A final order reclassifying shortwave diathermy (SWD) intended for adjunctive use in the palliative treatment of postoperative pain and edema of soft tissue by means other than the generation of deep heat within body tissues, a preamendments Class III device, into class II, and renaming the device "nonthermal shortwave therapy" (SWT), was published on October 13, 2015. See here: https://www.federalregister.gov/documents/2015/10/13/2015-25923/physical-medicine-devices-reclassification-of-shortwave-diathermy-for-all-other-uses-henceforth-to

While the device submitted and cleared through K070931 may serve as a valid predicate device for a new SWT device, please refer to the aforementioned final order for current regulatory requirements for this device type.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ProMedTek, Inc.
% The Weinberg Group, Inc.
Diane Mandell, Ph.D., RAC
Senior Consultant
1220 Nineteenth St NW, Suite 300
Washington, District of Columbia 20036

MAY 24 2007

Re: K070931
Trade/Device Name: Model PMT850
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave diathermy
Regulatory Class: Class III
Product Code: ILX
Dated: April 3, 2007
Received: April 3, 2007

Dear Dr. Mandell:

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

INDICATIONS FOR USE

510(K) Number (if known): K070931

Device Name: **Model PMT850**

Indications for Use:

The **Model PMT850** is indicated for adjunctive use in the palliative treatment of postoperative edema and pain in superficial soft tissue.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhern

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

510(k) Number K07 0931

K070931

PROMEDTEK

510(k) Summary

Model PMT850

MAY 24 2007

Name of Device:	**Model PMT850**
Common Name:	Shortwave Diathermy
Classification Name:	21 CFR 890.5290(b), Class III
Product Code:	ILX
Classification Panel:	Physical Medicines Devices Panel
Sponsor:	ProMedTek, Inc. 7272 East Indian School Road, Suite 102 Scottsdale, AZ 85251
Contact:	Daniel R. Puchek
Tele:	480-385-2468
Fax:	480-385-2499
Date Prepared:	May 14, 2007

A. LEGALLY MARKETED PREDICATE DEVICE

K903675, MRT sofPulse shortwave diathermy device, ElectroPharmacology, Inc.

B. DEVICE DESCRIPTION

The **Model PMT850** device is a pulsed shortwave diathermy device. The **Model PMT850** system consists of a Generating Unit connected by a cable to the Treatment Applicator. The Treatment Applicator and cable are a single unit which is connected or disconnected easily from the Generating Unit. The Generating Unit connects to a standard AC electrical outlet by a grounded 3-prong UL/CSA approved, medically rated electric cord.

Treatment with the **Model PMT850** requires placing the Treatment Applicator on top of any standard dressing over the area to be treated, setting the dials on the Generating Unit, and turning the device on. There are 6 possible pulse frequency and 6 possible power control settings on the generating unit of the **Model PMT850**, providing 36 setting options for treatment. Suggested treatment settings are discussed in the Operating Manual for the **Model PMT850**.

C. INTENDED USE

The **Model PMT850** is indicated for adjunctive use in the palliative treatment of postoperative edema and pain in superficial soft tissue.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **Model PMT850** has the same intended use and indications for use statement as the predicate device. The **Model PMT850** has the same technological characteristics as the predicate device, with the exception of the lower power required from the Generating Unit to provide an equivalent amount of Peak Power from the Treatment Applicator, which does not affect safety or effectiveness. In addition to a side-by-side comparison of the descriptive characteristics of the **Model PMT850** and the predicate presented below, performance studies were conducted to ensure equivalent performance compared with the predicate: Applicator Field Measurements, and Output Energy Comparison. The decision algorithm brings us to a determination of device substantial equivalence with the predicate.

E. TECHNOLOGICAL CHARACTERISTICS

The general technological characteristics of the **Model PMT850** and the predicate are equivalent. This includes: power supply, operating principle, energy transfer mechanism, treatment applicator, device physical conformation (weight and size), and packaging.

The following technical specifications are also found equivalent between the **Model PMT850** and the predicate: power required, fuse protection, operating frequency, RF Output Impedance, RF Pulse Width, RF Pulse waveform, pulse frequency, pulse duty cycle, pulse control accuracy, peak RF applicator power, average RF applicator output power, exposure timer, and timer accuracy (see Table 1 below). The only technical specification that differs is the lower peak RF generator power required for the **Model PMT850** Generating Unit to provide an equivalent amount of Peak Power as the predicate from the Treatment Applicator for each of the six power settings.

Table 1. COMPARISON OF TECHNICAL SPECIFICTIONS

	ProMedTek Inc. MODEL PMT850	**Predicate Device MRT sofPulse**
Power required	110 VAC, 60 Hz	110 VAC, 60 Hz
Fuse protection	AC: 1 Amp, 250 V	AC: 1 Amp, 250 V
Operating frequency	Short Wave RF 27.12 MHz ± 0.05%	Short Wave RF 27.12 MHz ± 0.05%
RF Output Impedance	50 Ohms	50 Ohms
RF Pulse width	65 µsec	65 µsec
RF Pulse waveform	27 MHz Sine Wave Envelope	27 MHz Sine Wave Envelope
Pulse control accuracy	0.0025%	Not reported
Exposure timer	0 - 30 minutes	0 - 30 minutes
Timer accuracy	0.001%	1%

F. TESTING

Substantial Equivalence

Applicator Field Measurements and Output Energy Comparison testing was conducted by two independent laboratories to determine equivalence in device performance of the **Model PMT850** and the predicate device. The results of these tests support the substantial equivalence of the **Model PMT850** with the predicate device.

Conformance to Standards

Prior to marketing, the **Model PMT850** will comply with all standard requirements listed by an NRTL and also will conform to electrical safety (UL 60601-1), electromagnetic compatibility (IEC 60601-1-2) and packaging guidelines (ASTM D4169-05).

Biocompatibility testing was determined not to be required because the device does not contact patient skin. However, it should be noted that the treatment applicator covering is made of a high-grade polyethylene foam, which has passed biocompatibility tests for cytotoxicity/irritancy (ISO 10993-5).

G. CONCLUSIONS

ProMedTek, Inc. has demonstrated through the comparison of characteristics and comparison of performance testing, that the **Model PMT850** is substantially equivalent to the predicate, MRT sofPulse shortwave diathermy device.