5. 510(k) Summary

APR 13 2007

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.

Date prepared: March 30, 2007

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

RS Medical
14401 SE First St.
Vancouver, WA 98684
Attn: Bill Carroll, Vice President, Research & Development
Telephone: 360-891-7290
Fax: 866-210-6928

Official Correspondent: Bill Carroll

2. Name of Device

Trade/Proprietary Name: RS-4i Sequential Stimulator
Common/Usual Name: Transcutaneous electrical nerve stimulator (TENS)
Classification Name:
882.5890 - Transcutaneous electrical stimulator for arthritis
Product code - NYN

3. Legally Market Predicate Devices

The RS-4i Sequential Stimulator is substantially equivalent to legally marketed devices including the RS-4i model (K032652), the Bionicare Model BIO-1000 (K971437, K030332), and the Healthonics MedRelief ST Series (K060669).

4. Indications for Use

The RS-4i Sequential Stimulator is indicated for use as adjunctive therapy in reducing the level of pain associated with osteoarthritis of the knee.

5. Device Description and Substantial Equivalence

The RS-4i Sequential Stimulator consists of a hardware/software system that is the same as was described in its previous 510(k) notification (K032652). The RS-4i Sequential Stimulator also includes a TENS output.

The RS-4i Sequential Stimulator incorporates traditional muscle stimulation and interferential current stimulation modalities, as well as TENS output into one unit.

Only one modality may be operated at a time, but modalities can be automatically sequenced. 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 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).

The RS-4i TENS (transcutaneous electrical nerve stimulation) modality operates from 0 volts to 54 volts maximum with 108 mA maximum current into a 500 ohm load resistor. The output pulse width is adjusted by a user control and determines the delivered charge. These variable-width pulses are delivered at a fixed 100 pulse-per-second rate. The output is biphasic meaning that every positive polarity pulse is followed by a negative polarity pulse. The alternating polarity also results in a *zero net charge* to the user.

The characteristics of the RS-4i TENS waveform were selected to maximize the stimulation of the sensory nerves (A-β fibres) and minimize the effect on motor neurons. The pulse width operates from 0 μs to 16 μs with a maximum current of 108 mA. This creates a narrow spike like waveform that optimizes the stimulation area between the sensory and motor neurons on the strength-duration curve which provides comfortable stimulation with a minimum of motor recruitment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

RS Medical
% Mr. Steven Chernoff
Vice President
Drug & Device Development Co.
P.O. Box 3515
Redmond, Washington 98073-3515

APR 13 2007

Re: K062325
Trade Name: RS-4i Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NYN
Dated: March 30, 2007
Received: April 4, 2007

Dear Mr. Chernoff :

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

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K062325

Device Name: RS-4i Sequential Stimulator

Indication for Use:

The RS-4i Sequential Stimulator is indicated for use as adjunctive therapy in reducing the level of pain associated with osteoarthritis of the knee.

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

510(k) Number K062325

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)