DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 3, 2016

Omron Healthcare, Inc.
% Paul Dryden
Consultant
Promedic, Inc.
24301 Woodsage Dr.
Bonita Springs, Florida 34134

Re: K160115
Trade/Device Name: Heat Pain Pro
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: May 2, 2016
Received: May 3, 2016

Dear Paul Dryden:

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 yours,

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 on last page.

510(k) Number *(if known)*

K160115

Device Name

Heat Pain Pro

Indications for Use *(Describe)*

The Omron Heat Pain Pro is intended for:

The relief of pain associated with sore or aching, muscles of the lower back, arms, legs, shoulder, or foot due to strain from exercise or normal household work activities.

Environments of Use: Clinics, hospital and home environments

Patient Population: Adult

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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Omron Healthcare, Inc.
1925 West Field Court
Lake Forest, IL 60045 USA

Tel - 847-247-5626
Fax - 847-680-6269

Official Contact: Renee Thornborough – Director QA/RA

Proprietary or Trade Name: Heat Pain Pro

Common/Usual Name: Transcutaneous electrical nerve stimulator for pain relief

Classification Name/Code:

21CFR 882.5890 NUH - stimulator, nerve, transcutaneous, over-the-counter

Device Name: Heat Pain Pro

Predicate Device: K141978 – Omron – PM3032
Reference Device: K070299 – ezFit Technology – ezFit Digital Heating TENS

Device Description:
The Heat Pain Pro is a small battery operated OTC device that provides a combination of transcutaneous electrical nerve stimulation (TENS) for pain relief and superficial heat for a warming sensation. It delivers TENS only or alternating combinations of TENS and heat. TENS and heat are never applied at the same time. The device can connect to a specified external IEC 60601-1 compliant power supply for charging of the internal lithium ion battery. The device complies with AAMI/ ANSI/ES60601-1, IEC 60601-1-2 and IEC 60601-2-10.

Stimulations from the device are intended for application to the following areas: lower back, arms, legs, shoulder or foot. Software controls all controls and indicators. Software controls waveform characteristics.

The accessories include: An external power adaptor, an electrode cord / cable attached to electrodes pads and a Pad holder for storage. The electrode pads Omron “HV-PAD with PMGEL” allow for stimulation and have resistive elements to provide heat which is powered by the device.

The device is battery powered and can be connected to an external power supply for charging the internal battery. The battery is lithium ion and is not user serviceable or accessible. The only external connections on the device are the power input and the electrode connector there is no connection to any other device.

Intended User
OTC

Indications for Use:
The Heat Pain Pro is intended for:
The relief of pain associated with sore or aching, muscles of the lower back, arms, legs, shoulder, or foot due to strain from exercise or normal household work activities.

Environments of Use: Clinics, hospital and home environments
Patient Population: Adult

Contraindications:
Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

Predicate Device Comparison:
The Omron Heat Pain Pro is compared to the predicates in the device comparison tables below.

Table 1 Device Comparison

Feature		**Proposed Omron Heat Pain Pro**	**Predicate Omron PM 3032 K141978**
Indications for Use		The Omron Heat Pain Pro is intended for: The relief of pain associated with sore or aching, muscles of the lower back, arms, legs, shoulder, or foot due to strain from exercise or normal household work activities. Environments of Use: Clinics, hospital and home environments Patient Population: Adult	This device is intended for the relief of pain associated with sore or aching, muscles of the lower back, arms, legs, shoulder or foot due to strain from exercise or normal household and work activities.
Over-the-Counter (OTC)		Yes	Yes
Power Source(s)		External supply Lithium-ion battery	AAA alkaline batteries x 2
- Method of Line Current Isolation		N.A.(internal power source)	N.A.(internal power source)
- Patient Leakage Current		---	---
- Normal Condition (uA)		1	1
- Single Fault Condition (uA)		5.52 max	8.9 max
Average DC current through electrodes when device is on but no pulse are being applied (uA)		0 (uA)	0 (uA)
Number of output Modes		-3 Therapies (2 TENS with HEAT combination therapies and 1 TENS therapy) -9 TENS Stimulation Modes -2 Heat Level Settings	9 TENS output Modes
Number of output channels	Synchronous or Alternating	1 ch	1 ch
	Method of Channel Isolation	None	None
Regulated Current or Regulated Voltage		Regulated Current	Regulated Current
Software/Firmware/Microprocessor Control?		Microprocessor	Microprocessor
Automatic Overload Trip?		No	No
Automatic No-Load Trip?		Yes	Yes
Automatic shut Off?		Yes	Yes
User over ride control?		User activated On/Off	User activated On/Off
Indication display	ON/Off	Yes	Yes

Feature		**Proposed Omron Heat Pain Pro**	**Predicate Omron PM 3032 K141978**
	status?		
	Low Battery?	Yes	Yes
	Voltage / Current Level?	Yes	Yes
Timer Range (minutes)		30	15
Compliance with Voluntary standards?		ES60601-1, IEC60601-1-2, IEC60601-2-10, IEC 60601-1-11 – same as PM3032 – K141978	ES60601-1, IEC60601-1-2, IEC60601-2-10, IEC 60601-1-11
Compliance with 21 CFR 898?		Yes	Yes
Weight		Approx. 200g (incl. batteries)	Approx. 100g (incl. batteries)
Dimensions (W x H x D)		71(W)x165(H)x30.5(D)mm	52(W)x112(H)x25(D)mm
Operating and Storage Temperature, Humidity		Operating Temperature, 10 to 40°C 30 to 80 %RH 700 to 1060 hPa Storage Temperature, 0 to 40°C 30 to 80 %RH 700 to 1060 hPa	10 to 40°C 30 to 80 % RH
Transportation Temperature, Humidity, Air Pressure		-20 to 60°C 10 to 95% RH, 700 to 1060 hPa	-20 to 60°C 10 to 95% RH, 700 to 1060 hPa
Electrode style		PMGEL Reusable	Long Life Pads Reusable
Patient contacting accessory		Electrode	Electrode

Table 2 Comparison to Reference Device - K070299 ezFit

Feature	Proposed Omron Heat Pain Pro	Reference ezFit Technology ezFit - K070299
Indications for Use	The Omron Heat Pain Pro is intended for: The relief of pain associated with sore or aching, muscles of the lower back, arms, legs, shoulder, or foot due to strain from exercise or normal household work activities. Environments of Use: Clinics, hospital and home environments Patient Population: Adult	For Transcutaneous Electrical Nerve Stimulation, ezFit Digital Heating TENS (Model No.: HR-661/ UC-101) is intended for * Symptomatic relief and management of chronic intractable pain. For powered heating therapy, ezFit Digital Heating TENS (Model No.: HR-661/ UC-101) is intended for Temporary relief of minor aches and pains and muscle spasms
Compliance with Voluntary standards?	ES60601-1, IEC60601-1-2, IEC60601-2-10, IEC 60601-1-11	IEC 60601-1, IEC 60601-1-2, ISO 14081
Power Source	AC adaptor / Rechargeable battery (Lithium Ion)	AC adaptor / Rechargeable battery (Ni-H)
Functions	TENS and electrical heating via electrode pad	TENS and electrical heating via electrode pad
TENS Modes	Nine Modes	Not specified
Heating Setting	High and low	Adjustable
Heating temperature	High: 43^{o}C maximum Low: 42^{o}C maximum	36-42^{o}C

Discussion of Substantial Equivalence - Differences Between A Legally Marketed Predicate Device:
The Omron Heat Pain Pro is viewed as substantially equivalent to the predicate device because: The Heat Pain Pro uses the exact same technology and has substantially equivalent indications for use. The differences that exist between the devices are insignificant in the terms of safety or effectiveness.

Indications – These indications are virtually identical to the predicate.

Prescriptive – The Heat Pain Pro and predicate are all OTC.

Design and Technology – The Heat Pain Pro has equivalent design and features when compared to the predicate.

Performance and Specifications – The Heat Pain Pro has equivalent specifications of performance when compared to the predicate.

Compliance with standards –The Heat Pain Pro and predicate comply with the same standards: AAMI ANSI ES60601-1, IEC 60601-1-2, IEC 60601-2-10 and IEC 60601-1-11 for home healthcare.

Materials – The patient contacting materials of the Heat Pain Pro are the PM-GELs. The PM-GELs are constructed of the same materials as the patient contacting portion of the Long Life Pads as cleared in K120516.

Patient Population – The Heat Pain Pro and predicate are indicated for adults

Environment of Use – Clinics, hospital and home environments. Identical to the predicate PM3032

Rationale for Reference Device:
The Omron Heat Pain Pro is combines the ability to provide some surface heat as well as TENS. We selected a reference, ezFit Technology ezFit - K070299, as a reference device as it incorporates heat and TENS through the same basic technology. The differences that exist between the devices are related to heat therapy provided by the reference device vs. heat to provide a warming sensation.

Indications – The indications are similar except the reference device provides heat therapy vs. the subject device provide a warming sensation.

Prescriptive – The Heat Pain Pro is OTC vs. the reference is Rx.

Design and Technology – The basic design of providing heat and TENS via a single electrode is similar.

Performance and Specifications – The Heat Pain Pro has similar maximum delivered heat specifications and TENS stimulation.

As indicated in **Table 2**, one can see that the subject device and reference device are similar and the difference between heat therapy of the reference device and providing a warming sensation for the subject does not raise any new safety concerns. The difference of OTC vs. prescriptive is has been addressed through our risk and hazard analysis and labeling as supported by the usability tested for the lay user population as an OTC device.

Non-Clinical Testing Summary:

The device has been tested to insure that all requirements have been met, this includes:

- Testing of all controls
- Testing of all indicators
- Testing of battery state indicators
- Testing of waveforms

The device has also been tested to the requirements of the following standards:

- AAMI / ANSI ES60601-1:2005 + A1: 2012 Medical electrical equipment - part 1: general requirements for basic safety and essential performance
- IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-1-11: 2015, medical electrical equipment - part 1-11: general requirements for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-2-10: 2012 Medical electrical equipment - part 2-10: particular requirements for the basic safety and essential performance of nerve and muscle stimulators

The device has also been tested for drop, vibration and environmental temperature and humidity.

Usability testing was performed.

Clinical Testing Summary:
No clinical testing was performed

Substantial Equivalence Conclusion
Omron maintains that the Heat Pain Pro is substantially equivalent to the predicate device in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards.

Parameter		Subject	PM3032	Subject	PM3032	Subject	PM3032	Subject	PM3032
Mode of Program Name		TAP	TAP	KNEAD	KNEAD	RUB	RUB	ARM	ARM
Waveform		Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage [V]	@500Ω	67.2	66.3	40.7	51.1	37.3	42.3	67.1	66.3
	@2kΩ	85.6	87.6	56.6	67.9	51.2	55.9	86.0	87.9
	@10kΩ	95.9	95.9	62.4	73.9	56.7	59.9	95.7	95.9
Maximum Output Current [mA]	@500Ω	134.4	132.6	81.4	102.2	74.6	84.6	134.2	132.6
	@2kΩ	42.8	43.8	28.3	34.0	25.6	28.0	45.0	44.0
	@10kΩ	9.6	9.6	6.2	7.4	5.7	6.0	9.6	9.6
Duration of primary phase [µsec]		32	32	32	32	32	32	32	32
Pulse Duration [µsec]		96	100	96	150	96	150	96	100
Frequency [Hz]		1 - 20.13	1 - 15.43	51.65	25.28 - 79.22	99	84.86 - 132	2 - 51.65	1 - 132
For multiphasic waveforms only:	Symmetrical phases	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Phase Duration	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Net Charge(µC per pulse) (@500Ω) [uC] *		0	0	0	0	0	0	0	0
Maximum Phase Charge (@500Ω) [µC]		4.30	4.24	2.60	3.27	2.39	2.71	4.29	4.24
Maximum Current Density (@500Ω) [mA/cm^2]		8.43	3.03	5.10	2.33	4.68	1.93	8.41	3.03
Maximum Current Density (@500Ω) [mA/cm2] r.m.s.		0.08	0.03	0.36	0.14	0.46	0.22	0.12	0.03
Maximum Average Power Density (@500Ω) [W/cm^2]		5.219E-09	0.00017	5.107E-06	0.00020	1.576E-05	0.00039	2.081E-08	0.00060
Burst Mode	(a) Pulses per burst	60.4	46	222.1	71	544.5	118	60.4	23
	(b) Bursts per second	0.32	0.33	0.12	0.59	0.09	0.59	0.32	1.00
	**(c) Burst duration	3.10	3.00	8.60	8.50	11.00	17.00	3.10	8.00
	(d) Duty cycle: Line(b)xLine(c)	1.00	1.00	1.00	5.00	1.00	10.00	1.00	8.00
ON Time (seconds)		3.00	3.00	7.80	0.90	10.50	0.90	3.00	0.30
OFF Time (seconds)		0.10	0.00	0.80	0.80	0.50	0.80	0.10	0.70
Additional Features		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Subject device is Heat Pain Pro

Parameter		Subject	PM3032	Subecjt	PM3032	Subject	PM3032	Subject	PM3032	Subject	PM3032
Mode of Program Name		LBACK	LBACK	LEG	LEG	FOOT	FOOT	JOINT	JOINT	SHLDR	SHLDR
Waveform		Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage [V]	@500Ω	67.1	66.3	66.4	66.3	66.9	66.3	40.3	66.3	67.1	66.3
	@2kΩ	84.0	87.9	85.5	87.9	85.9	87.9	56.8	87.9	84.8	87.9
	@10kΩ	94.0	95.9	95.5	95.9	95.8	95.9	63.1	95.9	95.4	95.9
Maximum Output Current [mA]	@500Ω	134.2	132.6	132.8	132.6	133.8	132.6	80.6	132.6	134.2	132.6
	@2kΩ	42.0	44.0	42.8	44.0	43.0	44.0	28.4	44.0	42.4	44.0
	@10kΩ	9.4	9.6	9.6	9.6	9.6	9.6	6.3	9.6	9.5	9.6
Duration of primary phase [µsec]		32	32	32	32	32	32	32	32	32	32
Pulse Duration [µsec]		96	150	96	100	96	100	96	100	96	100
Frequency [Hz]		2 - 108	1 - 237.6	2 - 51.65	1 - 19.16	2 -11	1 - 19.16	42.43 - 108	42.43 - 237.6	1 - 19	1 - 19.16
For multiphasic waveforms only:	Symmetrical phases	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Phase Duration	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Net Charge(µC per pulse) (@500Ω) [uC] *		0	0	0	0	0	0	0	0	0	0
Maximum Phase Charge (@500Ω) [µC]		4.29	4.24	4.25	4.24	4.28	4.24	2.58	4.24	4.29	4.24
Maximum Current Density (@500Ω) [mA/cm^2]		8.41	3.03	8.33	3.03	8.39	3.03	5.05	3.03	8.41	3.03
Maximum Current Density (@500Ω) [mA/cm2] r.m.s.		0.12	0.04	0.12	0.03	0.12	0.03	0.32	0.20	0.08	0.03
Maximum Average Power Density (@500Ω) [W/cm^2]		2.081E-08	0.00015	2.038E-08	0.00040	2.069E-08	0.00016	3.379E-06	0.00015	5.203E-09	0.00082
Burst Mode	(a) Pulses per burst	540.0	1425	258.3	57	55.0	57	324.0	1425	76.0	76
	(b) Bursts per second	0.10	0.14	0.10	0.25	0.19	0.25	0.25	0.14	0.20	0.20
	**(c) Burst duration	20.00	14.00	10.00	8.00	5.20	8.00	16.00	14.00	10.00	10.00
	(d) Duty cycle: Line(b)xLine(c)	2.00	2.00	1.00	2.00	1.01	2.00	4.00	2.00	2.00	2.00
ON Time (seconds)		20.00	6.00	9.00	3.00	5.00	3.00	11.00	6.00	8.00	4.00
OFF Time (seconds)		0.00	1.00	1.00	1.00	0.15	1.00	4.00	1.00	2.00	1.00
Additional Features		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Subject device is the Heat Pain Pro