October 19, 2017

Omron Healthcare, Inc.
% Ronald Warren
Senior Director, Regulatory Affairs
Experien Group
224 Airport Parkway, Suite 250
San Jose, California 95110

Re: K172079
Trade/Device Name: Avail, Model PM601
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: July 7, 2017
Received: July 10, 2017

Dear Ronald Warren:

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 (DICE) 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 (DICE) 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,

William J. Heetderks -S
2017.10.19 18:10:10 -04'00'

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)*
K172079

Device Name
Avail Model PM601

Indications for Use *(Describe)*
The Avail is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, legs, shoulders or feet due to strain from exercise or normal household work activities.

When used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis, use the Tap, Shoulder, Arm or Leg mode of stimulation.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Notification K172079

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Contact Person:

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USA
Phone: 408-505-3926
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Date Prepared: October 19, 2017

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

Avail™ (Model PM601)

Generic/Common Name:

Transcutaneous Electrical Nerve Stimulator for Pain Relief

Classification:

Class II per 21CFR882.5890

Product Code:

NUH and NYN

PREDICATE DEVICE(S) [807.92(a)(3)]

The Omron Avail™ (Model PM601) TENS device ("Avail") is substantially equivalent to the primary predicate device, the Philips Consumer Lifestyle PulseRelief (K151035) TENS, with regard to product labeling, intended use, anatomical sites, patient population, performance testing, technological characteristics and safety characteristics. In addition, the Avail device is similar to two other devices (i.e. reference devices), the Chattem, Inc. SmartRelief (K131159) TENS and the Omron Heat Pain Pro (K160115) with regard to indications for use and TENS function. The Avail is also similar to the Painmaster MCT Patch (K130114) with respect to delivery of microcurrent (low-level electrical stimulation).

DEVICE DESCRIPTION [807.92(a)(4)]

The Avail device is a wireless, independent dual channel wearable electrotherapy device that is designed to alleviate chronic muscle and joint pain on multiple body locations. It delivers TENS (Transcutaneous Electrical Nerve Stimulation) technology and microcurrent therapy through the simple, convenient use of the dedicated Omron TENS iOS or Android App. Reusable, self-adhesive, contouring pads allow for discreet and convenient placement on multiple pain locations on the body. The Avail system can be programmed to deliver nine different TENS modes and a microcurrent therapy mode.

The system contains two main TENS units which are rechargeable and each can be attached to either a medium or large size gel pad. The pad with attached TENS unit can then be applied to intact skin at the desired location for therapy and pain relief. Control of the Avail TENS system is completed through the available Omron TENS App. The Avail will be packaged with an Instruction Manual which provides details on setting up the device for use, installing of the Omron TENS App, setting and controlling therapy modes, and troubleshooting. The system includes two main TENS units, medium and large pads, an AC-powered charger, AC adapter, a pad holder and storage case.

INDICATIONS FOR USE [807.92(a)(5)]

The Avail is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, legs, shoulders or feet due to strain from exercise or normal household work activities.

When used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis, use the Tap, Shoulder, Arm or Leg mode of stimulation.

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

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]

In regard to technological characteristics, the Avail device is similar to the predicate and reference TENS devices. Like the predicate PulseRelief device, Avail device is paired

and controlled by a dedicated smartphone App. The mode, treatment duration and intensity can only be controlled by the App. However, both proposed and predicate devices can be turned off by pressing the on/off button on the main unit or button on App.

The Avail device offers nine different TENS treatment modes and a microcurrent mode, whereas the PulseRelief offers fifteen TENS treatment modes and five EMS (electrical muscle stimulation modes. Seven of the nine Avail waveforms are the same as the modes for the Heat Pain Pro reference device. The Avail device also offers a microcurrent mode, which is a minor technological difference as compared to the primary predicate device. The Avail device also offers a microcurrent mode, which is a minor technological difference as compared to the primary predicate device. To address this difference, reference is made to the Painmaster MCT Patch (K130114) which uses a microcurrent low-level electrical stimulation and shares the same regulation number (21 CFR 882.5890) and product code (NUH) as the proposed Avail device. The microcurrent mode is considered a very low current TENS (rectangular biphasic waveform) delivered at a very low frequency. A comparison of the Avail waveforms to the primary predicate and reference devices was included in this 510(k) submission.

In addition, the Avail offers certain TENS modes for treatment of arthritis pain. As specified in the proposed indications for use statement, Chronic intractable pain and arthritis pain can be treated with Avail using the Tap, Shoulder, Arm or Leg Mode. This intended use is the same as the SmartRelief reference device. Although the Avail waveforms are different from the single waveform of the SmartRelief device, the electrical parameters of both are quite similar. This is due to the presence of:

- High frequency (50+) Hz for chronic pain that requires non-contracting stimulation modes for a comfortable smoother therapy for chronic pain therapy
- Modulation via different pulse trains to prevent muscle accommodation for both chronic pain and arthritis
- Variation of both high and low rate pulses within the mode to address both muscle and joint pain from arthritis and various chronic pain

A detailed comparison of the Avail waveforms to the SmartRelief waveform in the context of treatment of arthritis pain was provided in this submission.

In regard to other technological characteristics, summary tables of output parameters for the Avail, predicate and reference devices were also provided in this submission. In general, the Avail output parameters fall within the range of output parameters for PulseRelief. For example, the maximum current density (mA/cm^2) range for Avail is 0.0008 ~ 0.17, while the PulseRelief range is 0.12 ~ 0.44. This range is also well below the IEC60601-2-10:2012 (Clause 201.4.2) limit of less than $2mA/cm^2$. The maximum average power density (W/cm^2) range is $1.4x10^{-8}$ ~ $6.8x10^{-4}$ for Avail, whereas the PulseRelief maximum average power density range is $1.9x10^{-4}$ ~ $2.36x10^{-3}$.

In regard to treatment duration, the instructions for use of the PulseRelief provide no specified time duration for six treatment modes (Conventional, Thorough stimulus, Pre-activity, Soft stimulus, Deep stimulus, Radiating pulse). For Avail, the selectable time duration for TENS therapy is 5 to 60 minutes (in 5 minute increments). The selectable time duration for Microcurrent therapy is 30 to 180 minutes (in 30 minute increments).

The labeling of the Painmaster MCT Patch for microcurrent therapy indicates the device can be used continuously for up to 300 hours. Thus, the PulseRelief has higher current density, power density and longer recommended treatment time ranges compared to Avail. In this regard, Avail should be considered at least as safe as the PulseRelief, while offering similar TENS modes for pain therapy. Further, the Avail microcurrent recommended therapy durations falls within the range recommended for the Painmaster MCT Patch.

SUBSTANTIAL EQUIVALENCE

The proposed device, predicate device and reference devices are all intended for use as transcutaneous electrical nerve stimulation in adult populations for use in clinic, hospital or home settings. Omron has completed comprehensive design verification testing, electrical safety and electromagnetic compatibility testing, software verification and validation, and usability testing to ensure that the Avail device performs as intended. The Avail also passed testing requirements for electrical safety and EMC, and the device patient-contacting were tested to demonstrate biocompatibility. The minor differences in labeling and technological characteristics between the proposed device and the predicate device have been evaluated and determined to not raise different questions of safety or effectiveness. As such, the proposed Avail is substantially equivalent to the predicate device. A comparison table summarizing the specifications and features of the proposed Avail device, the predicate and reference devices is included in the Substantial Equivalence Table (Table 1) below.

In regard to other technological characteristics, summary tables (Tables 2, 3, 4 and 5) of output parameters for the Avail, predicate and reference devices are provided below.

PERFORMANCE DATA [807.92(b)]

All necessary non-clinical and usability testing was conducted on the Avail to confirm that the device performs as intended.

Nonclinical Testing Summary:

The nonclinical, bench testing included:

- Performance verification to confirm acceptable performance of device features and functions
- Usability testing with a representative population of study participants in a simulated home use environment

Other nonclinical safety testing included:

- Biocompatibility of patient-contacting materials per ISO 10993-1 requirements
- Electrical safety and electromagnetic compatibility testing
- Software verification and validation

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the Avail meet the established specifications

necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the Avail does not raise different questions of safety or effectiveness for TENS therapy when compared to the predicate devices.

Clinical Testing Summary:

Not applicable. Clinical testing was not performed to support this 510(k) submission.

CONCLUSIONS [807.92(b)(3)]

Based on the results from the nonclinical and usability tests performed in support of Avail, it is concluded that that the proposed device is safe, is effective, and performs at least as safely and effectively as the legally marketed predicate device.

SUMMARY

The proposed device, predicate device and reference devices are all intended for use as transcutaneous electrical nerve stimulation in adult populations for use in clinic, hospital or home settings. Omron has completed comprehensive design verification testing, electrical safety and electromagnetic compatibility testing, software verification and validation, and usability testing to ensure that the Avail device performs as intended. The Avail also passed testing requirements for electrical safety and EMC, and the device patient-contacting components were tested to demonstrate biocompatibility. The minor differences in labeling and technological characteristics between the proposed device and the predicate device have been evaluated and determined to not raise different questions of safety or effectiveness. As such, the proposed Avail is substantially equivalent to the predicate device.

Table 1. Substantial Equivalence Summary

Feature	Proposed Device Omron Avail Wireless Dual Channel TENS PM601	For TENS Function			For Microcurrent	Analysis of Technological Differences
		Primary Predicate Device Philips PulseRelief (K151035)	Reference Device SmartRelief (K131159)	Reference Device Omron Heat Pain Pro (K160115)	Reference Device Painmaster MCT Patch (K130114)	
Classification-Regulation	21 CFR§882.5890, Transcutaneous electrical nerve stimulator for pain relief	21 CFR§882.5890, Transcutaneous electrical nerve stimulator for pain relief	21 CFR§882.5890, Transcutaneous electrical nerve stimulator for pain relief	21 CFR§882.5890, Transcutaneous electrical nerve stimulator for pain relief	21 CFR§882.5890, Transcutaneous electrical nerve stimulator for pain relief	No difference. Proposed device and predicate devices have the same medical device classification number.
Classification-Product Code	Primary: NUH - Transcutaneous electrical nerve stimulator for pain relief Secondary: NYN-Transcutaneous electrical nerve stimulator for pain relief.	Primary: NUH - Transcutaneous electrical nerve stimulator for pain relief Secondary: NGX - Stimulator, Muscle, Powered, For Muscle Conditioning	Primary: NUH - Transcutaneous electrical nerve stimulator for pain relief Secondary: NYN-Transcutaneous electrical nerve stimulator for pain relief.	NUH - Transcutaneous electrical nerve stimulator for pain relief	NUH - Transcutaneous electrical nerve stimulator for pain relief	No difference. Proposed device and predicate devices have the same medical device product code.
Indications for Use	The Avail is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, legs, shoulders or feet due to strain from exercise or normal household work activities. When used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with	The OTC TENS/EMS stimulator PulseRelief is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or	To be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities. To be used for symptomatic relief and management of chronic, intractable pain and relief of pain associated	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:	The Painmaster MCT Patch is indicated for temporary relief of pain associated with sore and aching muscles in upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.	Similar to PulseRelief and Heat Pain Pro for temporary relief of pain with sore and aching muscles. Similar to SmartRelief with respect to symptomatic relief and management of chronic, intractable pain, and relief of pain associated with arthritis.

Feature	Proposed Device Omron Avail Wireless Dual Channel TENS PM601	For TENS Function			For Microcurrent	Analysis of Technological Differences
		Primary Predicate Device Philips PulseRelief (K151035)	Reference Device SmartRelief (K131159)	Reference Device Omron Heat Pain Pro (K160115)	Reference Device Painmaster MCT Patch (K130114)	
	arthritis, choose Tap, Shoulder, Arm or Leg mode. Environments of Use: Clinics, hospital and home environments Patient Population: Adult	normal household work activities. It should be applied to normal, healthy, dry and clean skin of adult patients, and is to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	with arthritis.	Adult		
Environment of Use	Clinics, hospitals and home environments	Home	Unknown	Clinics, hospital and home environments	Home	Same as Heat Pain Pro, SmartRelief and Painmaster
Patient Population	Adults	Adults	Adults	Adults	Over 12 years of age, unless under physician supervision	Predicate device intended for same population. Painmaster indicated for over 12 years of age, unless physician supervised.

Feature	Proposed Device Omron Avail Wireless Dual Channel TENS PM601	For TENS Function			For Microcurrent	Analysis of Technological Differences
		Primary Predicate Device Philips PulseRelief (K151035)	Reference Device SmartRelief (K131159)	Reference Device Omron Heat Pain Pro (K160115)	Reference Device Painmaster MCT Patch (K130114)	
Contraindications/ Warnings/ Precautions	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.	Contraindications Do not use this device with the following medical devices: -- Implanted electronic medical devices, such as pacemakers. This may cause electric shock, burns, or death. -- Electronic life support equipment, such as respirators. -- Electronic medical devices worn on the body, such as electrocardiographs. If you use this device together with other electronic medical devices, these devices may not work correctly.	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.	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.	Contraindications Do not use with pacemakers or anyone using transdermal drug delivery Do not place patches along neck Do not place patches in a way that causes flow of current through head	Contraindications are similar for all devices.

Feature	Proposed Device Omron Avail Wireless Dual Channel TENS PM601	For TENS Function			For Microcurrent	Analysis of Technological Differences
		Primary Predicate Device Philips PulseRelief (K151035)	Reference Device SmartRelief (K131159)	Reference Device Omron Heat Pain Pro (K160115)	Reference Device Painmaster MCT Patch (K130114)	
Single Use	Patient-contacting Pads are for single patient use	Patient-contacting electrodes are for single patient use	Unknown	Pads are for single patient use	Pads should only be used by one person	No difference. Proposed and predicate TENS devices are durable medical equipment intended for multiple uses. Patient-contacting components are for use by a single adult patient.
Sterility	External contacting device, nonsterile	Unknown	Unknown	External contacting device, nonsterile	Unknown	No difference. Proposed and predicate device are provided nonsterile.
Specification/Features						
Over-the-Counter (OTC)	Yes	Yes	Yes	Yes	Yes	No difference
Power Source(s)	Rechargeable Lithium-ion battery	Rechargeable Lithium-ion battery	3V CR2032 lithium battery	Rechargeable Lithium-ion battery	Primary battery only. One-time use.	Same battery type as Heat Pain Pro and PulseRelief
Method of Line Current Isolation	N/A (internal power source)	N/A	N/A	N/A (internal power source)	N/A	No difference
Patient Leakage Current:	---	---	---	---	---	---
-Normal Condition (uA)	<10uA	<10uA	Unknown	1	Unspecified	Same as PulseRelief
-Single Fault Condition (uA)	<50uA	<50uA	Unknown	5.52 max	Unspecified	Same as PulseRelief

Feature	Proposed Device Omron Avail Wireless Dual Channel TENS PM601	For TENS Function			For Microcurrent	Analysis of Technological Differences
		Primary Predicate Device Philips PulseRelief (K151035)	Reference Device SmartRelief (K131159)	Reference Device Omron Heat Pain Pro (K160115)	Reference Device Painmaster MCT Patch (K130114)	
Average DC current through electrodes when device is on but no pulse are being applied (uA)	0	0	0	0	0	No difference
Number of output Modes	9 TENS modes 1 Microcurrent mode	15 TENS 5 EMS	1 mode	-3 Therapies (2 TENS with HEAT combination therapies and 1 TENS therapy) -9 TENS Stimulation Modes -2 Heat Level Settings	1 (Microcurrent)	Similar Minor difference of the number of mode does not affect safety and effectiveness of use.
Number of output channels						
Synchronous or Alternating	1ch	1ch	1ch	1ch	1ch, monophasic	No difference
Method of Channel Isolation	None	None	None	None	N/A	No difference
Regulated Current or Regulated Voltage	Regulated Current	Regulated Current	Unknown	Regulated Current	Regulated Current	Same as Heat Pain Pro and PulseRelief
Software/Firmware/ Microprocessor Control?	Microprocessor	Microprocessor	Microprocessor	Microprocessor	Yes	No difference
Automatic Overload Trip?	No	Yes	Unknown	No	No	Same as Heat Pain Pro

Feature	Proposed Device Omron Avail Wireless Dual Channel TENS PM601	For TENS Function			For Microcurrent	Analysis of Technological Differences
		Primary Predicate Device Philips PulseRelief (K151035)	Reference Device SmartRelief (K131159)	Reference Device Omron Heat Pain Pro (K160115)	Reference Device Painmaster MCT Patch (K130114)	
Automatic No-Load Trip?	Yes	Yes	Unknown	Yes	Yes	Same as Heat Pain Pro and PulseRelief
Automatic shut Off?	Yes	Yes	Yes	Yes	Yes	No difference
User over ride control?	Yes, Power On/Off button on the device and in the App software	Yes, Power On/Off button on the device and in the App software	Yes, Power On/Off button	Yes, Power On/Off button	No	Same as PulseRelief
Indication display						
On/Off Status?	Yes on App and LED indicator on main unit	Yes on App and LED indicator on main unit	Yes	Yes	Yes	Same as PulseRelief
Low Battery?	Yes on App	Yes on App	No	Yes	No	Same as PulseRelief
Voltage/Current Level?	Yes on App	Yes on App	Yes	Yes	No	Same as PulseRelief
Timer Range (Minutes)	5-60minutes and 30-180minutes	1-59minutes and continuous	30 minutes, fixed	30 minutes	Not adjustable. Up to 300 hours	Similar to PulseRelief
Compliance with Voluntary standards?	ES 60601-1, IEC60601-1-2, IEC60601-2-10, IEC 60601-1-11	ES 60601-1, IEC60601-1-2, IEC60601-2-10, ISO10993-5/10	EN 60601-1, EN60601-1-2	ES60601-1, IEC60601-1-2, IEC60601-2-10, IEC 60601-1-11	Yes, UL260, EN60601-2 Part1 A1 & A2, EN 60601-2-10 Part 2-10, EN60601-1-2 EMI	Same as Heat Pain Pro
Compliance with 21 CFR898?	N/A (no patient cable)	Yes	Unknown	Yes	N/A	Similar structure to SmartRelief

Feature	Proposed Device Omron Avail Wireless Dual Channel TENS PM601	For TENS Function			For Microcurrent	Analysis of Technological Differences
		Primary Predicate Device Philips PulseRelief (K151035)	Reference Device SmartRelief (K131159)	Reference Device Omron Heat Pain Pro (K160115)	Reference Device Painmaster MCT Patch (K130114)	
Weight	Device: Approx. 42 g (Both units have same weight) Pad-L: Approx. 21 g Pad-M: Approx. 17.5 g Charger: Approx. 100 g	62g (excludes electrodes)	20g	Approx. 200g (incl. batteries)	0.03lb. (14g)	Similar Difference does not affect safety and effectiveness of use.
Dimensions (W x H x D)	Device: Approx. 60 × 72 × 15.5mm (Both units have same dimensions) Charger: Approx. 158 x 90 x 20.5mm Pad-L: Approx. 219 × 83.5 × 9.3mm Pad-M: Approx. 180 × 79.5 × 9.3mm	2 units, each 54 x 54 x 14mm (excludes electrodes)	64 × 38 × 13mm	71 x 165 x 30.5mm	1.55" x 0.29" x 1" (39.4mm x 7.4mm x 25.4mm)	Similar Difference does not affect safety and effectiveness of use.
Operating conditions	10 to 40 °C 30 to 80 %RH 700 to 1060 hPa (non-condensing)	5 to 40 °C 15 to 93 %RH 700 to 1060 hPa (non-condensing)	10 to 40°C 30 to 75% RH 500 to 1060 hPa	10 to 40 °C 30 to 80 %RH 700 to 1060 hPa (non-condensing)	10-45 °C, 20%-90%	Same as Heat Pain Pro
Charging conditions	5 to 35 °C (non-condensing)	5 to 40 °C 15 to 93 %RH 700 to 1060 hPa (non-condensing)	10 to 40°C 30 to 75% RH 500 to 1060 hPa	5 to 35 °C (non-condensing)	N/A	Same as Heat Pain Pro
Storage conditions	0 to 40 °C 30 to 80 % RH (non-condensing)	0 to 40 °C(electrodes) and -10 to 50°C(device) less than 93% RH (non-condensing) 700 to 1060 hPa	-40 to 70°C 10 to 90% RH 500 to 1060 hPa	0 to 40oC 30 to 80 %RH 700 to 1060 hPa (non-condensing)	Store patches at room temperature in a dry place.	Same as Heat Pain Pro

Feature	**Proposed Device Omron Avail Wireless Dual Channel TENS PM601**	**For TENS Function**			**For Microcurrent**	**Analysis of Technological Differences**
		Primary Predicate Device Philips PulseRelief (K151035)	**Reference Device SmartRelief (K131159)**	**Reference Device Omron Heat Pain Pro (K160115)**	**Reference Device Painmaster MCT Patch (K130114)**	
Transporting conditions	-20 to 60 °C 10 to 90 % RH (non-condensing)	0 to 40 °C (electrodes) and -10 to 50°C (device) less than 93% RH (non-condensing) 700 to 1060 hPa	-40 to 70°C 10 to 90% RH 500 to 1060 hPa	-20 to 60oC 10 to 95% RH, 700 to 1060 hPa (non-condensing)	Unknown	Similar Difference does not affect safety and effectiveness of use.
Electrode style	HV-WPAD-M or HV-WPAD-L Reusable	Philips Self-Adhesive Electrode Reusable	Self-Adhesive Electrode Reusable	PMGEL Reusable	CE Certified Attached to reusable pads	Similar to PulseRelief and SmartRelief
Patient Contact Accessory	Yes	Yes	Yes	Yes	Yes	No difference

Table 2. Output Comparison for Avail

Parameter		PM601									
Mode of Program Name		Steady	AcupunctureLike	Knead	Tap	Lower Back	Shoulder	Joint	Leg	Arm	Microcurrent
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	25.9	38.4	27.9	38.3	38.2	38.4	25.6	36.7	38.2	0.025
	@2kΩ	45.2	50.8	37.2	50.3	50.4	50.4	35.7	49.5	50.4	0.100
	@10kΩ	59.9	55.2	40.7	54.9	55.8	55.8	39.2	54.6	55.2	0.500
Maximum Output Current [mA]	@500Ω	51.8	76.8	55.8	76.6	76.4	76.8	51.2	73.4	76.4	0.050
	@2kΩ	22.6	25.4	18.6	25.2	25.2	25.2	17.9	24.8	25.2	0.050
	@10kΩ	6.0	5.5	4.1	5.5	5.6	5.6	3.9	5.5	5.5	0.050
Duration of primary phase [µsec]		96	96	96	96	96	96	96	96	96	2500000
Pulse Duration [µsec]		96	96	96	96	96	96	96	96	96	2500000
Frequency [Hz]		99	2	51.65	1-20.13	2-108	1-19	42.43-108	2-51.65	2-51.65	0.2
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]		4.97	7.37	5.36	7.35	7.33	7.37	4.92	7.05	7.33	125.00
Maximum Current Density (@500Ω) [mA/cm2] r.m.s.		0.16	0.03	0.09	0.11	0.17	0.10	0.12	0.12	0.12	0.0008
Maximum Average Current (average absolute value), mA		0.98	0.03	0.28	0.30	0.79	0.28	0.53	0.36	0.38	0.03
Maximum Average Power Density (@500Ω) [W/cm^2]		5.705E-04	2.533E-05	1.727E-04	2.537E-04	6.769E-04	2.407E-04	3.040E-04	2.988E-04	3.237E-04	1.398E-08
Burst Mode	(a) Pulses per burst	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	(b) Bursts per second	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	(c) Burst duration	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	(d) Duty cycle: Line(b)xLine(c)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ON Time (seconds)		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OFF Time (seconds)		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Additional Features		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Table 3. Output Comparison for PulseRelief (K151035)

Parameter		Philips PulseRelief K151035														
Mode of Program Name		Conventional	Thorough Stimulus	Pre-Activity	Soft Stimulus	Deep Stimulus	Radiating Pulse	Continuous Burst	Slow Kneading	Mild Kneading	Deep Kneading	Diffuse Burst	Mixed Frequency	Pulsing Massage	Deep Massage	Gentle Massage
Waveform		Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage [V]	@500Ω	35.9	35.9	36.0	36.0	36.0	36.0	35.8	35.4	35.2	35.6	35.9	35.9	35.9	36.4	36.0
	@2kΩ	74.4	73.9	74.4	74.3	74.8	74.3	73.6	74.3	73.8	74.2	74.2	74.4	74.1	74.2	74.3
	@10kΩ	76.0	75.8	76.0	76.5	76.0	76.0	75.8	75.7	75.9	75.8	76.0	76.7	75.9	76.0	76.0
Maximum Output Current [mA]	@500Ω	71.8	71.8	72.0	72.0	72.0	72.0	71.6	70.8	70.4	71.2	71.8	71.8	71.8	72.8	72.0
	@2kΩ	37.2	37.0	37.2	37.2	37.4	37.2	36.8	37.2	36.9	37.1	37.1	37.2	37.1	37.1	37.2
	@10kΩ	7.6	7.6	7.6	7.7	7.6	7.6	7.6	7.6	7.6	7.6	7.6	7.7	7.6	7.6	7.6
Duration of primary phase [µsec]		96	96	54	30	54	54	115	94	94	54	86	115	115	86	54
Pulse Duration [µsec]		96	96	54	30	54	54	115	94	94	54	86	115	115	86	54
Frequency [Hz]		100	40	100	80	80	60	100	80	80	80	80	8-100	2-8	2-80	8-80
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	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	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	0	0	0	0	0
Maximum Phase Charge (@500Ω) [µC]		6.89	6.89	3.89	2.16	3.89	3.89	8.23	6.66	6.62	3.84	6.17	8.26	8.26	6.26	3.89
Maximum Current Density (@500Ω) [mA/cm2] r.m.s.		0.40	0.25	0.30	0.20	0.27	0.23	0.43	0.35	0.35	0.26	0.34	0.44	0.12	0.34	0.27
Maximum Average Current (average absolute value), mA		1.38	0.55	0.78	0.35	0.62	0.47	1.65	1.06	1.06	0.62	0.99	1.65	0.13	1.00	0.62
Maximum Average Power Density (@500Ω) [W/cm^2]		1.980E-03	7.918E-04	1.120E-03	4.977E-04	8.958E-04	6.718E-04	2.358E-03	1.508E-03	1.491E-03	8.760E-04	1.419E-03	2.371E-03	1.897E-04	1.459E-03	8.958E-04
Burst Mode	(a) Pulses per burst	N/A	N/A	N/A	N/A	N/A	N/A	7	5	5	7	7	N/A	N/A	N/A	N/A
	(b) Bursts per second	N/A	N/A	N/A	N/A	N/A	N/A	2.00	1.00	3.00	2.00	2.00	N/A	N/A	N/A	N/A
	(c) Burst duration	N/A	N/A	N/A	N/A	N/A	N/A	0.06	0.05	0.05	0.08	0.08	N/A	N/A	N/A	N/A
	(d) Duty cycle: Line(b)xLine(c)	N/A	N/A	N/A	N/A	N/A	N/A	0.12	0.05	0.15	0.15	0.15	N/A	N/A	N/A	N/A
ON Time (seconds)		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OFF Time (seconds)		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Additional Features		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Table 4. Output Comparison for SmartRelief (K131159) and Heat Pain Pro (K160115)

Parameter		Smart Relief K131159	Heat Pain Pro (PM311) K160115								
Mode of Program Name		Smart Rerief 1.0	TAP	KNEAD	RUB	ARM	LBACK	LEG	FOOT	JOINT	SHLDR
Waveform		Asymmetrical Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape		Rectangular - Pulse	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage [V]	@500Ω	33.6	67.2	40.7	37.3	67.1	67.1	66.4	66.9	40.3	67.1
	@2kΩ	64.7	85.6	56.6	51.2	86.0	84.0	85.5	85.9	56.8	84.8
	@10kΩ	69.6	95.9	62.4	56.7	95.7	94.0	95.5	95.8	63.1	95.4
Maximum Output Current [mA]	@500Ω	67.2	134.4	81.4	74.6	134.2	134.2	132.8	133.8	80.6	134.2
	@2kΩ	32.4	42.8	28.3	25.6	45.0	42.0	42.8	43.0	28.4	42.4
	@10kΩ	7.0	9.6	6.2	5.7	9.6	9.4	9.6	9.6	6.3	9.5
Duration of primary phase [µsec]		32	32	32	32	32	32	32	32	32	32
Pulse Duration [µsec]		224	96	96	96	96	96	96	96	96	96
Frequency [Hz]		2.5-99.4	1 - 20.13	51.65	99	2 - 51.65	2 - 108	2 - 51.65	2 -11	42.43 - 108	1 - 19
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]		2.15	4.30	2.60	2.39	4.29	4.29	4.25	4.28	2.58	4.29
Maximum Current Density (@500Ω) [mA/cm2] r.m.s.		0.19	0.08	0.36	0.46	0.12	0.12	0.12	0.12	0.32	0.08
Maximum Average Current (average absolute value), mA		0.21	0.01	0.40	0.71	0.03	0.03	0.03	0.03	0.16	0.01
Maximum Average Power Density (@500Ω) [W/cm^2]		3.552E-04	5.219E-09	5.107E-06	1.576E-05	2.081E-08	2.081E-08	2.038E-08	2.069E-08	3.379E-06	5.203E-09
Burst Mode	(a) Pulses per burst	20	60.4	222.1	544.5	60.4	540.0	258.3	55.0	324.0	76.0
	(b) Bursts per second	5.00	0.32	0.12	0.09	0.32	0.10	0.10	0.19	0.25	0.20
	(c) Burst duration	0.20	3.10	8.60	11.00	3.10	20.00	10.00	5.20	16.00	10.00
	(d) Duty cycle: Line(b)xLine(c)	1.00	1.00	1.00	1.00	1.00	2.00	1.00	1.01	4.00	2.00
ON Time (seconds)		0.20	3.00	7.80	10.50	3.00	20.00	9.00	5.00	11.00	8.00
OFF Time (seconds)		0.00	0.10	0.80	0.50	0.10	0.00	1.00	0.15	4.00	2.00
Additional Features		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

TABLE 5. OUTPUT COMPARISON (MICROCURRENT) FOR PAINMASTER MCT PATCH (K130114)

Parameter		PM601 K172079	Painmaster MCT K130114
Mode of Program Name		Microcurrent	Microcurrent
Waveform		Biphasic	Monophasic
Shape		Rectangular	Rectangular
Maximum Output Voltage [V]	@500Ω	0.025	0.022
	@2kΩ	0.100	0.084
	@10kΩ	0.500	0.370
Maximum Output Current [mA]	@500Ω	0.050	0.044
	@2kΩ	0.050	0.042
	@10kΩ	0.050	0.037
Duration of primary phase [µsec]		2500000	1130000
Pulse Duration [µsec]		2500000	1130000
Frequency [Hz]		0.2	0.63
For multiphasic waveforms only:	Symmetrical phases	N/A	N/A
	Phase Duration	N/A	N/A
Net Charge(µC per pulse) (@500Ω) [uC]		0	49.72
Maximum Phase Charge (@500Ω) [µC]		125.00	49.72
Maximum Current Density (@500Ω) [mA/cm2] r.m.s.		0.0008	0.0015
Maximum Average Current (average absolute value), mA		0.025	0.031
Maximum Average Power Density (@500Ω) [W/cm^2]		1.398E-08	2.871E-08
Burst Mode	(a) Pulses per burst	N/A	N/A
	(b) Bursts per second	N/A	N/A
	(c) Burst duration	N/A	N/A
	(d) Duty cycle: Line(b)xLine(c)	N/A	N/A
ON Time (seconds)		N/A	N/A
OFF Time (seconds)		N/A	N/A
Additional Features		N/A	N/A