DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 17, 2016

ProMedTek Inc.
% Diane Horwitz
President
Mandell Horwitz Consultants LLC
2995 Steven Martin Dr.
Fairfax, Virginia 22031

Re: K162240
Trade/Device Name: ProMedTek Model C1400 Shortwave Diathermy Device
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave Diathermy
Regulatory Class: Class II
Product Code: IMJ
Dated: October 14, 2016
Received: October 15, 2016

Dear Ms. Horwitz:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162440

Device Name
ProMedTek Model C1400 Shortwave Diathermy Device

Indications for Use *(Describe)*
The ProMedTek Model C1400 Shortwave Diathermy device delivers energy in the radio band of 27.12 MHz to provide deep heating therapeutic effects to body tissues. When shortwave diathermy is delivered to the body at intensities capable of generating a deep tissue temperature increase, it can be used to treat selected medical conditions such as:

1. Relieving pain
2. Reducing muscle spasm
3. Increasing range of motion of contracted joints using heat and stretch techniques
4. Increasing blood flow to tissues in the treatment area

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

1. GENERAL INFORMATION

1.1 Submitter and 510(k) Owner

Dan Puchek, President and CEO
ProMedTek Inc.
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Scottsdale AZ 85251

1.2 Official Correspondent

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2995 Steven Martin Dr.
Fairfax, VA 22031

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Email: dmh@mandellhorwitzconsulting.com

1.3 Date of Preparation

November 15, 2016

2. NAME OF THE DEVICE

2.1.1 Trade/Proprietary Name

ProMedTek Model C1400 Shortwave Diathermy

2.1.2 Common/Usual Name

Diathermy, Shortwave, for use in Applying Therapeutic Deep Heat

2.1.3 Classification Information

Classification Name:	Shortwave diathermy
Classification Regulation:	21 CFR 890.5290
Class:	II
Product Code:	IMJ
Panel:	Physical Medicine

3. PREDICATE DEVICE

The predicate device is Auto Therm 390, Model ME 390 (Mettler Electronics Corp., K042554).

4. DESCRIPTION OF THE DEVICE

The ProMedTek C1400 shortwave diathermy device operates at 27.12 MHz. It provides traditional shortwave diathermy using an inductive drum or soft-rubber electrodes. The unit offers both continuous or pulsed modes of operation with a variety of frequencies and pulse widths to choose from. An easy-to-use LCD Touch Screen guides the user through setup. A Patient Safety Pull-Cord allows the patient to stop all output. The base of the ProMedTek C1400 is a sturdy cart with large locking wheels that allows the ProMedTek C1400 to be moved easily around the clinic and supports the arm and drum applicator during treatment.

5. INTENDED USE

The intended use / indications for use for the Model C1400 Shortwave Diathermy is as follows:

"The ProMedTek Model C1400 Shortwave Diathermy device delivers energy in the radio band of 27.12 MHz to provide deep heating therapeutic effects to body tissues. When shortwave diathermy is delivered to the body at intensities capable of generating a deep tissue temperature increase, it can be used to treat selected medical conditions such as:

1. Relieving pain
2. Reducing muscle spasm
3. Increasing range of motion of contracted joints using heat and stretch techniques.
4. Increasing blood flow to tissues in the treatment area."

6. SUBSTANTIAL EQUIVALENCE COMPARISON

The Model C1400 Shortwave Diathermy and the predicate device share intended use and technological features. The intended use and indications for use statements are almost identical. There are no differences in technology between the two devices. A comparison of the characteristics to the predicate device follows.

TECHNOLOGY OF THE MODEL C1400 SHORTWAVE DIATHERMY AND THE PREDICATE DEVICE

Characteristic	ProMedTek Model C1400 Shortwave Diathermy New device	Predicate (K042554) AutoTherm 390 Mettler Electronics Corp.
INTENDED USE / INDICATIONS FOR USE STATEMENT		
Statement	The ProMedTek Model C1400 Shortwave Diathermy device delivers energy in the radio band of 27.12 MHz to provide deep heating therapeutic effects to body tissues. When shortwave diathermy is delivered to the body at intensities capable of generating a deep tissue temperature increase, it can be used to treat selected medical conditions such as: 1. Relieving pain 2. Reducing muscle spasm	Shortwave diathermy delivers energy in the radio band of 27.12 MHz to provide deep heating therapeutic effects to body tissues. When shortwave diathermy is delivered to the body at intensities capable of generating a deep tissue temperature increase, it can be used to treat selected medical conditions such as: 1. Relieving pain 2. Reducing muscle spasm

Characteristic	ProMedTek Model C1400 Shortwave Diathermy New device	Predicate (K042554) AutoTherm 390 Mettler Electronics Corp.
	3. Increasing range of motion of contracted joints using heat and stretch techniques. 4. Increasing blood flow to tissues in the treatment area.	3. Increasing range of motion of contracted joints using heat and stretch techniques. 4. Increasing blood flow to tissues in the treatment area.
TECHNOLOGY		
System Components	Unit with Cart and Arm for Inductive Drum Applicator	Same
Applicator Components	Inductive Drum Applicator Soft-Rubber Applicators (2)	Same
Accessories	Felt spacers for Soft-Rubber Applicators (6) Cloth cover for Soft-Rubber Applicators (2) Velcro Receptive Elastic Straps (2)	Same
Input	100-240 VAC, 50-60 Hz	Same
Frequency	27.12 MHz	Same
Output Types	Continuous Pulsed	Same
HF Output Continuous	100 W Average Power	Same
HF Output Pulsed	200 W Peak Power	Same
Pulse Rate Settings	10Hz, 20 Hz, 50 Hz, 100 Hz, 400 Hz	Same
Pulse Width Settings	65 µs, 100 µs, 200 µs, 300 µs, 400 µs	Same
Modes	Inductive Capacitive	Same
Treatment Time	1-30 minutes	Same
Software controlled	Yes	Same
User Display and Interface	LCD Touch Screen displays interactive instructions and indicators	Similar User interface has tactile selection buttons and LED indicators

7. PERFORMANCE TESTING

The 510(k) submission provided performance data to establish the substantial equivalence of the ProMedTek Model C1400 to the predicate device. A summary of these performance tests is provided below.

Software verification and validation testing: Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and

FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern.

Electrical safety and electromagnetic compatibility: The Model C1400 complies with IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-3 and was found to meet all applicable requirements.

8. CONCLUSIONS

This 510(k) submission demonstrates that the ProMedTek Model C1400 is substantially equivalent to the predicate device.