7. 510(k) SUMMARY

7.1 SUBMITTER INFORMATION

Submitter and Contact Person:

Valmed Corp.
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This summary was prepared April 23, 2003 and last revised 12 September 2004.

7.2 DEVICE NAME

Name of the Device: Powered Muscle Stimulator

Trade/Proprietary Name: **P4-FITNESS**

Generic Name: Muscle Stimulator, Neuromuscular Stimulator, NMS

Panel Code and Product Code: 89 IPF

Proposed Classification: 21 CFR 890.5850 "Powered Muscle Stimulator" Class II

7.3 PREDICATE DEVICES

The **P4-FITNESS** neuromuscular stimulator is substantially equivalent to the COMPEX® Sport (K011880) neuromuscular stimulator.

Comparisons between the NEW DEVICE (P4-FITNESS) and the PREDICATE DEVICE were made using physical laboratory bench tests at the Valmed manufacturing site in Martigny, Switzerland. In these tests, the NEW DEVICE, made in Switzerland with a serial number 04 011001, was compared to a PREDICATE DEVICE with serial number CSM 00625 and labeled "Made by COMPEX REHABILICARE legally marketed in the US". The detailed results and waveforms of these measurements are in Valmed file and available for inspection. The tests, provided herein as Attachment 3, confirmed technical substantial equivalence between the PREDICATE and NEW DEVICES.

7.4 DEVICE DESCRIPTION

The **P4-FITNESS** is a battery-powered device for transcutaneous neuromuscular electro-stimulation. It has two channels (outputs) of stimulation, each with independent intensity control. The **P4-FITNESS** delivers low voltage stimulation impulses at both of

its outputs synchronously. The stimulation output voltage waveforms are in form of trains of monophasic, rectangular, compensated impulses with a zero net current. Such waveform character is true, when the outputs are connected to any resistor in a range from 100 Ω to 10,000 Ω.

The **P4-FITNESS** device has six (6) different stimulation timing sequences. The users can select any of these stimulation programs, as appropriate for their objectives. For each stimulation program, the stimulation ON and OFF times, the impulse frequencies and impulse durations are different; all of these parameters are preset at the factory. There are no user accessible controls that can change either the frequency or impulse duration during a treatment. The only user accessible controls are ON/OFF switches, intensity knobs (increase or decrease) and the Program Select switch. The stimulation impulses are low voltage, low frequency, rectangular in shape. The device is housed in a plastic enclosure and is powered by a 9-volt alkaline, non-rechargeable battery. Accessories include output cables, battery, electrode pads and User Manual. There is no provision for an AC adapter; the device can not be connected to any AC electrical power circuit.

The device delivers stimulation pulses of 50v (peak value) ± 10% onto 500Ω at maximum settings, which corresponds to 100 mA (peak value) current intensity. The impulse frequencies produced by the device are in a range of 1 Hz to 120 Hz, with the frequency modulation patterns and timing thereof dependant on the choice of stimulation program. The waveform is rectangular, compensated monophasic with duration time from 40 μs to 340 μs. The current impulses are also rectangular, monophasic and compensated, with zero net charge (no DC current) when measured on 500 ohms load. The tetanization stimulation impulses include ramp modulation, which permits for gradual increase of the contraction intensity during training.

To establish substantial equivalence under 510(k) the **P4-FITNESS** is compared to the "COMPEX" Model Sport 3 muscle stimulator made by COMPEX S.A., [510(k) number K011880] under regulation 21CFR 890.5850 Class II, Code NGX.

7.5 LABELING

Attachment 2 shows the labeling on the outside of the device and on its controls.

7.5.1 User Manual

The User Manual (Attachment 4) for the **P4-FITNESS** conforms to the FDA/CDRH Guidance document issued on June 9, 1999.

7.5.2 Statement of Intended Use

The **P4-FITNESS** is intended for stimulation of healthy muscles in order to enhance and facilitate improved muscle performance. The **P-4 FITNESS** is therefore properly considered as a technique or method for muscle training.

The **P4-FITNESS** is **NOT** intended for use in any therapy or for treatment of any medical conditions or diseases. The **P4-FITNESS** training programs are not designed or intended for injured or otherwise impaired muscles and use of the **P4-FITNESS** on such muscles is contraindicated.

The **P4-FITNESS** provides six muscle stimulation programs. Each program addresses a specific stimulation application for skeletal muscles. The detailed description of the timing sequences of impulses is found in Attachment 3, entitled "COMPARISON TABLE OF 6 STIMULATION PROGRAMS". The programs are defined as follows:

Program 1: Potentiation

The Potentiation Program prepares muscles to work faster and easier at the very beginning of training. This program features two continuous (no pause) stimulation patterns. Muscle contractions are tetanic or subtetanic in the first pattern and the frequency of impulses is variable. Contractions in the second pattern are twitch-like. The two patterns are alternatively repeated ten times.

Program 2: Endurance

Impulse sequences in this program are designed to improve the body's resistance to fatigue (improved endurance) and consist of warm-up and workout periods. During the warm-up period, the stimulation is continuous and muscle contractions are twitch-like. In the work period, stimulation is intermittent and consists of ON and OFF periods. During the ON period, contractions are subtetanic while during the OFF period there is a pause with no stimulation and no muscle contractions.

Program 3: Resistance

The impulse sequences in this program are intended to increase the time a muscle is able to maintain high power work over short time periods. The intensive contractions of stimulated muscles may induce an exhaustion state in these muscle fibers without psychological fatigue and little cardiovascular stress. The Resistance Program activates the anaerobic metabolism and induces the production of lactic acid. This program consists of warm-up and workout periods. During the warm-up period, the stimulation is continuous (no pauses). During the workout periods it alternates between tetanic and twitch contractions. There are no pauses during the workout phase.

Program 4: Strength

This program imposes high power work on the muscle fibers and is intended to develop the maximum contractile force in a muscle. The program consists of warm-up and workout periods. Stimulation is subtetanic (twitch) and continuous during the warm-up phase and alternates between strong tetanic and weak twitch contractions during the workout phase. Intensity of stimulation during the continuous twitch periods is automatically reduced in order to provide some rest between strong tetanic contractions. There are no silent pauses during the workout phase.

Program 5: Explosive Strength

This program increases the speed at which maximum muscle force is achieved. This program consists of warm-up and workout phases. During warm-up, the stimulation is continuous at subtetanic (twitch) frequency, while during the workout phase, the stimulation alternates between short and strong tetanic and long periods of twitch contractions. There is no pause during these phases.

Program 6: Active Recovery

This program consists of low frequency muscle twitches that simulate a massage and induce increased blood flow. The program is one continuous (no pause) low frequency subtetanic stimulation. The frequency of impulses and the impulse phase duration are constant during the entire program.

7.5.3 Medical Contraindications:

1. An implanted cardiac pacemaker, defibrillator or other implanted electronic or metallic devices
2. Undiagnosed pain syndromes
3. Injured or otherwise impaired muscles.

7.5.4 Warnings

1. Long-term effects of chronic electrical stimulation are unknown.
2. Apply electrodes ONLY to normal, intact, clean skin.
3. DO NOT APPLY STIMULATION:
   - Over the carotid sinus nerves.
   - Over the neck or mouth. Severe spasms of the laryngeal and pharyngeal muscles may occur with contractions strong enough to close the airway and/or cause difficulty in breathing. Stimulation over the neck could also have a adverse effects on the heart rhythm or blood pressure.
   - Transcerebrally.
   - Over swollen, infected or inflamed areas of skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins, etc.).
   - Transthoracically; introduction of electrical current into the heart may cause rhythm disturbances, which could be fatal.
   - Over, or in proximity to, cancerous lesions.
   - If you are epileptic
   - After experiencing acute trauma or fracture
   - Following recent surgery
   - If you have a hernia (abdominal or lingual)
   - To the frontal, laryngeal and temporal regions of the neck.
4. Never use the **P4 FITNESS** while driving, operating machinery or during activities in which involuntary muscle contractions may endanger the user or others.
5. Do not use the **P4 FITNESS** in the bath or shower.
6. Persons with suspected heart problems or epilepsy should obtain appropriate medical advice.
7. Never use the **P4 FITNESS** while sleeping.
8. Never immerse the **P4 FITNESS** unit in any liquid.

7.5.5 Precautions

1. The safety of neuromuscular stimulation during pregnancy has not been established.
2. Use caution when/if:
   - User has skin areas that lack normal sensation.

- Following surgical procedures if muscle contractions might impede the healing process.
- Over a menstruating or pregnant uterus.
- There is a tendency to hemorrhage following acute trauma or fracture.

3. Place electrodes in accordance with illustrations in the User Manual.
4. Users should start all sessions in a sitting or prone position (as a minimum, for the first 5 minutes).
5. Users should ensure that extremities are ***isometrically fixed*** (braced) during treatment sessions to prevent movement that results from muscle stimulation.
6. This unit should not be used while driving, operating machinery or during any activity in which involuntary muscle contractions may place the user at undue risk of injury.
7. Some users may experience skin irritation or hypersensitivity due to the electrical stimulation or the conductive medium.
8. Keep the **P4 FITNESS** neuromuscular stimulator out of the reach of children.
9. Application of moderate heat (thermal wrap) to muscles as well as moistening skin prior to treatment improves treatment efficacy; use of cold packs on treated muscles after treatment is likewise recommended.
10. This unit should only be used with the leads, electrodes and accessories provided by the manufacturer.

7.5.6 Adverse Reactions

Skin irritation and burns beneath the electrodes have been reported with the use of some electrical muscle stimulators.

7.5.7 Effectiveness

Human muscle properties are, in large part, due to hereditary properties but they are not static. That muscle properties can be modified through specific activities is well established. These modifications include changes in muscle endurance, resistance and strength. Physical activity, electrical stimulation, or both, can induce such changes.

As indicated in the attached clinical studies (Attachment 5), these changes include increases in muscle contraction speed, muscle strength and endurance, increases in muscle mass and vascularization as well as changes in muscle cell metabolism from anaerobic to aerobic and vice versa.

The **P4-FITNESS** signals impose activity (contraction) patterns on muscles similar to those imposed by normal physical training.

The research that enables this type of effective muscle stimulation dates to the 1980's and was performed by O. M. Scott, G. Vrbova, V. Dubovitz in 1982, by G. L. Kidd and J. A. Oldham in 1988 and by G. L. Kidd, D. V. Maher and J. Cywinski in 1985. J. Cywinski accomplished the synthesis of this combined research in 1993.

7.5.7.1 Comparison of Stimulation Intensity

For the PREDICATE DEVICE (Compex Sport) and the NEW DEVICE (**P4-FITNESS**), the higher the intensity of stimulated contractions of the muscles, the higher is the effectiveness of stimulation treatments. The **P4-FITNESS** stimulates muscles (via motor nerves) at the equivalent energy of the PREDICATE DEVICE (Compex Sport).

7.5.7.2 Comparison of Stimulation Frequencies

The frequencies and timing patterns of the electrical impulses delivered by the NEW DEVICE and the PREDICATE DEVICE for all 6 common programs are compared in Attachment 3.

7.5.8 Safety

The safety of stimulators is determined by the amount of electrical energy that is delivered to the electrodes placed on patient skin in order to achieve an effective level of stimulation. While lower levels of electrical energy are safer, stimulation is ineffective when energy levels are too low. The research to establish the safety of electrostimulators was done in the 1970's and 1980's by Cywinski, Zoll and others, and resulted in the establishment of the safety standard for transcutaneous (through the skin) electrical stimulators. This standard was issued by the American National Standard Institute in the United States as ANSI/AAMI NS-4-1985 and adopted by the U.S. Food and Drug Administration (FDA). The main safety features of the **P4-FITNESS** device are as indicated in the following sections.

7.5.8.1 Stimulation Charge and Stimulator Safety.

The **P4-FITNESS** neuromuscular stimulator delivers a maximum impulse charge of 34 microcoulombs when measured across 500Ω at maximum settings.

The PREDICTE DEVICE, Compex Sport, is rated by the manufacturer as delivering up to 40 microcoulombs when measured across 500Ω at maximum settings.

7.5.8.2 Control of Current Density and Safety of Skin.

A unique safety feature of the **P4-FITNESS** is automatic limitation of stimulation current density (i.e. electrical energy delivered per square centimeter) on the skin under the stimulating electrodes. The skin burn hazard potential from electrostimulators has been widely reported in medical literature, and by the FDA. Due to the **P4 FITNESS** voltage-source type of output circuitry (a voltage source generator similar to that used in implantable cardiac pacemakers), it presents no risk of skin burns, even if used by an unqualified and non-medically supervised person, and even if wrong or partially contacting skin electrodes are used. The skin current densities of Valmed stimulators are, at all times, well below the safe limit of 2 milliamperes (mA) per square centimeter, as required by the ICE 601-2-10 standard.

The **P4-FITNESS** has been legally marketed without prescription in Europe and Asia (as the P4-Sport) for the past seven years, with over 30,000 units sold. The P4-Sport is the official neuromuscular stimulator for several national sports teams, including Swiss Ski. The stimulator is manufactured in accordance with ISO 9001/2000 International Quality Standard, IEC-601-2-10 European Safety Standard and in compliance with all EC medical device directives applicable to Class IIA medical devices.

Valmed, S.A. has not received notification of any adverse safety events related to the P4-devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 2004

Guy Poitout
President
Valmed Corporation
5080 North Ocean Drive 1A
Singer Island, Florida 33404

Re: K031611
Trade/Device Name: P4 Fitness
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: September 10, 2004
Received: September 15, 2004

Dear Mr. Poitout:

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,

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

Indications for Use

510(k) Number (if known): K031611

Device Name: P4 Fitness

Indications For Use:

The P4-Fitness is intended for stimulation of healthy muscles in order to enhance and facilitate improved muscle performance. The P4-Fitness is therefore properly considered as a technique or method for muscle training.

The P4-Fitness is NOT intended for use in any therapy or for the treatment of any medical conditions or diseases. The P4-Fitness training programs are not designed or intended for injured or otherwise impaired muscles and use of the P4-Fitness on such muscles is contraindicated.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous

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

510(k) Number K031611