



November 9, 2018

Omron Healthcare, Inc.  
% Paul Dryden  
Consultant  
ProMedic, LLC.  
131 Bay Point Dr. NE  
St. Petersburg, Florida 33704

Re: K181992

Trade/Device Name: Heat Pain Pro Model PM311B  
Regulation Number: 21 CFR 882.5890  
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief  
Regulatory Class: Class II  
Product Code: NUH, NYN  
Dated: October 9, 2018  
Received: October 10, 2018

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**Pamela D. Scott -S**

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

## Indications for Use

510(k) Number (if known)

K181992

Device Name

Heat Pain Pro Model PM311B

Indications for Use (Describe)

The Omron Heat Pain Pro Model PM311B is intended for:

The relief of pain associated with sore or aching, muscles of the lower back, arm, legs, shoulder, or foot 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.

Environment 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) Summary

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**Date:** November 8, 2018

**Sponsor:**

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

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

**Official Contact:** Renee Thornborough – Executive Director QA/RA

**Proprietary or Trade Name:** Heat Pain Pro Model PM311B

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

**CFR / Code / Classification Name / Class:**

21CFR 882.5890

NUH - stimulator, nerve, transcutaneous, over-the-counter

NYN - stimulator, electrical, transcutaneous, for arthritis

Class II

**Device Name:** Heat Pain Pro Model PM311B

**Primary Predicate:** K160115– Omron – Heat Pain Pro (Model PM311)

**Secondary Predicate:** K172079 – Omron – Avail (PM601)

**Device Description:**

The Heat Pain Pro (PM311B) 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.

Stimulation from PM311B is 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 Omron Heat Pain Pro Model PM311B 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.
- 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.

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 PM311B. These are the identical accessories cleared under K160115 for the Model PM311.

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.

The PM311B is identical to the PM311 cleared under 510(k) K160115, this submission is for expanded indications under product code NYN.

The PM311 and PM311B are considered – OTC devices.

**Patient Population**

Adults

**Indications for Use:**

The Omron Heat Pain Pro Model PM311B 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.

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.

**Environment of Use:**

Clinics, hospital and home environments

**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 PM311B is compared to the predicates in the device comparison table below.

## Device Comparison

| Feature                       | Proposed<br>Omron<br>PM311B                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Primary Predicate<br>Omron<br>PM311<br>K160115                                                                                                                                                                                                                                                                                   | Secondary Predicate<br>Omron<br>Avail<br>K172079                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Discussion of Differences                                                                                                                                                                                                        |
|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Indications for Use           | <p>The Omron Heat Pain Pro Model PM311B 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.</p> <p>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.</p> <p>Environments of Use: Clinics, hospital and home environments</p> <p>Patient Population: Adult</p> | <p>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.</p> <p>Environments of Use: Clinics, hospital and home environments</p> <p>Patient Population: Adult</p> | <p>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.</p> <p>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.</p> <p>Environments of Use: Clinics, hospital and home environments</p> <p>Patient Population: Adult</p> | <p>Indications between Omron PM311B and predicate PM311 are identical except for the addition indication for chronic, intractable pain and relief of pain associated with arthritis which is identical to that of the Avail.</p> |
| 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                                                                                                                                                                                                                                                                                                                                                                                                                                   | Identical                                                                                                                                                                                                                        |
| Classification - Product Code | <p>Primary: NUH - Transcutaneous electrical nerve stimulator for pain relief</p> <p>Secondary: NYN - Transcutaneous electrical nerve stimulator for pain relief.</p>                                                                                                                                                                                                                                                                                                                                                                       | NUH - Transcutaneous electrical nerve stimulator for pain relief                                                                                                                                                                                                                                                                 | <p>Primary: NUH - Transcutaneous electrical nerve stimulator for pain relief</p> <p>Secondary: NYN - Transcutaneous electrical nerve stimulator for pain relief.</p>                                                                                                                                                                                                                                                                                                                                           | Proposed device adds product code NYN                                                                                                                                                                                            |
| Over-the-Counter (OTC)        | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Yes                                                                                                                                                                                                                                                                                                                              | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Identical to predicate PM311 K160115                                                                                                                                                                                             |

| Feature                                                                                     |                             | Proposed<br>Omron<br>PM311B                                                                                                                | Primary Predicate<br>Omron<br>PM311<br>K160115                                                                                             | Secondary Predicate<br>Omron<br>Avail<br>K172079 | Discussion of Differences            |
|---------------------------------------------------------------------------------------------|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|--------------------------------------|
| Power Source(s)                                                                             |                             | External supply Lithium-ion battery                                                                                                        | External supply Lithium-ion battery                                                                                                        | Lithium-ion battery                              | Identical to predicate PM311 K160115 |
| - Method of Line Current Isolation                                                          |                             | N.A.(internal power source)                                                                                                                | N.A.(internal power source)                                                                                                                | N.A.(internal power source)                      | Identical to predicate PM311 K160115 |
| - Patient Leakage Current                                                                   |                             | ---                                                                                                                                        | ---                                                                                                                                        | ---                                              | ---                                  |
| - Normal Condition (uA)                                                                     |                             | 1                                                                                                                                          | 1                                                                                                                                          | <10                                              | Identical to predicate PM311 K160115 |
| - Single Fault Condition (uA)                                                               |                             | 5.52 max                                                                                                                                   | 5.52 max                                                                                                                                   | <50                                              | Identical to predicate PM311 K160115 |
| Average DC current through electrodes when device is on but no pulse are being applied (uA) |                             | 0 (uA)                                                                                                                                     | 0 (uA)                                                                                                                                     | 0 (uA)                                           | Identical to predicate PM311 K160115 |
| Number of output Modes                                                                      |                             | -3 Therapies<br>(2 TENS with HEAT combination therapies and I TENS therapy)<br><br>-9 TENS Stimulation Modes<br><br>-2 Heat Level Settings | -3 Therapies<br>(2 TENS with HEAT combination therapies and I TENS therapy)<br><br>-9 TENS Stimulation Modes<br><br>-2 Heat Level Settings | 9 TENS modes<br>1 Microcurrent mode              | Identical to predicate PM311 K160115 |
| Number of output channels                                                                   | Synchronous or Alternating  | 1 ch                                                                                                                                       | 1 ch                                                                                                                                       | 1 ch                                             | Identical to predicate PM311 K160115 |
|                                                                                             | Method of Channel Isolation | None                                                                                                                                       | None                                                                                                                                       | None                                             | Identical to predicate PM311 K160115 |
| Regulated Current or Regulated Voltage                                                      |                             | Regulated Current                                                                                                                          | Regulated Current                                                                                                                          | Regulated Current                                | Identical to predicate PM311 K160115 |
| Software/Firmware/Microprocessor Control?                                                   |                             | Microprocessor                                                                                                                             | Microprocessor                                                                                                                             | Microprocessor                                   | Identical to predicate PM311 K160115 |
| Automatic Overload Trip?                                                                    |                             | No                                                                                                                                         | No                                                                                                                                         | No                                               | Identical to predicate PM311 K160115 |

| Feature                                     |                          | Proposed<br>Omron<br>PM311B                                                                                                | Primary Predicate<br>Omron<br>PM311<br>K160115                                                                             | Secondary Predicate<br>Omron<br>Avail<br>K172079                             | Discussion of Differences            |
|---------------------------------------------|--------------------------|----------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|--------------------------------------|
| Automatic No-Load Trip?                     |                          | Yes                                                                                                                        | Yes                                                                                                                        | Yes                                                                          | Identical to predicate PM311 K160115 |
| Automatic shut Off?                         |                          | Yes                                                                                                                        | Yes                                                                                                                        | Yes                                                                          | Identical to predicate PM311 K160115 |
| User over ride control?                     |                          | User activated On/Off                                                                                                      | User activated On/Off                                                                                                      | Yes, Power On/Off button on the device and in the App software               | Identical to predicate PM311 K160115 |
| Indication display                          | ON/Off status?           | Yes                                                                                                                        | Yes                                                                                                                        | Yes on App and LED indicator on main unit                                    | Identical to predicate PM311 K160115 |
|                                             | Low Battery?             | Yes                                                                                                                        | Yes                                                                                                                        | Yes on App                                                                   | Identical to predicate PM311 K160115 |
|                                             | Voltage / Current Level? | Yes                                                                                                                        | Yes                                                                                                                        | Yes on App                                                                   | Identical to predicate PM311 K160115 |
| Timer Range (minutes)                       |                          | 30                                                                                                                         | 30                                                                                                                         | 5-60 (minutes) and 30-180 (minutes)                                          | Identical to predicate PM311 K160115 |
| Compliance with Voluntary standards?        |                          | ES60601-1, IEC60601-1-2, IEC60601-2-10, IEC 60601-1-11                                                                     | ES60601-1, IEC60601-1-2, IEC60601-2-10, IEC 60601-1-11                                                                     | ES60601-1, IEC60601-1-2, IEC60601-2-10, IEC 60601-1-11                       | Identical to predicate PM311 K160115 |
| Compliance with 21 CFR 898?                 |                          | Yes                                                                                                                        | Yes                                                                                                                        | N/A (no patient cable)                                                       | Identical to predicate PM311 K160115 |
| Weight                                      |                          | Approx. 200g (incl. batteries)                                                                                             | Approx. 200g (incl. batteries)                                                                                             | Approx 42g                                                                   | Identical to predicate PM311 K160115 |
| Dimensions (W x H x D)                      |                          | 71(W)x165(H)x30.5(D)mm                                                                                                     | 71(W)x165(H)x30.5(D)mm                                                                                                     | Device: Approx. 60 × 72 × 15.5mm                                             | Identical to predicate PM311 K160115 |
| Operating and Storage Temperature, Humidity |                          | Operating<br>10 to 40°C<br>30 to 80 %RH<br>700 to 1060 hPa<br><br>Storage,<br>0 to 40°C<br>30 to 80 %RH<br>700 to 1060 hPa | Operating,<br>10 to 40°C<br>30 to 80 %RH<br>700 to 1060 hPa<br><br>Storage<br>0 to 40°C<br>30 to 80 %RH<br>700 to 1060 hPa | Operating<br>10 to 40 °C<br>30 to 80 %RH<br>700 to 1060 hPa (non-condensing) | Identical to predicate PM311 K160115 |

| Feature                                               | Proposed<br>Omron<br>PM311B                     | Primary Predicate<br>Omron<br>PM311<br>K160115  | Secondary Predicate<br>Omron<br>Avail<br>K172079                      | Discussion of Differences               |
|-------------------------------------------------------|-------------------------------------------------|-------------------------------------------------|-----------------------------------------------------------------------|-----------------------------------------|
| Transportation Temperature,<br>Humidity, Air Pressure | -20 to 60°C<br>10 to 95% RH,<br>700 to 1060 hPa | -20 to 60°C<br>10 to 95% RH,<br>700 to 1060 hPa | -20 to 60 °C<br>10 to 95% RH,<br>700 to 1060 hPa (non-<br>condensing) | Identical to predicate PM311<br>K160115 |
| Electrode style                                       | PMGEL<br>Reusable                               | PMGEL<br>Reusable                               | HV-WPAD-M or HV-WPAD-L<br>Reusable                                    | Identical to predicate PM311<br>K160115 |
| Patient contacting accessory                          | Electrode                                       | Electrode                                       | Electrode                                                             | Identical to predicate PM311<br>K160115 |

**Differences Between Other Legally Marketed Predicate Devices:**

The Omron PM311B is viewed as substantially equivalent to the predicate devices because: The PM311B uses the exact same technology and has substantially equivalent indications for use. The differences that exist between the devices does not raise new or different concerns of safety or effectiveness.

**Indications –**

The indications for the PM311B have added “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.” when compared to predicate PM311( K160115). The added indication is identical to the predicate Avail (K172079).

**Prescriptive –**

The PM311B and predicates are all OTC.

**Design and Technology –**

The PM311B is identical to the PM311 (K160115) and has equivalent design and features when compared to the Omron Avail (K172079).

**Performance and Specifications –**

The PM311B is identical to the PM311 (K160115) and has equivalent performance specifications when compared to the Omron Avail (K172079).

**Patient Population –**

The PM311B and predicates are indicated for adults

**Environment of Use –**

Clinics, hospital and home environments are identical to the predicates.

**Non-Clinical Testing Summary:****Compliance with standards –**

The PM 311B and predicates comply with the same standards: AAMI ANSI ES6060-1, IEC 60601-1-2, IEC 60601-2-10, and IEC 60601-1-11

The device has been tested to ensure 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: 2014 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic disturbances - 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: 2016 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 as part of IEC 60601-1-11.

**Patient Contacting Materials –**

The patient contacting materials of the PM311B are the PM-GELs. The PM-GELs are exactly the same as cleared with the PM311( K160115).

**Clinical Testing Summary:**

No clinical testing was performed

**Substantial Equivalence Conclusion**

Omron maintains that the PM311B is substantially equivalent to the predicate devices in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards.

## Output of Subject device PM311B

Output Specification Comparison

| Parameter                                                    |                                 | PM311B      |             |             |             |             |             |             |             |             |
|--------------------------------------------------------------|---------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|
| Mode of Program Name                                         |                                 | Tap         | Knead       | Rub         | Arm         | Lback       | Leg         | Foot        | Joint       | Shldr       |
| 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                           | 67.2        | 40.7        | 37.3        | 67.1        | 67.1        | 66.4        | 66.9        | 40.3        | 67.1        |
|                                                              | @2kΩ                            | 85.6        | 56.6        | 51.2        | 86.0        | 84.0        | 85.5        | 85.9        | 56.8        | 84.8        |
|                                                              | @10kΩ                           | 95.9        | 62.4        | 56.7        | 95.7        | 94.0        | 95.5        | 95.8        | 63.1        | 95.4        |
| Maximum Output Current [mA]                                  | @500Ω                           | 134.4       | 81.4        | 74.6        | 134.2       | 134.2       | 132.8       | 133.8       | 80.6        | 134.2       |
|                                                              | @2kΩ                            | 42.8        | 28.3        | 25.6        | 43.0        | 42.0        | 42.8        | 43.0        | 28.4        | 42.4        |
|                                                              | @10kΩ                           | 9.6         | 6.2         | 5.7         | 9.6         | 9.4         | 9.6         | 9.6         | 6.3         | 9.5         |
| Duration of primary phase [μsec]                             |                                 | 96          | 96          | 96          | 96          | 96          | 96          | 96          | 96          | 96          |
| Pulse Duration [μsec]                                        |                                 | 96          | 96          | 96          | 96          | 96          | 96          | 96          | 96          | 96          |
| Frequency [Hz]                                               |                                 | 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         |
|                                                              | 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) [μC]                        |                                 | 0           | 0           | 0           | 0           | 0           | 0           | 0           | 0           | 0           |
| Maximum Phase Charge (@500Ω) [μC]                            |                                 | 12.90       | 7.81        | 7.16        | 12.88       | 12.88       | 12.75       | 12.84       | 7.74        | 12.88       |
| Maximum Current Density (@500Ω) [mA/cm <sup>2</sup> ] r.m.s. |                                 | 0.52        | 0.36        | 0.46        | 0.59        | 0.86        | 0.83        | 0.39        | 0.73        | 0.51        |
| Maximum Average Current (average absolute value), mA         |                                 | 0.52        | 0.40        | 0.71        | 0.67        | 1.39        | 1.32        | 0.28        | 1.67        | 0.49        |
| Maximum Average Power Density (@500Ω) [W/cm <sup>2</sup> ]   |                                 | 2.19E-03    | 1.03E-03    | 1.66E-03    | 2.80E-03    | 5.85E-03    | 5.48E-03    | 1.19E-03    | 4.22E-03    | 2.06E-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         |

Output of Predicate Heat Pain Pro (K16011) with revised values

**Output Specification Comparison**

| Parameter                                                    |                                 | PM311B      |             |             |             |             |             |             |             |             |
|--------------------------------------------------------------|---------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|
| Mode of Program Name                                         |                                 | Tap         | Knead       | Rub         | Arm         | Lback       | Leg         | Foot        | Joint       | Shldr       |
| 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                           | 67.2        | 40.7        | 37.3        | 67.1        | 67.1        | 66.4        | 66.9        | 40.3        | 67.1        |
|                                                              | @2kΩ                            | 85.6        | 56.6        | 51.2        | 86.0        | 84.0        | 85.5        | 85.9        | 56.8        | 84.8        |
|                                                              | @10kΩ                           | 95.9        | 62.4        | 56.7        | 95.7        | 94.0        | 95.5        | 95.8        | 63.1        | 95.4        |
| Maximum Output Current [mA]                                  | @500Ω                           | 134.4       | 81.4        | 74.6        | 134.2       | 134.2       | 132.8       | 133.8       | 80.6        | 134.2       |
|                                                              | @2kΩ                            | 42.8        | 28.3        | 25.6        | 43.0        | 42.0        | 42.8        | 43.0        | 28.4        | 42.4        |
|                                                              | @10kΩ                           | 9.6         | 6.2         | 5.7         | 9.6         | 9.4         | 9.6         | 9.6         | 6.3         | 9.5         |
| Duration of primary phase [μsec]                             |                                 | 96          | 96          | 96          | 96          | 96          | 96          | 96          | 96          | 96          |
| Pulse Duration [μsec]                                        |                                 | 96          | 96          | 96          | 96          | 96          | 96          | 96          | 96          | 96          |
| Frequency [Hz]                                               |                                 | 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         |
|                                                              | 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) [μC]                        |                                 | 0           | 0           | 0           | 0           | 0           | 0           | 0           | 0           | 0           |
| Maximum Phase Charge (@500Ω) [μC]                            |                                 | 12.90       | 7.81        | 7.16        | 12.88       | 12.88       | 12.75       | 12.84       | 7.74        | 12.88       |
| Maximum Current Density (@500Ω) [mA/cm <sup>2</sup> ] r.m.s. |                                 | 0.52        | 0.36        | 0.46        | 0.59        | 0.86        | 0.83        | 0.39        | 0.73        | 0.51        |
| Maximum Average Current (average absolute value), mA         |                                 | 0.52        | 0.40        | 0.71        | 0.67        | 1.39        | 1.32        | 0.28        | 1.67        | 0.49        |
| Maximum Average Power Density (@500Ω) [W/cm <sup>2</sup> ]   |                                 | 2.19E-03    | 1.03E-03    | 1.66E-03    | 2.80E-03    | 5.85E-03    | 5.48E-03    | 1.19E-03    | 4.22E-03    | 2.06E-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         |

Output of Reference Avail (K172079)

**Output Specification Comparison**

| Parameter                                                    |                                 | Avail<br>(K172079) |                 |             |             |             |             |             |             |             |              |
|--------------------------------------------------------------|---------------------------------|--------------------|-----------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|--------------|
| 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) [μC]                        |                                 | 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/cm <sup>2</sup> ] r.m.s. |                                 | 0.16               | 0.03            | 0.09        | 0.11        | 0.17        | 0.10        | 0.12        | 0.12        | 0.12        | 0.00         |
| 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 <sup>2</sup> ]   |                                 | 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     |
| 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          |