January 10, 2019

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

Re: K182120
Trade/Device Name: Omron Healthcare Maxpower Relief Model PM3032B
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 11, 2018
Received: October 12, 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) 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

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)*
K182120

Device Name
Omron Healthcare Maxpower Relief Model PM3032B

Indications for Use *(Describe)*
This device is intended for the relief of pain associated with sore or aching, muscles of the lower back, arms, legs, shoulder, or foot due to strain from exercise or normal household work activities. When used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis, use the Shoulder 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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Lake Forest, IL 60045 USA

Tel - 847-247-5626
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Official Contact: Renee Thornborough – Executive Director QA/RA

Proprietary or Trade Name: Omron Healthcare Maxpower Relief Model PM3032B

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

Classification Name/Code:
21CFR 882.5890
NUH – stimulator, nerve, transcutaneous, over-the-counter
NYN - stimulator, electrical, transcutaneous, for arthritis
Class II

Device Name: Omron Healthcare Maxpower Relief Model PM3032B

Predicate Devices: K141978 - Omron – PM3032
K172079 – Omron – Avail

Device Description:
The Omron Healthcare Maxpower Relief Model PM3032B is a small, battery operated TENS device for pain relief intended for OTC use. It complies with ES60601-1, IEC60601-1-2, IEC60601-2-10 and IEC 60601-1-11.

The output modes are intended for application to the following areas: lower back, arms, legs, shoulder or foot. The specifications of each mode will be discussed in greater detail later in this section.

The Omron Healthcare Maxpower Relief Model PM3032B is software controlled which includes all functions, indicators and waveform characteristics.

This device is intended for the relief of pain associated with sore or aching, muscles of the lower back, arms, legs, shoulder, or foot due to strain from exercise or normal household work activities. When used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis, use the Shoulder mode of stimulation.

The accessories include an electrode cord / cable and electrodes pads (Long Life) which are placed on the specific body part. These are identical to the accessories cleared in K141978.

As above the device is battery powered there is no connection to AC mains supply nor connection to any other device.

This submission is for expanding the indications for use to include indications associated with product code NYN. The device is identical to the Maxpower Relief (Model PM3032) cleared under K141978 except the CPU and related components are changed for cost saving purpose. UDI has also added on the main unit and the packaging. There are no other changes (appearance, dimension, materials, waveforms, modes). The accessories are identical to the Maxpower Relief (Model PM3032) cleared under K141978

We have provided the information suggested in *Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use* from April 5, 2010. A checklist in accordance with this guidance can be found in Section 2 of this submission

Intended User
OTC

Patient Population
Adults

Indications for Use:
This device is intended for the relief of pain associated with sore or aching, muscles of the lower back, arms, legs, shoulder, or foot due to strain from exercise or normal household work activities.
When used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis, use the Shoulder 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:
Table 1 outlines the features of the Omron Healthcare Maxpower Relief Model PM3032B and compares it to the predicates that are being used to establish substantial equivalence.

Device Comparison

Feature	New Device Omron Healthcare Maxpower Relief Model PM3032B	Primary Predicate Device PM3032 (MaxPower relief) K141978	Secondary Predicate Device Omron Avail K172079	Comment
Indications for use	This device is intended for the relief of pain associated with sore or aching, muscles of the lower back, arms, legs, shoulder, or foot due to strain from exercise or normal household work activities. When used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis, use the Shoulder mode of stimulation. Environments of Use: Clinics, hospital and home environments Patient Population: Adult .	This device is intended for the relief of pain associated with sore or aching, muscles of the lower back, arms, legs, shoulder, or foot due to strain from exercise or normal household work activities. Environments of Use: Clinics, hospital and home environments Patient Population: Adult	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	Identical to Maxpower Relief for temporary relief of pain with sore and aching muscles. Similar to Avail with respect to symptomatic relief and management of chronic, intractable pain, and relief of pain associated with arthritis.
Environments of Use:	Clinics, hospitals and home environments	Clinics, hospitals and home environments	Clinics, hospitals and home environments	Identical
Patient Population	Adult	Adult	Adult	Identical
Classification - Regulation	21 CFR §882.5890, Transcutaneous electrical	21 CFR §882.5890, Transcutaneous electrical	21 CFR §882.5890, Transcutaneous electrical	Identical

Feature	New Device Omron Healthcare Maxpower Relief Model PM3032B	Primary Predicate Device PM3032 (MaxPower relief) K141978	Secondary Predicate Device Omron Avail K172079	Comment
	nerve stimulator for pain relief	nerve stimulator for pain relief	nerve stimulator for pain relief	
Classification - Product Code	Primary: NUH - stimulator, nerve, transcutaneous, over-the-counter Secondary: NYN - stimulator, electrical, transcutaneous, for arthritis.	NUH - stimulator, nerve, transcutaneous, over-the-counter	Primary: NUH - stimulator, nerve, transcutaneous, over-the-counter Secondary: NYN - stimulator, electrical, transcutaneous, for arthritis.	Proposed device and secondary predicate device have the same medical device product code.
Prescriptive	No, OTC	No, OTC	No, OTC	Identical
Contraindications/Warning/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 otherimplanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.	Identical
Single Use	Pads are for single patient use	Pads are for single patient use	Patient-contacting Pads are for single patient use	Identical to MaxPower Relief
Sterility	External contacting device, nonsterile	External contacting device, nonsterile	External contacting device, nonsterile	Identical
Specification Features				
Over-the-Counter (OTC)	Yes	Yes	Yes	Identical

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Feature		**New Device Omron Healthcare Maxpower Relief Model PM3032B**	**Primary Predicate Device PM3032 (MaxPower relief) K141978**	**Secondary Predicate Device Omron Avail K172079**	**Comment**
Power Source(s)		Two AAA alkaline batteries	Two AAA alkaline batteries	Rechargeable lithium Ion battery	Identical to Maxpower Relief
- Method of Line Current Isolation		N.A.(internal power source)	N.A.(internal power source)	N.A.(internal power source)	Identical
Patient Leakage Current - Normal Condition (uA)		1	1	<10uA	Identical to Maxpower Relief
Patient Leakage Current - Single Fault Condition (uA)		8.9 max	8.9 max	<50uA	Identical to Maxpower Relief
Average DC current through electrodes when device is on but no pulse are being applied (uA)		0 (uA)	0 (uA)	0 (uA)	Identical
Number of output Modes		9 TENS modes	Same	9 TENS modes 1 Microcurrent mode	Identical to Maxpower Relief
Number of output channels	Synchronous or Alternating	1 ch	1 ch	1 ch	Identical
	Method of Channel Isolation	None	None	None	Identical
Regulated Current or Regulated Voltage		Regulated Current	Regulated Current	Regulated Current	Identical
Software/Firmware/Microprocessor Control		Microprocessor	Microprocessor	Microprocessor	Identical
Automatic Overload Trip		No	No	No	Identical
Automatic No-Load Trip		Yes	Yes	Yes	Identical
Automatic shut Off		Yes	Yes	Yes	Identical

Feature		**New Device Omron Healthcare Maxpower Relief Model PM3032B**	**Primary Predicate Device PM3032 (MaxPower relief) K141978**	**Secondary Predicate Device Omron Avail K172079**	**Comment**
User over ride control		Yes, Power On/Off button	Yes, Power On/Off button	Yes, Power On/Off button on the device and in the App software	Identical to Maxpower Relief
Indication display	ON/Off status	Yes	Yes	Yes on App and LED indicator on main unit	Identical to Maxpower Relief
	Low Battery	Yes	Yes	Yes on App	Identical to Maxpower Relief
	Voltage/Current Level	Yes	Yes	Yes on App	Identical to Maxpower Relief
Timer Range (minutes)		15 (minutes)	15 (minutes)	5-60 (minutes) and 30-180 (minutes)	Identical to Maxpower Relief
Compliance with Voluntary standards		ES60601-1, IEC60601-1-2, IEC60601-2-10, IEC60601-1-11	ES60601-1, IEC60601-1-2, IEC60601-2-10, IEC60601-1-11	ES60601-1, IEC60601-1-2, IEC60601-2-10, IEC60601-1-11	Identical
Compliance with 21 CFR 898		Yes	Yes	N/A (no patient cable)	Identical to Maxpower Relief
Weight		Approx. 100g (incl. batteries)	Approx. 100g (incl. batteries	Device: Approx. 42 g (Both units have same weight) Pad-L: Approx. 21 g Pad-M: Approx. 17.5g Charger: Approx. 100g	Identical to Maxpower Relief
Dimensions (W x H x D)		52 x 112 x 25mm	52 x 112 x 25mm	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	Identical to Maxpower Relief

Feature	**New Device** **Omron Healthcare** **Maxpower Relief Model** **PM3032B**	**Primary Predicate Device** **PM3032** **(MaxPower relief)** **K141978**	**Secondary Predicate Device** **Omron Avail** **K172079**	**Comment**
			Pad-M: Approx. 180 × 79.5 × 9.3mm	
Operating conditions	10 to 40 ℃ 30 to 80 %RH 700 to 1060 hPa (non-condensing)	10 to 40 ℃ 30 to 80 %RH	10 to 40 ℃ 30 to 80 %RH 700 to 1060 hPa (non-condensing)	Similar to Maxpower Relief and same as Avail
Charging conditions	N/A (Battery-operated)	N/A (Battery-operated)	7 to 35 ℃(non-condensing)	Identical to Maxpower Relief
Transporting conditions	-20 to 60 ℃ 10 to 95% RH, 700 to 1060 hPa (non-condensing)	-20 to 60 ℃ 10 to 95% RH, 700 to 1060 hPa (non-condensing)	-20 to 60 ℃ 10 to 90% RH, 700 to 1060 hPa (non-condensing)	Identical to Maxpower Relief
Electrode style	Long Life Pad Reusable	Long Life Pad Reusable	HV-WPAD-M or HV-WPAD-L reusable	Identical to Maxpower Relief

In **Table 1** we have compared the Omron Healthcare Maxpower Relief Model PM3032B to the predicates for equivalence of:

Indications –
The indications for the Omron Healthcare Maxpower Relief Model PM3032B for the indications related to ProCode - NUH are identical to the predicate PM3032 (K141978). The added indications of "When used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis, use the Shoulder mode of stimulation." is similar to the predicate Avail (K172079) which also includes the ProCode - NYN.

Discussion – These indications are substantially equivalent to the predicates.

Prescriptive –
The Omron Healthcare Maxpower Relief Model PM3032B and predicates are all OTC.

Design, Technology and Principle of Operation –
The Omron Healthcare Maxpower Relief Model PM3032B is identical to the Maxpower Relief (K141978) as well as it has the equivalent design and features when compared to the Omron Avail (K172079).

Performance and Specifications –
The Omron Healthcare Maxpower Relief Model PM3032B is identical to the Maxpower Relief (K141978) and has equivalent performance specifications when compared to the Omron Avail (K172079).

Compliance with standards –
The Omron Healthcare Maxpower Relief Model PM3032B and predicate devices declare compliance with standards: AAMI ANSI ES6060-1, IEC 60601-1-2, IEC 60601-2-10, and IEC 60601-1-11 for home settings.

Materials –
The patient contacting materials (the LongLife Pads) of the PM3032B and predicate Maxpower Relief (K141978) are identical.

Patient Population –

The Omron Healthcare Maxpower Relief Model PM3032B and predicates are indicated for adults

Environment of Use –
Clinics, hospital and home environments, identical to the predicates

Differences –
There are no differences between the proposed device and the predicate devices that raise safety and efficacy concerns.

Non-Clinical Testing Summary -

Bench testing
The device has been tested to ensure that it 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 in accordance with IEC 60601-1-11

Clinical Testing Summary -
No clinical testing was performed

Usability –
Usability testing has not been performed on the PM3032B as it is identical to the predicate device Maxpower Relief (K141978)

This submission is for expanded indications as discussed in Sections 5 and 11, the expanded indications do not impact use of the device,

Biocompatibility of Patient Contacting Materials –
In accordance with ISO 10993-1 this is a surface device, skin (un-breached, not compromised), limited duration (<24 hours)

The patient contacting materials of the Omron Healthcare Maxpower Relief Model PM3032B and predicate Maxpower Relief (K141978) are identical.

Differences –
There are no differences between the proposed device and the predicate devices that raise any new safety and efficacy concerns. The results demonstrate that the devices perform as intended

are substantially equivalent to the performance of the predicate and in accordance with applicable standards.

Substantial Equivalence Conclusion

The Omron Healthcare Maxpower Relief Model PM3032B is substantially equivalent to the predicates in: indications for use, patient population, environment of use, technology characteristics, materials, specifications / performance and compliance with international standards. Minor differences as detailed in the substantial equivalence table above do not raise new or different questions of safety and effectiveness.