September 7, 2019

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

Re: K183215
Trade/Device Name: Focus TENS Therapy, Model PM710-M/-L
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: August 5, 2019
Received: August 6, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert Kang, PharmD
Acting Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183215

Device Name
Omron Focus TENS Model PM710-M/-L

Indications for Use *(Describe)*
The device is intended for the relief of pain associated with sore or aching muscles of the lower extremities (leg) due to strain from exercise or normal household work activities.
It is also intended for the use of symptomatic relief and management of chronic, intractable pain associated with arthritis.
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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510(k) Notification K183215

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

Omron Healthcare, Inc.
1925 West Field Court
Lake Forest, IL 60045
USA
Phone: 847-247-5626
FAX: 847-680-6269

Contact Person:

Ronald S. Warren
Vice President, Regulatory Affairs
Experien Group, LLC
224 Airport Parkway, Suite 250
San Jose, CA 95110
USA
Phone: 408-505-3926
FAX: 408-400-0856

Date Prepared: December 11, 2018

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

Focus TENS Model PM710-M/-L

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 Focus TENS Model PM710-M/-L ("PM710") is substantially equivalent to the predicate device, the Omron Avail Wireless Dual Channel TENS PM601 (K172079), with regard to product labeling, intended use, anatomical sites, patient population, performance testing, technological characteristics and safety characteristics. In addition, the PM710 device is also similar to two other reference devices, the Neurometrix, Inc. Quell (K152954) and the Shenzhen Roundwhale Technology Co., Ltd Model R-T1 TENS stimulator (K180956) in regard to intended use and features.

DEVICE DESCRIPTION [807.92(a)(4)]

The PM710 is a wearable electrotherapy device that is designed to alleviate chronic, acute and arthritic muscle leg pain. It delivers TENS (Transcutaneous Electrical Nerve Stimulation) technology through the simple, convenient control on the main unit. The reusable, self-adhesive contouring pads allow for discreet and convenient placement on the pain locations below the knee.

The device contains one main TENS unit which is rechargeable and can be attached to a single sized gel and a medium or large band (model number follow by "-M" / "-L") which helps to attach the device to the leg. The pad with attached TENS unit can then be applied to intact skin at the desired location below the knee for therapy and pain relief. Control of the PM710 TENS system is through the control buttons on the main unit and the intensity of the therapy is displayed by the Intensity Level Indicators during treatment. The PM710 will be packaged with an Instruction Manual which provides details on setting up the device for use, setting and controlling intensity levels, and troubleshooting. The system accessories include one charger, one AC adapter for the charger, and one pad holder and storage case.

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

The device is intended for the relief of pain associated with sore or aching muscles of the lower extremities (leg) due to strain from exercise or normal household work activities.

It is also intended for the use of symptomatic relief and management of chronic, intractable pain associated with arthritis.

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 PM710 device is similar to the predicate Avail TENS devices in respect to the intended use and indication for use. PM710 is specifically intended for relieving pain of sore or aching muscles of the leg, whereas the Avail device is intended to relieve pain with sore or aching muscles for a wider range of body sites including the lower back, arms, legs, shoulders or feet. Both PM710 and Avail are also intended for the use of symptomatic relief and management of chronic, intractable pain associated with arthritis, and can be used in clinics, hospitals and home for adults.

The PM710 device offers one TENS treatment mode similar to the reference device Quell, whereas the predicate Avail device offers nine TENS treatment modes and one microcurrent mode. The waveform generated by PM710 is also different from the waveforms of the Avail system, however the electrical parameters of both are very similar. As such, the waveforms produced by PM710 and Avail can both achieve the same therapeutic outcome of "symptomatic relief and management of chronic, intractable pain as well as the discomfort associated with arthritis". 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.

The composite action of the low and high rate Hz stimulation produces rhythmic muscle contractions which then produces improved local blood vessel vasodilation thus reducing edema and retained metabolites commonly occurring from excessive muscle strain to support weak/arthritic joints. In addition, it enhances the supply of fresh oxygen and nutrients that can further result in decreased discomfort.

In regard to other output characteristics, summary tables of output parameters for the PM710, predicate and reference devices are provided in this submission. In general, the PM710 output parameters fall within the range of output parameters for the predicate Avail device. For example, the maximum current density (mA/cm^2) range for PM710 is 0.97, while the Avail is 0.0008 ~ 0.17 which are both 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 $7.59x10^{-3}$ for PM710, whereas the Avail maximum average power density range is $1.4x10^{-8}$ ~ $6.8x10^{-4}$, and the reference device R-T1 TENS is $1.08x10^{-4}$ ~$1.48x10^{-2}$, which has a closer match to PM710.

In regard to treatment duration, the PM710 offers a specified timer duration for 30 minutes. For Avail, there are two selectable time ranges for TENS therapy; 5 to 60 minutes and 30 to180 minutes, depending on the selected mode. The same time duration of 30 minutes is also offered by the reference device of R-T1. In this regard, PM710 should be considered at least as safe as the predicate and reference devices. A comparison of the PM710 output specification to the predicate device Avail and reference device R-T1 TENS are also provided in this submission.

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 PM710 device performs as intended. The PM710 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 PM710 is substantially equivalent to the predicate device. A comparison table summarizing the specifications and features of the proposed PM710 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 and 4) of output parameters for the PM710, predicate and reference devices are provided below.

PERFORMANCE DATA [807.92(b)]

All necessary bench and nonclinical testing were conducted on the PM710 to support a determination of substantial equivalence to the predicate device.

[807.92(b)(1)]Nonclinical Testing Summary:

All necessary non-clinical and usability testing was conducted on the PM710 to confirm that the device performs as intended. The nonclinical, bench testing included:

- Current Consumption
- Output Waveform
- PAD Peeling-off Detection
- Function Check
- AD Voltage Detection Accuracy
- Charging Current
- Voltage Endurance, Insulation Resistance
- Battery Characteristics
- Charger:
    - Current Consumption
    - Voltage Endurance, Insulation Resistance
- Durability test for the connector (between the unit and pad)
- Dispersion
- Adhesion (EC12 and Cutaneous Electrode)
- Adhesion on Human Skin
- Impedance for PAD
- Battery Characteristics after Drop/Vibration Testing

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the PM710 meet the established specifications necessary for consistent performance during its intended use. In addition, the collective bench testing demonstrates that the PM710 does not raise different questions of safety or effectiveness for TENS therapy when compared to the predicate device.

[807.92(b)(2)]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 PM710, 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 and predicate device are both 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 PM710 device performs as intended. The PM710 also passed testing requirements for electrical safety and EMC, and the device patient-contacting components were tested to demonstrate biocompatibility. The minor differences in 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, PM710 is substantially equivalent to the predicate device.

Table 1: Substantial Equivalence Table – Regulatory Information

Feature	Proposed Device Focus TENS PM710-M/PM710-L	Primary Predicate Device Omron Avail Wireless Dual Channel TENS PM601 K172079	Reference Device Quell K152954	Reference Device Model R-T1 TENS Stimulator K180956	Analysis of Technological Differences
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	No difference. Proposed device and predicate device 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: 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 device have the same medical device product code.
Indications for Use	The Focus TENS is intended for the relief of pain associated with sore or aching muscles of the lower extremities (leg) due to strain from exercise or normal household work activities. It is also intended for the use of symptomatic relief and management of chronic, intractable pain associated with arthritis. Environments of Use: Clinics, hospital and home environments Patient Population: Adult	The Avail Wireless Dual Channel TENS 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, choose Tap, Shoulder, Arm or Leg mode. Environments of Use: Clinics, hospital and home environments	Quell is intended for use as a transcutaneous electrical nerve stimulation device for temporary relief of pain associated with sore and aching muscles in the lower extremities due to strain from exercise or normal household and work activities. Quell is intended for use as a transcutaneous electrical nerve stimulation device for the symptomatic relief and management of chronic intractable pain. The device may be used during sleep. The device is labeled for use only with	This device 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 normal household work activities.	Similar to Avail but with narrower use for knee rather than the leg generally.

Table 1: Substantial Equivalence Table – Regulatory Information (cont.)

Feature	Proposed Device PM710-M/PM710-L	Primary Predicate Device Omron Avail Wireless Dual Channel TENS PM601 K172079	Reference Device Quell K152954	Reference Device Model R-T1 TENS Stimulator K180956	Analysis of Technological Differences
		Patient Population: Adult	compatible NeuroMetrix electrodes.		
Environment of Use	Clinics, hospitals and home environments	Clinics, hospitals and home environments	Unknown	Unknown	Same as Avail
Patient Population	Adults	Adults	Adults	Adults	No difference. Intended for same population.
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 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 1) 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. 2) The device should not be used when cancerous lesions or other lesions are present in the treatment area. 3) Stimulation should not be applied over swollen, infected, inflamed areas or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins, etc.). 4) Electrode placements must be avoided in the carotid sinus area (anterior neck) or tran-scerebrally (through the head). 5) This device should not be used in overly enervated	Same as Avail and Quell for Contraindications

Table 1: Substantial Equivalence Table – Regulatory Information (cont.)

Feature	Proposed Device PM710-M/PM710-L	Primary Predicate Device Omron Avail Wireless Dual Channel TENS PM601 K172079	Reference Device Quell K152954	Reference Device Model R-T1 TENS Stimulator K180956	Analysis of Technological Differences
				areas. 6) Inguinal hernia. 7) Do not use on scarred areas following a surgery for at least 10 months after the operation. 8) Do not use with serious arterial circulatory problems in the lower limbs.	
Single Use	Pads are for single patient use	Pads are for single patient use	Pads are for single patient use	Pads are for single patient use	No difference. Proposed and predicate devices are durable medical equipment intended for multiple uses.
Sterility	External contacting device, nonsterile	External contacting device, nonsterile	Unknown	Unknown	No difference. Proposed and predicate device are provided nonsterile.
Specifications/ Features					
Over-the-Counter (OTC)	Yes	Yes	Yes	Yes	No difference
Power Source(s)	Rechargeable Lithium-ion battery	Rechargeable Lithium-ion battery	Rechargeable Lithium-ion battery	6.0 V D.C., 4 x AAA batteries	Same battery type as Avail and Quell
Method of Line Current Isolation	N/A (internal power source)	N/A (internal power source)	N/A (internal power source)	N/A (internal power source)	No difference
Patient Leakage Current	---	---	---	---	---

Table 1: Substantial Equivalence Table – Regulatory Information (cont.)

Feature	Proposed Device PM710-M/PM710-L	Primary Predicate Device Omron Avail Wireless Dual Channel TENS PM601 K172079	Reference Device Quell K152954	Reference Device Model R-T1 TENS Stimulator K180956	Analysis of Technological Differences
-Normal Condition (uA)	<10uA	<10uA	<10uA	11.4uA	Same as Avail
-Single Fault Condition (uA)	<50uA	<50uA	<100uA	9.6uA	Same as Avail
Average DC current through electrodes when device is on but no pulse are being applied (uA)	0	0	<1uA	0	No difference
Number of output Modes	1 TENS mode	9 TENS modes	1 TENS mode	18 TENS modes	Same as Quell
Number of output channels Synchronous or Alternating	1ch	1ch	1ch	Alternating 2 channels	Same as Avail and Quell
Method of Channel Isolation	None	None	N/A	By electrical circuit and software	Same as Avail
Regulated Current or Regulated Voltage	Regulated Current	Regulated Current	Regulated current	Regulated current	No difference
Software/Firmware/ Microprocessor Control?	Microprocessor	Microprocessor	Yes	Yes	No difference
Automatic Overload Trip?	No	No	Yes	Yes	Same as Avail
Automatic No-Load Trip?	Yes	Yes	Yes	Yes	No difference
Automatic shut Off?	Yes	Yes	Yes	Yes	No difference
User over ride control?	Yes, Power On/Off button on the device	Yes, Power On/Off button on the device and in the App software	4 button presses	Yes	Similar to Avail but with no App associated with Focus TENS

Table 1: Substantial Equivalence Table – Regulatory Information (cont.)

Feature	Proposed Device PM710-M/PM710-L	Primary Predicate Device Omron Avail Wireless Dual Channel TENS PM601 K172079	Reference Device Quell K152954	Reference Device Model R-T1 TENS Stimulator K180956	Analysis of Technological Differences
Indication display On/Off Status?	Yes. LED indicator on main unit	Yes on App and LED indicator on main unit	Yes	Yes	Similar to Avail but with no App associated with Focus TENS
Low Battery?	Yes. LED indicator on main unit	Yes on App	Yes	Yes	Similar to Avail but with no App associated with Focus TENS
Voltage/Current Level?	Yes. LED indicator on main unit	Yes on App	No	Yes	Similar to Avail but with no App associated with Focus TENS
Timer Range (Minutes)	30 minutes	5-60minutes and 30-180minutes	60 minutes	30 minutes	Same as R-T1 and within range of Avail
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, IEC 60601-1-11	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 62304, IEC 60601-1-11	IEC 60601-1, IEC60601-1-2, IEC60601-2-10, IEC 60601-1-11	Same as Avail
Compliance with 21 CFR898?	N/A (no patient cable)	N/A (no patient cable)	Yes	Yes	Same as Avail
Weight	Device: Approx. 1.9 oz (55 g) Knee pad: Approx. 0.7 oz (20 g) Knee band M: Approx. 1.0 oz (27 g) Knee band L: Approx. 1.0 oz (29 g) Charger: Approx. 3.5 oz (100 g)	Device: Approx. 42 g (Both units have same weight) Pad-L: Approx. 25 g Pad-M: Approx. 20 g Charger: Approx. 100 g	62g (2.2 oz)	0.243 (lbs., oz.)	Similar. Difference does not affect safety and effectiveness of use.

Table 1: Substantial Equivalence Table – Regulatory Information (cont.)

Feature	Proposed Device PM710-M/PM710-L	Primary Predicate Device Omron Avail Wireless Dual Channel TENS PM601 K172079	Reference Device Quell K152954	Reference Device Model R-T1 TENS Stimulator K180956	Analysis of Technological Differences
Dimensions (W x H x D)	Device: Approx. 2.3 (W) × 2.8'' (H) × 0.6'' (D) (60 × 72 × 16 mm) Charger: Approx. 3.5'' (W) × 3.1'' (H) × 0.9'' (D) (90 x 80 x 23.5 mm) Knee pad: Approx. 5.1'' (W) × 2.3'' (H) × 0.6'' (D) (130 × 60 × 16 mm) Knee Band M: Approx. 15.1'' (W) × 2.5'' (H) (385 × 64 mm) Knee Band L: Approx. 17.7'' (W) × 2.5'' (H) (450 × 64 mm)	Device: Approx. 60 (W)× 72 (H)× 15.5 (D)mm (Both units have same weight) Charger: Approx. 158 (W)x 90 (H)x 20.5 (D)mm Pad-L: Approx. 219 (W) × 83.5 (H) × 7.5 (D)mm Pad-M: Approx. 180 (W) × 79.5 (H) × 7.5 (D)mm	11mm (0.4") x 74mm (2.9") x 98mm (3.9")	4.82x2.78x1.08 (in.)	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)	10 to 40 °C 30 to 80 %RH 700 to 1060 hPa (non-condensing)	-5° C to 40° C 15% to 93% 70 kPa to 106 kPa	5°C~40°C 15%RH~93%RH 700 hPa to 1060 hPa	Same as Avail
Charging conditions	5 to 35 °C (non-condensing)	5 to 35 °C (non-condensing)	-5° C to 40° C 15% to 93% 70 kPa to 106 kPa	N/A(no rechargeable battery)	Same as Avail
Storage conditions	0 to 40 °C 30 to 80 % RH (non-condensing)	0 to 40 °C 30 to 80 % RH (non-condensing)	-25° C to 70° C 10% to 93% 70 kPa to 106 kPa	-10°C~55°C 10%RH~90%RH 700 hPa to 1060 hPa	Same as Avail
Transporting conditions	-20 to 60 °C 10 to 90 % RH (non-condensing)	-20 to 60 °C 10 to 90 % RH (non-condensing)	-25° C to 70° C 10% to 93% 70 kPa to 106 kPa	-10°C~55°C 10%RH~90%RH 700 hPa to 1060 hPa	Same as Avail
Electrode style	HV-KNPAD-Z Reusable	HV-WPAD-M or HV-WPAD-L Reusable	Quell electrodes Reusable	Reusable	Similar to Avail and Quell

Table 1: Substantial Equivalence Table – Regulatory Information (cont.)

Feature	Proposed Device PM710-M/PM710-L	Primary Predicate Device Omron Avail Wireless Dual Channel TENS PM601 K172079	Reference Device Quell K152954	Reference Device Model R-T1 TENS Stimulator K180956	Analysis of Technological Differences
Patient Contact Accessory	Yes	Yes	Yes	Yes	No difference

Table 2: Output Comparison for PM710

Parameter		Focus TENS PM710-M/-L	Avail K172079										Quell K152954	
Mode of Program Name		Knee	Steady	Acupuncture Like	Knead	Tap	Lower Back	Shoulder	Joint	Leg	Arm	Microcurrent	Standard	Alternative
Waveform		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
Maximum Output Voltage [V]	@500Ω	45.0	25.9	38.4	27.9	38.3	38.2	38.4	25.6	36.7	38.2	0.0	49.2	49.4
	@2kΩ	68.6	45.2	50.8	37.2	50.3	50.4	50.4	35.7	49.5	50.4	0.1	-	-
	@10kΩ	78.5	59.9	55.2	40.7	54.9	55.8	55.8	39.2	54.6	55.2	0.5	-	-
Maximum Output Current [mA]	@500Ω	90.0	51.8	76.8	55.8	76.6	76.4	76.8	51.2	73.4	76.4	0.1	98.4	98.8
	@2kΩ	34.3	22.6	25.4	18.6	25.2	25.2	25.2	17.9	24.8	25.2	0.1	-	-
	@10kΩ	7.9	6.0	5.5	4.1	5.5	5.6	5.6	3.9	5.5	5.5	0.1	-	-
Duration of primary phase [µsec]		60	96	96	96	96	96	96	96	96	96	2500000	100	100
Pulse Duration [µsec]		60	96	96	96	96	96	96	96	96	96	2500000	100	100
Frequency [Hz]		1-250	99	2	51.65	1-20.13	2-108	1-19	42.43-108	2-51.65	2-51.65	0.2	60-100	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
	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
Net Charge(µC per pulse) (@500Ω) [uC]		0	0	0	0	0	0	0	0	0	0	0	0	0

Table 2: Output Comparison for PM710 (cont.)

Maximum Phase Charge (@500Ω) [µC]		5.40	4.97	7.37	5.36	7.35	7.33	7.37	4.92	7.05	7.33	125.00	9.84	9.88
Maximum Current Density (@500Ω) [mA/cm2] r.m.s.		0.97	0.16	0.03	0.09	0.11	0.17	0.10	0.12	0.12	0.12	0.00	0.50	0.45
Maximum Average Current (average absolute value), mA		2.70	0.98	0.03	0.28	0.30	0.79	0.28	0.53	0.36	0.38	0.03	1.97	1.58
Maximum Average Power Density (@500Ω) [W/cm^2]		7.59E-03	5.71E-04	2.53E-05	1.73E-04	2.54E-04	6.77E-04	2.41E-04	3.04E-04	2.99E-04	3.24E-04	1.40E-08	3.46E-03	2.79E-03
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	N/A	N/A	4.0
	(b) Bursts per second	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	2.1
	(c) Burst 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	0.1
	(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	N/A	N/A	0.2
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	0.1
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	0.4
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

Table 3: Output Comparison for R-T1 TENS #1

Parameter		R-T1 TENS Stimulator K180956								
Mode of Program Name		Shoulder(P1)	Shoulder(P2)	Shoulder(P3)	Back(P1)	Back(P2)	Back(P3)	Arm(P1)	Arm(P2)	Arm(P3)
Waveform		Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic	Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular	Rectangular
Maximum Output Voltage [V]	@500Ω	29.4	29.6	29.0	30.0	29.2	28.8	29.2	28.4	29.4
	@2kΩ	104.5	108.0	109.0	111.5	107.0	111.5	106.5	109.5	111.5
	@10kΩ	111.5	113.0	112.5	114.5	112.0	115.5	108.0	113.0	115
Maximum Output Current [mA]	@500Ω	58.8	59.2	58.0	60.0	58.4	57.6	58.4	56.8	58.8
	@2kΩ	52.3	54.0	54.5	55.8	53.5	55.8	53.3	54.8	55.75
	@10kΩ	11.2	11.3	11.3	11.5	11.2	11.6	10.8	11.3	11.5
Duration of primary phase [μsec]		250	253	205	256	253	332	252.4	197	201
Pulse Duration [μsec]		250	253	205	256	253	332	252.4	197	201
Frequency [Hz]		2-6	4-8	2-125	10-80	6-10	100	2	2-100	100
For multiphasic waveforms only:	Symmetrical phases	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
Net Charge(μC per pulse) (@500Ω) [uC]		0	0	0	0	0	0	0	0	0
Maximum Phase Charge (@500Ω) [μC]		14.70	14.98	11.89	15.36	14.78	19.12	14.74	11.19	11.82

Table 3: Output Comparison for R-T1 TENS #1 (cont.)

Parameter		R-T1 TENS Stimulator K180956								
Maximum Current Density (@500Ω) [mA/cm2] r.m.s.		0.20	0.24	0.82	0.76	0.26	0.93	0.12	0.70	0.74
Maximum Average Current (average absolute value), mA		0.18	0.24	2.97	2.46	0.30	3.82	0.06	2.24	2.36
Maximum Average Power Density (@500Ω) [W/cm^2]		3.24E-04	4.43E-04	5.39E-03	4.61E-03	5.39E-04	6.88E-03	1.08E-04	3.97E-03	4.34E-03
Burst Mode	(a) Pulses per burst	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
	(c) Burst duration	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
ON Time (seconds)		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
Additional Features		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Table 4: Output Comparison for R-T1 TENS #2

Parameter		R-T1 TENS Stimulator K180956											
Mode of Program Name		Hip(P1)	Hip(P2)	Hip(P3)	Leg(P1)	Leg(P2)	Leg(P3)	Joint(P1)	Joint(P2)	Joint(P3)	Knead	Rub	Tap
Waveform		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
Maximum Output Voltage [V]	@500Ω	29.2	29.4	29	29.6	29.4	28.6	29.6	29.6	29.6	30	29.6	30
	@2kΩ	111.5	112.5	112.5	112.5	111	108	111	109.5	112	106	109.5	111.5
	@10kΩ	114	115.5	112.5	114	113	112.5	112.5	115.5	114	114	114	116.5
Maximum Output Current [mA]	@500Ω	58.4	58.8	58	59.2	58.8	57.2	59.2	59.2	59.2	60	59.2	60
	@2kΩ	55.75	56.25	56.25	56.25	55.5	54	55.5	54.75	56	53	54.75	55.75
	@10kΩ	11.4	11.55	11.25	11.4	11.3	11.25	11.25	11.55	11.4	11.4	11.4	11.65
Duration of primary phase [µsec]		152.8	255	203.5	250.7	155	253	201.4	156.9	155.2	220	219	225.5
Pulse Duration [µsec]		152.8	255	203.5	250.7	155	253	201.4	156.9	155.2	220	219	225.5
Frequency [Hz]		100	6-50	100	4-50	100	6-10	2-100	100	80	83-132	25-79	147-291
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
	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
Net Charge(µC per pulse) (@500Ω) [uC]		0	0	0	0	0	0	0	0	0	0	0	0

Table 4: Output Comparison for R-T1 TENS #2 (cont.)

Parameter		R-T1 TENS Stimulator K180956											
Maximum Phase Charge (@500Ω) [μC]		8.92	14.99	11.80	14.84	9.11	14.47	11.92	9.29	9.19	13.20	12.96	13.53
Maximum Current Density (@500Ω) [mA/cm2] r.m.s.		0.64	0.59	0.73	0.59	0.65	0.25	0.74	0.66	0.58	0.90	0.69	1.36
Maximum Average Current (average absolute value), mA		1.78	1.50	2.36	1.48	1.82	0.29	2.38	1.86	1.47	3.48	2.05	7.87
Maximum Average Power Density (@500Ω) [W/cm^2]		3.26E-03	2.76E-03	4.28E-03	2.75E-03	3.35E-03	5.17E-04	4.41E-03	3.44E-03	2.72E-03	6.53E-03	3.79E-03	1.48E-02
Burst Mode	(a) Pulses per burst	N/A	N/A	25	N/A	25	N/A	N/A	25	N/A	N/A	N/A	N/A
	(b) Bursts per second	N/A	N/A	2.00	N/A	2.06	N/A	N/A	2.00	N/A	N/A	N/A	N/A
	(c) Burst duration	N/A	N/A	0.24	N/A	0.24	N/A	N/A	0.24	N/A	N/A	N/A	N/A
	(d) Duty cycle: Line(b)xLine(c)	N/A	N/A	0.48	N/A	0.49	N/A	N/A	0.48	N/A	N/A	N/A	N/A
ON Time (seconds)		N/A	N/A	0.24	N/A	0.24	N/A	N/A	0.241	N/A	N/A	N/A	N/A
OFF Time (seconds)		N/A	N/A	0.26	N/A	0.245	N/A	N/A	0.258	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