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 14, 2016

Zimmer MedizinSysteme GmbH
% Scott Blood
Principal Consultant
Quality & Regulatory Consulting
22 Nichols Street #2
Salem, Massachusetts 01970

Re: K161862
Trade/Device Name: ThermoPro
Regulation Number: 21 CFR 890.5290
Regulation Name: Shortwave Diathermy
Regulatory Class: Class II
Product Code: IMJ
Dated: October 5, 2016
Received: October 11, 2016

Dear Scott Blood:

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)*
K161862

Device Name
ThermoPro

Indications for Use *(Describe)*
Indications for use in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as disorders of the musculoskeletal system, muscle spasm, joint stiffness, contractures, and chronic inflammatory or infective conditions such as tenosynovitis, bursitis, synovitis and chronic inflammatory pelvic diseases.

Generally accepted indications for use:
o Pain Relief
o Contractures
o Reduce Muscle Spasm
o Localized increase Blood Flow
o Chronic Inflammatory Conditions
o Bursitis
o Decrease Joint Stiffness
o Tenosynovitis
o Synovitis
o Chronic Inflammatory Pelvic Disease

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. Basic Information-Submitter:

510(k) Owner: Zimmer MedizinSysteme GmbH
Junkersstrasse 9
D-89231 Neu-Ulm
Germany
Establishment Registration: 8010720

Official Contact: Mr. Armin Petraschka
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Date Summary Prepared: 30 June 2016

2. Device Name:

Trade Name: *ThermoPro*
Common Name: Shortwave Diathermy
Classification Name: Diathermy, Shortwave, for use in applying therapeutic deep heat
Regulation Number: 21 CFR 890.5290
Product Code: IMJ
Classification: Class II

3. Predicate Devices:

INTELECT SWD 100, MODEL 1600; SENIOR SOLUTIONS SHORTWAVE DIATHERMY, MODEL 1601 – K083433

4. Device Description:

Thermo*Pro* is a shortwave diathermy device for use in applying therapeutic deep heat for selected medical conditions by applying electromagnetic energy in the radio frequency band of 27.12 MHz. The Thermo*Pro* is a device with a metal enclosure that includes a display touchscreen. The device also features an applicator that is a standard monode electrode. The applicator is connected to the device housing, where an electronic power module drives electromagnetic energy into applicator. This

electromagnetic energy is generated using a sine wave synthesizer in combination with a RF power amplifier. The energy can be applied either in constant wave mode or in pulsed mode.

5. Indications for Use Statement:

   Indications for use in applying therapeutic deep heat in body tissues for the treatment of selected medical conditions such as disorders of the musculoskeletal system, muscle spasm, joint stiffness, contractures, and chronic inflammatory or infective conditions such as tenosynovitis, bursitis, synovitis and chronic inflammatory pelvic diseases.

   Generally accepted indications for use:
   - Pain Relief
   - Contractures
   - Reduce Muscle Spasm
   - Localized increase Blood Flow
   - Chronic Inflammatory Conditions
   - Bursitis
   - Decrease Joint Stiffness
   - Tenosynovitis
   - Synovitis
   - Chronic Inflammatory Pelvic Disease

6. Technological Characteristics:

   Shortwave diathermic therapy relies on the conversion of electric power into heat energy that takes place directly inside the tissue, as opposed to a typical heat treatment method in which heat (e.g. heat packs) is supplied from the outside of the tissue. A high-frequency field generates eddy currents in the treated tissues that lead to molecular excitations and convert the electrical energy into heat.

   The energy can be applied either in constant wave mode or in pulsed mode. To run a therapy, the user selects the mode, pulse frequency and duty cycle (if applicable), power level and duration of therapy .The coupling is dependent on the distance between the applicator and the patient and can easily be controlled by supervising the coupling indicator on the display.

The Thermo*Pro* shares the same intended use and the same basic characteristics and features as the predicate device, the Intelect SWD100. The table below summarizes the comparison of those critical features of the *ThermoPro* device with the predicate device:

Technological Characteristics	SUBJECT DEVICE Zimmer MedizinSysteme GmbH Thermo*Pro*	PREDICATE DEVICE Chattanooga Group Intelect SWD 100 K083433
Dimensions (in.)	33.6 h x 22.9 w x 18.0 d	45.0 h x 16.5 w x 16.1 d
Weight (lbs)	81.6	60.0
Enclosure material	Metal	Metal
Applicator	Standard: Monode electrode	Standard: Monode electrode Optional: Flexible electrode, Diplode electrode, Capacitive electrodes
Frequency (MHz)	27.12	27.12
Power Source	100 – 240 VAC, 50 / 60Hz	100 – 240 VAC, 50 / 60Hz
Output power (W)	100	100
Pulsed Output Power (W)	200 Limited to 64W peak mean power	200 Limited to 64W peak mean power
Applied Part Type (applicator)	BF	BF
Protection Class	I	I
Touch screen Interface	Yes	Yes
External Memory	No	No
Modifiable waveform parameters / Customizable treatment parameters	Yes	Yes
Pulse Rate	CW mode 10 - 1000 Hz Adjustable from: 10 Hz – 200 Hz in 10 Hz increments 200 Hz – 800 Hz in 100 Hz increments 1000 Hz	CW mode 10 - 800 Hz Adjustable in 10 Hz increments
Duty Cycle (%)	10 – 90%	0.02 – 32% preset - not adjustable
Pulse Width	250µs – 90ms in 250µs increments ,	20 – 400µs in 20µs increments

Technological Characteristics	SUBJECT DEVICE Zimmer MedizinSysteme GmbH Thermo*Pro*	PREDICATE DEVICE Chattanooga Group Intelect SWD 100 K083433
	preset - not adjustable	
Accuracy (%)	+ / - 20%	+ / - 20%
Maximum Treatment Time (mins)	30	30
Favorites / named user defined programs	Yes	Yes
Calculated and displayed energy	Yes	Yes
Displayed treatment time	Yes	Yes

Any differences in their technological characteristics are explained to demonstrate in this submission that these differences do not raise any new questions of safety and effectiveness.

7. Performance data:

   The *ThermoPro* device has been tested against and complies with the following voluntary standards:

ANSI/AAMI/ISO 10993-1	Biological evaluation of medical devices – Part 1:Evaluation and testing
IEC 60601-1	Medical Electrical Equipment, Part 1
IEC 60601-1-2	Medical Electrical Equipment, Part 1-2, Electromagnetic Compatibility
IEC 60601-1-6	Medical Electrical Equipment, Part 1-6, Usability
IEC 60601-2-3	Medical Electrical Equipment, Part 2-3, Shortwave Therapy Equipment
IEC 62366-1	Medical Devices – Part 1, Application of Usability Engineering to Medical Devices
ISO 62304	Software Development Life Cycle
ISO 14971	Medical devices -- Application of risk management to medical devices

Testing has been performed and all components, subassemblies and/or full devices and systems have met the required specifications for the completed tests.

8. 510(k) Summary:

   Zimmer MedizinSysteme GmbH has demonstrated that the *ThermoPro* device is substantially equivalent to the predicate device listed above.