SUMMARY OF SAFETY AND EFFECTIVENESS
REHABILICARE INC. PROMAX® TENS AND MICROCURRENT DEVICE
MODELS XP-4400, TN-4410, LBR-4420, MC-4440

SUBMITTER INFORMATION

A.	**Company name:**	REHABILICARE, INC.
B.	**Company Address:**	Rehabilicare, Inc. 1811 Old Highway 8 New Brighton, MN 55112
C.	**Company Phone:** **Company Fax:**	(651) 638-0590 (651) 638-0479
D.	**Contact Person:**	Edward F. Valdez Regulatory Affairs, Rehabilicare Inc.
E.	**Date Summary Prepared:**	May 13, 2002

DEVICE IDENTIFICATION

A.	**Common name:**	Transcutaneous electrical nerve stimulator (TENS) for pain relief
B.	**Trade name:**	Promax-XP TENS and Microcurrent device, Model XP-4400 Promax-TENS, TENS device, Model TN-4410 Promax-Libra, Basic TENS Device, Model LBR-4420 Promax-MC, Microcurrent Device, Model MC-4440
C.	**Classification:**	Class II
D.	**Product Code:**	GZJ

IDENTIFICATION OF PREDICATE DEVICE

The Rehabilicare, Inc. Model 4400 series of Promax Transcutaneous Electrical Nerve Stimulator (TENS) and Microcurrent devices are of comparable type and are substantially equivalent to the following predicate devices.

Device Name	Type	Manufacturer	510(k) No.	Date Cleared
SMP-Plus, SMP, and SX	TENS	Rehabilicare Inc.	K982410	October 7, 1998
Max III	TENS	Stayodyn Inc.	K930865	February 17, 1993
Ultrapac II SX	TENS	Rehabilicare Inc.	K872657	June 25, 1987
HMC- Home Microcurrent	Micro-current	Rehabilicare Inc.	K935132	December 21, 1993

Additionally, the Promax-Libra has an external switch that allows the patient receiving the therapy to manually switch between the two modes with out the amplitude dropping to zero. This feature only available on the Promax-Libra model provides for a therapeutic option directed toward spontaneous pain episodes that appropriately is controlled manually through the discretion of the patient experiencing the painful episode.

These low frequency devices meet the latest electrical medical standards and safety requirements, including the EN-60601 standard for electrical safety, EMC and the Performance Standard for Electrode Lead wires and Patient Cables, CFR 898.

The Promax devices are lightweight, portable and designed to for ease of use. The Promax's trim, oval shape has dimensions (0.875 X 2.5 X 3.5 inches) that require minimal dexterity. The user can interact with the device through seven soft key buttons and a clearly visible, thirty two-character liquid crystal display (LCD) that displays the operating status and parameters.

The devices are fitted with a belt clip and a leadwire management system so the device can be attached to clothing, or concealed under clothing, and worn without excessive exposed leadwires inhibiting the patient's mobility.

All the Promax devices are provided in a kit that includes; lead wires, electrodes, and an operator's manual. Accessories such as skin care products, leadwire, electrode types and garments have been tested with the Promax devices and can be ordered to augment the standard kit. The garment-accessories are used to facilitate the ease of electrode placement, so the therapy is targeted to specific areas of the human anatomy and more beneficial to the patient. The garment-accessories are designed to assist the home user of electrical -therapy with electrode placement with little or no assistance, and are worn under normal attire.

INDICATION 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. The device has no curative value and should only be used in conjunction with medical supervision.

SUBSTANTIAL EQUIVALENCE

The Promax family of devices is of comparable type and is substantially equivalent to legally marketed predicate devices.

TECHNOLOGICAL CHARACTERISTICS

The Promax family of TENS and Microcurrent devices are portable, battery-powered, electronic pulse generator devices like all of the predicate devices. The microprocessor-based technology of the Promax provides options and safety features that are not available on many other predicate devices. A direct result of this technology is the availability of a dual modality device.

PERFORMANCE DATA

The performance data for the Promax family Models XP-4400, TN-4410, TN 4430, LBR-4420 and MC-4440 are substantially equivalent to the TENS and Microcurrent devices distributed under K982410, K930865 and K935132, respectively.

DEVICE DESCRIPTION

The Promax® family of non-invasive nerve stimulation therapy devices are user-interactive microprocessor controlled stimulators, designed for end-user comfort, ease of use, and to assist with therapy compliance. The Promax device has combined two modalities of electrical stimulation; (TENS and Microcurrent) used in a number of legally marketed predicate devices into one device. The Promax family of devices provide low frequency, non-invasive electrical stimulating therapy used for the symptomatic relief of chronic, intractable pain and the management of pain associated with post-traumatic or post-operative conditions. Although only one modality can be operated at a time the Promax with its six available preprogrammed TENS modes and three Microcurrent modes provide a plethora of options, so the patients unique therapeutic requirements can easily be selected. The following ten preprogrammed modes are available within the Promax family: Normal, Strength Duration (SD), SMP, Burst, Rate Modulated, Width Modulated, Multi-modulated, Positive-DC Microcurrent, Biphasic Microcurrent, and Negative-DC Microcurrent.

Each mode is made of a different pattern of electrical impulses and intensity settings. The SD mode delivers the unique pattern of electrical impulses with maximum intensity of 11microColumbs. The SMP mode delivers its pattern of electrical impulses at the highest intensity level (24 microColumbs) the Promax delivers. The intensity variety is another therapeutic option directed to meet the prescribed patients therapy requirements.

Additional to the therapeutic option menu, the Promax devices provide a variety of features such as; last therapy recall, low battery notification, patient usage timers, open channel notification, as well as a self-diagnostic feature. The self-diagnostic feature is credited with notifying the user if the device requires maintenance prior to use. The many functions and features available with the Promax device-family are attributed to the size of the microprocessor. Many of these features available with the Promax are not available on other devices where the microprocessors size limitation or electrical mechanical controls are a factor. The microprocessor performance and unique operating software in the Promax provides for the pull-tables and algorithms that generate the waveforms, pulses, and duration/ time curves that are not available on other devices. One such feature is the last therapy recall protocol. This software driven feature allows the patient to resume therapy with little effort, following shut down or an open lead occurrence, (a result of poor continuity) with the same therapeutic settings. Another software driven feature is the Strength Duration Compensation protocol. This protocol starts out at zero amplitude or no stimulation to prevent patient-startling, and in a short time span based upon the Power Curve algorithm works the patient to the therapy settings without the patients experiencing uncomfortable sensations. This protocol is not available when the Promax is in the SMP mode.

Different models of the Promax family provide different therapeutic modes to support more specifically the therapist with the modes and modalities needed to implement the prescribed clinical-protocol. Only the Promax XP-4400 model will have all 10 modes serving both the TENS and Microcurrent therapy menu. The Promax TN-4410 will have the TENS modes, while the Promax MC-4440 presents the Microcurrent modes. The Promax-Libra model LBR-4420 is the basic TENS model with a Constant and Burst mode.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 2002

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

Re: K022405
Trade/Device Name: PROMAX-XP, TENS and Microcurrent Device, Model XP-4400
PROMAX-TN, TENS Device, Model TN-4410;
PROMAX-Libra, TENS Device, Model LBR-4420
PROMAX-MC, Microcurrent Device, Model MC-4440
Regulation Number: 21 CFR §882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: June 15, 2002
Received: July 16, 2002

Dear Mr. Valdez:

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 and additionally 21 CFR Part 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 device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N Melkerson

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

510(k) NUMBER (IF KNOWN): K022405

DEVICE NAME: PROMAX-XP, TENS and Microcurrent model XP-4400
PROMAX-TN, TENS model TN-4410
PROMAX-Libra, TENS model LBR-4420
PROMAX-MC, Microcurrent model MC-4440

INDICATIONS FOR USE:

The model 4400 series of TENS and Microcurrent devices are indicated 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 ✓ OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milham
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K022405