
Camas, Washington 98607

Re: K032652
Trade/Device Name: RS-4i Muscle Stimulator family
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF, LIH
Dated: August 21, 2003
Received: August 28, 2003

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 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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification

Indications For Use

Device Name: RS-4i Muscle Stimulator family

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ _____ OR Over-The-Counter: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K632652