K062616

JUL - 6 2007

510(k) Summary

Wellness Pro 2010

IntelSource Group, Inc.
3104 E. Camelback Road #528
Phoenix, AZ 85016
Phone: 888-880-7888
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Contact: Mathew Wolfson
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Summary Prepared: Revised February 26, 2007

Trade Name: Wellness Pro 2010

Common Name: TENS device

Classification Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief. 21 CFR 882.5890, Class II, Product Code 84GZJ (prescription) or Stimulator, Nerve, Transcutaneous, for Pain Relief.

Predicate Device Identification:

21CFR:882.5890
Product Code: GZJ
Device Class: II
Legally Marketed Device: Medrelief ST-100, ST-150, ST-200, ST-300
Manufacturer: Healthonics, Inc.
K#: K060669

21CFR:882.5890
Product Code: GZJ
Device Class: II
Legally Marketed Device: Fenzian Treatment System
Manufacturer: Eumedic, Ltd
K#: K041575

Device Description

The Wellness Pro 2010 is designed to provide electrical stimulation, for the relief of chronic, intractable pain and as an adjunctive treatment of post-surgical or post-traumatic acute pain, in a single compact, lightweight user friendly package. Stimulation does not always cause sensation to relieve pain.

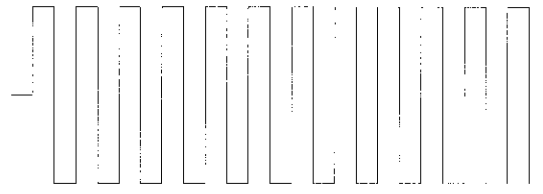
The WellnessPro 2010 has 2 modes of waveforms: Continuous and Premodulated. The device gives the clinician ability to store frequencies or to choose from a set of 250 frequencies that allow quick and easy selection, for prescription of stimulation regimens that can be later stored in any of the 1000 available memory slots.

The Wellness Pro 2010 package is comprised of the following items:

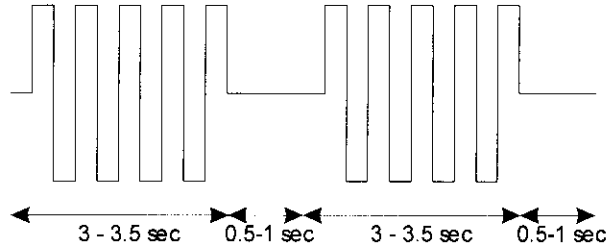
1. 7.5 Volt medical power adapter, conforming to industry standards.
2. Four industry standard wires for electrodes conforming to FDA standard,
3. Four standard commercially available and FDA approved, round 50(mm) self adhesive electrodes.
4. An instruction Manual.

Waveform Description

The **Continuous mode** produces a continuous train of impulses. The stimulation parameters are not automatically interrupted nor vary in any way. The continuous mode is quite versatile because it may be applied with a variety of rate settings.

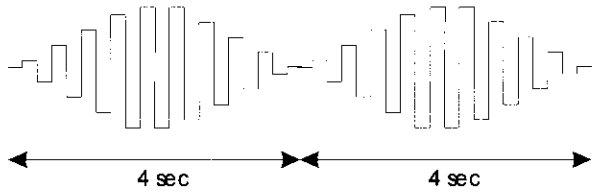


Variations of this mode look like this:

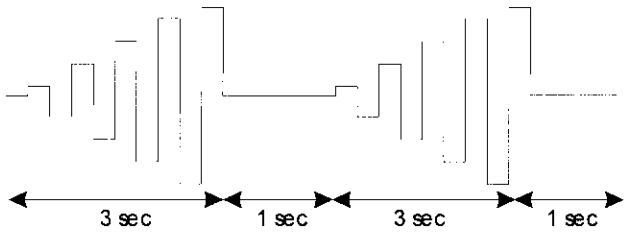


It is still the same continuous mode with a continuous train of impulses (3-3.5 sec) with a small pause (0.5-1 sec) in between.

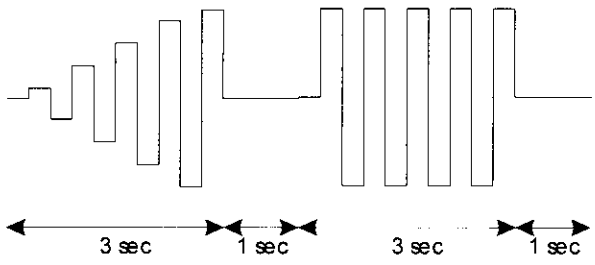
The **Premodulated mode** produces an amplitude-modulated impulse. The current intensity is modulated: The frequency remains the same while the intensity is modulated, (the Amplitude Modulation Frequency).



Variations of this mode looks like this:



The next variation is just a combination of the previously described modes



Note: In order to name these modes and variations, we simply label them as variations 1,2,3,4 and 5. All wave variations have same indications of use. See Below.

Indications for use

There is no clinical basis or benefit for selecting one variation over the other. It is up to the physician to choose the correct placement, regimen and waveform variation to be used for symptomatic relief and management of chronic, intractable pain, post- traumatic acute pain, post-surgical acute pain.

Intended Use

The WellnessPro 2010 is an Electrotherapy Unit that is used for the following:

1. Relief of chronic, intractable pain.
2. Adjunctive treatment of post-surgical or post-traumatic acute pain

Declaration of Conformity

- ISO 10993
- UL 60601-1-1: 2003
- IEC 60601-2-10: 1987
- IEC 60601-1-1: 1998 = A1 = A2:1995
- EN 60601-1-2:2001

Summary of Safety and Effectiveness

The WellnessPro 2010 is substantially equivalent to the Healthonics, Inc - MedRelief ST-100, ST-150, ST-200 and ST-300 devices as well as the Eumedic, Ltd – Fenzian Treatment System because of similar indication for use and unit characteristics.

The WellnessPro 2010 does not raise new issues of safety and effectiveness based on the above similarities.

Basis for substantial equivalence

The Wellness Pro 2010 is equivalent in function and intended use to the predicate devices. Both offer similar user options and functions. However the Wellness Pro 2010 offers simplified user interface, memory slot options and does not have a frequency range as great as the Medrelif ST series.

Non-Clinical Data:

1. Risk Analysis results demonstrate acceptable and mitigated potential hazards.

2. The device meets the requirements for EMC, Radiated Emissions, Electrostatic Discharge, Radiated Immunity and device safety: UL 60601-1-1: 2003, IEC 60601-2-10: 1987, EC 60601-1-1: 1998 = A1 = A2:1995, EN 60601-1-2:2001, ISO 10993.

Conclusion:

The device is designed and labeled and verified for performance and safety.
The performance is equivalent to legally marketed predicate devices. Risk Analysis does not demonstrate any design or performance potential hazards that are not adequately mitigated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 6 2007

IntelSource Group, Inc.
% Mr. Mathew Wolfson
3104 E. Camelback Road, #528
Phoenix, AZ 85016

RE: K062616
Trade/Device Name: Wellness Pro 2010
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: GZJ
Dated: June 22, 2007
Received: July 2, 2007

Dear Mr. Wolfson:

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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Indications for Use

510(k) Number (if known): _____

Device Name: *Wellness Pro 2010*

Indications for Use:

The Wellness Pro 2010 is an Electrotherapy Unit that is used for the following:

1. Relief of chronic, intractable pain.
2. Adjunctive treatment of post surgical or post-traumatic acute pain

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number k062616