DEC - 8 2011

K110068

510(k) Summary
Page 1 of 6
7-Jan-11

Omron Healthcare, Inc.
1200 Lakeside Dr.
Bannockburn, IL 60015

Tel – 847-247-5626
Fax – 847-680-6911

Official Contact: Mirna DiPano – Director of Quality & Regulatory

Proprietary or Trade Name: PM3030

Common/Usual Name: Stimulator, nerve, transcutaneous, over-the-counter

Classification Name/Code: NUH – stimulator, nerve, transcutaneous, over-the-counter
21 CFR 882.5890

Device: PM3030

Predicate Devices: Endurance Therapeutics, Model T1040, 510(k) K060846

Device Description:
The PM3030 is a small, battery operated, three (3) output mode TENS device for pain relief intended for OTC use.

The output modes are intended for application to the following areas: Shoulder/Arm, Lower Back and Leg/Foot. The specifications of each mode will be discussed in greater detail later in this section.

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

As above the device is battery powered there is no connection to AC mains supply.

The device has been tested to and meets the requirements of the following recognized consensus standards:

- IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995

510(k) Summary
Page 2 of 6
7-Jan-11

- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004)).

Indications for Use:
This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.

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.
- Do not use this device together with a life-supporting medical electronic device such as an artificial heart or lung.
- Do not use this device together with a body-worn medical electronic device such as an ECG.

510(k) Summary
Page 3 of 6
7-Jan-11

Summary of substantial equivalence

Attribute	**Model PM3030**	**Predicate Endurance Model T1040 K060846**
Product Code	NUH	NUH, NGX, GZX
CFR	882.5890	882.5890, 890.5850
Indications for Use	This device is intended for the relief of pain associated with sore or aching muscles of the lower back, arms, or legs due to strain from exercise or normal household and work activities.	To be used for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household work activities choose Manual modes 1, 2, 3, 4, 5, 6 or Auto 4 To be used for temporary relief of pain associated with sore and aching muscles in the upper extremities (arm) due to strain from exercise or normal household work activities choose Manual modes 1, 2, 3, 4, 5, 6 or Auto 1 or Auto 3 To be used for temporary relief of pain associated with sore and aching muscles in the lower extremities (leg) due to strain from exercise or normal household work activities choose Manual modes 1, 2, 6 or Autol or Auto 4 Used to stimulate healthy muscles in order to improve and facilitate muscle performance choose Manual Mode 1 or Auto Mode 2 Prescription
Patient Population	Adult	Not specified
Prescriptive or OTC	OTC	OTC

510(k) Summary
Page 4 of 6
7-Jan-11

Environment of use	Clinics, hospital and home environments	Not specified
Contraindications – do not use if you have a cardiac pacemaker, implanted defibrillator or other implanted metallic or electronic device	Yes	Yes
Warnings standard	Yes	Yes
Precautions – standard	Yes	Yes
Adverse reactions – standard	Yes	Yes
Power source	2 - AAA	3 - AAA
Number of Output modes	3	10
Number of output channels	1	1
Waveform	Biphasic	
Shape	Rectangular	
Maximum Output Voltage (max) 500 ohm 2k ohm 10k ohm	 35.4 V 46.7 V 50.8 V	 40.7 105.1 154.1
Maximum Output Current (max) 500 ohm 2k ohm 10k ohm	 4.4 mA 1.7 mA 0.4 mA	 81.4 47.8 15.4
Maximum Phase charge (500 ohm)	133 microC	16.9 microC
Maximum Current Density (500 ohm)	0.095 mA/cm^2	2.71 mA/ cm^2
Maximum Average Current (500 ohm)	3.5 mA	Not specified
Maximum Average Power Density (500 ohm)	89 mW/cm^2	10.2 mW/cm^2
Frequency (Hz)	< 100 Hz	245 Hz
Burst Mode	None	
Timer range (min)	15 minutes	30 minutes
Indication display On/Off status Low battery Voltage / Current level Output mode Time to cut-off	 Yes No Yes Yes No	 Yes Yes Yes Yes Yes
Dimensions	55 mm x 95 mm x 19 mm	150 mm x 68 mm x 26 mm
Weight	60 grams	90 grams

510(k) Summary
Page 5 of 6
7-Jan-11

Housing material	ABS	Not specified
Microprocessor control	Yes	Yes
Automatic Overload trip	Yes	Not specified
Automatic no-load trip	Yes	Not specified
Automatic shut-off	Yes	Not specified
User override control	Power On/Off button	Not specified
Electrode compliance with 21 CFR 898	Yes	Not specified
Electrode cable	Yes	Yes

Differences Between Other Legally Marketed Predicate Devices
The Omron PM3030 OTC TENSis viewed as substantially equivalent to the predicate device because: The electrical stimulation provided by the PM3030 is substantially equivalent to that commonly employed by TENS devices that have been cleared for marketing without prescription labeling; i.e., for OTC sale. The pulses in the waveform combinations are restricted in amplitude and duration to values consistent with other cleared devices.
Technological characteristics, features, specifications, materials and intended uses of the PM3030 are substantially equivalent to the quoted predicate devices.
The differences that exist between the devices are insignificant in the terms of safety or effectiveness.

Indications –

The PM3030 and the predicate (Endurance Model T1040 K060846) are for the temporary relief of pain associated with sore and aching muscles in the upper and lower extremities and lower back due to strain from exercise or normal household and work activities and we view them as equivalent. Performance testing has been performed that shows equivalent waveform characteristics.

Technology –

- Identical both the PM3030 and the predicate provide electrically generated pulses applied to the skin via electrodes.

Operating specifications –

- Equivalent. Section 12 provides detailed descriptions of the characteristics of the PM3030 and the predicate. They are equivalent.

510(k) Summary.
Page 6 of 6
7-Jan-11

Materials –

- The patient contacting materials of the electrode has been tested in accordance to ISO 10993-1 and FDA Guidance.

Environment of Use –

- Both are OTC devices so assume same environment

Patient Population –

- PM3030 is restricted to adults

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 8 2011

Omron Healthcare, Inc.
c/o Mr. Paul E. Dryden
President, Regulatory Consultant
ProMedic, Inc.
24301 Woodsage Drive
Bonita Springs, FL 34134-2958

Re: K110068
Trade/Device Name: Model PM3030
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: October 25, 2011
Received: October 26, 2011

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: _____ (To be assigned)

Device Name: Model PM3030

Indications for Use:

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

Prescription Use __ (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use XX** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marsha L. Burke Nicholas

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K110068