Premarket Notification [510(k)] Summary

K982410/S1

Submitters name: REHABILICARE, INC.

Submitters Address: Rehabilicare, Inc.
1811 Old Highway 8
New Brighton, MN 55112

Phone: (612) 638-0590

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Contact name: Edward F. Valdez

Date: July 1, 1998

Trade name: SMP-Plus, 9 volt, TENS DEVICE, Model 4930
SX-Plus, 9 volt, TENS DEVICE, Model 4920
SX, 9 volt, TENS DEVICE, Model 4910

Common name: Transcutaneous electrical nerve stimulator for pain relief (TENS)

Classification name: Transcutaneous electrical nerve stimulator (TENS).

Equivalent device(s):
SMP, Model 4800S, Transcutaneous Electrical Nerve Stimulator, Rehabilicare, In
Ultrapac, Model 4500, Transcutaneous Electrical Nerve Stimulator,Rehabilicare
MAXIMA III, Transcutaneous Electrical Nerve Stimulator, Stayodyn, Inc.

Device Description

Basic Design

Transcutaneous Electrical Nerve Stimulation (TENS) has been used successfully for many years in the symptomatic relief and management of chronic, intractable pain.

The model 4900 series of Transcutaneous Electrical Nerve Stimulation (TENS) devices are user-interactive, microcontrolled-stimulators designed to provide low-frequency, non-invasive electrical stimulating therapy to patients for the management of chronic, intractable pain. The model 4900 series design meets the latest electromedical standards and safety requirements, including the Performance

Standard for Electrode Lead Wires and Patient Cables. The devices are microprocessor controlled and contain six preprogrammed therapy modes. The TENS devices (model 4900 series) firmware memory functions include: a non-volatile read-only memory (ROM), last therapy recall, low battery notification and a self-check feature, which notifies the operator when a service condition exists. The ROM is designed to provide the therapy-mode accessibility, while providing the safety features, such as, zero amplitude at "startup" or when an "open channel condition is identified.

The 4900 series of TENS devices are "user friendly" with a user interactive, soft-key pad and a clearly visible, two-line, sixteen character, liquid crystal display (LCD) to show the operating parameters.

The Model 4900S TENS device(s) are portable, personnel and designed to be easily handled with its light weight, trim (0.875" wide by 2.5" by 3.5") rectangular shaped, durable plastic shell. The device is fitted with a belt clip and can easily be worn without inhibiting the mobility of the patient.

The device operates efficiently with a 9-volt battery power supply. The device delivers an output of 25 mAmp for 55 hours under a 500K Ohm load. The efficient power allocation (between the operation of the device and the electrical stimulation delivered to the patient) results from the interaction of a microcontroller; microprocessor; a crystal-controlled oscillator; RAM memory; circuit interface drivers; and a custom ROM.

The crystal-controlled oscillator insures accurate timing of all pulse waveforms.

The microprocessor-controller, in addition to operating the "house keeping functions", such as the LCD readouts, power on, open channel-control and the power off functions, maintains communications to the custom ROM and the variety of modalities available for the different models. The six available preprogrammed modalities: Constant mode; SMP mode; Burst Mode; Rate Modulated Mode; Width Modulated Mode, and Multi-Modulated Mode.

The physician or physical therapist may choose to use, depending on the specific model of TENS device, any one of six available modalities. A description for the six operating modes is as follows.

Constant Mode: The constant mode describes a constant output at a selected pulse width and pulse rate.

SMP Mode: The pulse rate and pulse width modulate inversely to each other.

Burst Mode: The pulse rate is preprogrammed at 125 PPS. The pulse width is selectable over the available range.

Rate Modulated Mode: The output is delivered with modulated pulse rate. The pulse rate modulates between the set rate and 60% of the set rate every 2.5 seconds.

Width Modulated Mode: The output is delivered with modulated pulse width. The pulse width modulates between the set rate and 60% of the set rate every 2.5 seconds.

Multi-Modulated Mode: In this operating mode the output is delivered with modulated pulse rate and pulse width. The pulse rate and pulse width modulates between the set rate and 60% of the set rate every 2.5 seconds.

The SX (model 4910), SX-Plus (model 4920) and SMP-Plus (model 4930) have accessible, (because of the preprogrammed ROM mode selector feature) different combinations of the six available modalities. To support the physician or physical therapist directed patients therapy needs, more specifically, other models will be made available that will have different combinations of the six modalities discussed. Only the SMP-Plus model has all six modalities. The SX-Plus has all modalities except for the SMP mode. The SX model is the basic TENS model with only a constant and burst mode. Additionally, the SX model has a switch that allows the end user to manually switch between the two modes without the amplitude dropping to zero. This feature only available on the SX model provides a therapeutic option directed toward spontaneous pain episodes that appropriately can be controlled manually through the discretion of the patient experiencing the painful episode.

Function

Any mode function, if available with the specific model, is obtained by depressing the mode key repeatedly and cycling through the available modalities until the desired mode is viewed on the LCD display. During mode selection, the amplitude defaults to zero. The amplitude returns to zero when an open channel occurs from an electrode-continuity defect or the electrode becomes unplugged from the TENS device. This safety feature allows the end user control of the ramp-up to the desired therapeutic dose or to reestablish electrical continuity, preventing the uncomfortable sensation from unexpected pulses of electrical stimulation.

By depressing the increasing (+) or decreasing (-) switch for either Channel (CH1 or CH 2) on the keypad initiates, the amplitude function for the designated channel. The LCD displays the current amplitude setting and the channel identity. Continuing to press either the increasing (+) or decreasing (-) switch increases or decreases the PULSE AMPLITUDE by 1 milliampere. If the switch is depressed for greater than ½ second the rate of increasing or decreasing amplitude changes faster. The minimum setting of 0 milliamperes can be achieved in 10 seconds from 60 milliamperes, the maximum amplitude capability. Conversely, 0 to 60 milliamperes can be obtained in 10 seconds.

The pulse rate and the pulse width functions are obtained by depressing the RATE and WIDTH keys on the keypad. Pressing the switch on the key pad displays the chosen function can be viewed on the LCD display, along with the numerical output value for that function. The pulse rate and pulse width are not channel-specific functions so pressing the increasing (+) or decreasing (-) switch on either CH1 or CH2 will only change the numerical output value for that function. The pulse rate output range is selectable from 2 to 120 pulses per second (PPS). The pulse width output range is selectable from 40 to 300 microseconds.

Following therapeutic application press the OFF switch on the keypad, to turn off the TENS device. Immediately after pressing the OFF switch, the amplitude for both CH1 and CH2 defaults to zero. The "house keeping" functions that store the parameters and output conditions of pulse width, pulse rate and the modality, at the time of use, are allowed sufficient time to finish the shut-down sequence before the device is powered down. This parameter storage feature allows the patient to conveniently resume therapy, at a later time, with the same therapeutic conditions used in the subsequent therapy (and eliminates the use of switches and knobs whose settings can become dislocated over time).

A DC internal power source , powers the model 4900 series TENS composed of a single 9.0 Volt DC alkaline battery or a single 8.4 Volt, rechargeable battery. The batteries are replaceable. The power source for the 4900 series is designed to complies with safety standards EN60601-1, UL2601 and ANSI/AAMI NS4-85 requirements so that the device does not operate and no damage can occur if the batteries are reversed.

Accessories

The device is packaged in a protective carrying case with a user-identity tag and sufficient-storage space for the operators manual, electrodes, patient cable and batteries

The operators manual identifies the indications and contraindication for the 4900 series of TENS device. It also includes: warning and caution sections, as well as; instructions for use; maintenance and trouble shooting. The labeling in the users manual and on the device comply with international requirements with international symbols and pictographs. The manual and the device contain the Prescription labeling statement "Caution: Federal law restricts this device to sale by or on the order of a physician."

The device is provided in a kit that includes: lead wires and individually packaged electrodes. The electrodes used with the model 4900 series of TENS devices are manufactured by different manufactures and have been accepted through the 510(k) process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 1998

Mr. Edward F. Valdez
Regulatory Affairs Manager
Rehabilicare, Inc.
1811 Old Highway 8
New Brighton, Minnesota 55112

Re: K982410
Trade Names: SX, Model 4910; SX-Plus, Model 4920; and SMP-Plus, Model 4930 TENS Devices
Regulatory Class: II
Product Code: GZJ
Dated: October 7, 1998
Received: October 14, 1998

Dear Mr. Valdez:

We have reviewed your Section 510(k) notifications of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) to 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 requirement, 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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) 594-4659. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for

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

Enclosures

510(k) NUMBER (IF KNOWN): K982410

DEVICE NAME:

SX	**model 4910**
SX-Plus	**model 4920**
SMP-Plus	**model 4930**

INDICATIONS FOR USE:

TENS stimulation is used for symptomatic relief and management of chronic intractable pain. It is also used as an adjunctive treatment in the management of post-surgical and post-traumatic pain. It has no curative value and should be used only in conjunction with medical supervision.

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

Concurrence of CDRH, Office of Device valuation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over-The-Counter-Use ____
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982410