DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 5, 2016

Newmark, Inc
c/o Cherita James
Regulatory Consultant
M Squared Associates, Inc.
575 8th Ave, Suite 1212
New York, NY 10018

Re: K151995
Trade/Device Name:
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator
Regulatory Class: Class II
Product Code: NUH
Dated: August 31, 2016
Received: September 1, 2016

Dear Ms. James:

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 Parts 801 and 809]); medical device reporting

(reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.10.05 16:32:48 -04'00'

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151995

Device Name
Painmaster MCT Patch

Indications for Use *(Describe)*
The Painmaster MCT Patch is indicated for:

-temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

-temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

-symptomatic relief of chronic, intractable pain.

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

The following information is provided as required by 21 CFR § 807.87 for the Painmaster MCT Patch 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

Sponsor: Newmark Inc.
131 Quarry Village Rd.
Cheshire, CT 06410

Manufacturer Newmark Inc.
PO Box 896
Cheshire, CT 06410
Registration Number: 1226514

Contact: M Squared Associates, Inc.
Cherita James
575 8th Ave, Suite 1212
New York, New York 10018
Ph. 703-562-9800 Ext 257
Fax. 703-562-9797

Date of Submission: August 31, 2016

Proprietary Name: Painmaster MCT Patch

Common Name: Transcutaneous electrical nerve stimulator for pain relief , over-the-counter

Regulation Number: 21 CFR 882.5890

Regulatory Class: II

Product Code: NUH**Predicate Device(s):** Painmaster MCT Patch (K090042 & K130114), Newcare MCT F5 (K013167)

Device Description: The Painmaster MCT Patch operates in a single non-programmable microcurrent mode, delivering a pulsed monophasic waveform that provides electrical stimulation to the body to relieve pain. The Painmaster MCT Patch consists of two electrodes mounted on adhesive material connected by a small-diameter wire. One electrode contains the control unit that includes a small circuit board, a battery, and an LED light.

Intended Use: The Painmaster MCT Patch is indicated for:

- temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.
- temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.
- symptomatic relief of chronic, intractable pain.

Technological Characteristics

The technological characteristics of the Painmaster MCT Patch are identical to the device cleared under K090042, K130114, and MCT F5 model K013167.

Performance Testing

Additional performance testing was not required to determine the substantial equivalence of this device because the device is the same as the device previously cleared via 510(k) K090442, K130114 and MCT F5 model K013167.

The MCT Patch is compliant with the following standards.

- IEC/EN60601-1, 3rd Ed, (2012) Medical Electrical Equipment Part1: General Requirements for Safety and essential performance.
- UL2601-1 Medical Electrical Equipment Part1: General Requirements for Safety and essential performance
- IEC 60601-2-10, Medical Equipment Part2: Particular Requirements for the Safety of Nerve and Muscle Stimulators.
- IEC/EN60601-1-2: Electromagnetic Emissions and Immunity Requirements for Medical Electrical Equipment.

Usability Study

A usability study was conducted in support of the K090042 submission and demonstrated that users could correctly identify themselves as candidates for treatment, and could properly assemble and apply the device according to the instructions for use. The revised labeling is comparable to the previous labeling in presentation of device selection and application.

No additional usability evaluation or clinical data was required in support of this submission.

Device Comparisons-Prior MCT Patch Clearance

	Painmaster MCT Patch(Newmark Inc) Subject device	**Painmaster MCT Patch (Newmark Inc)**	**MCT F5 model (Newcare currently DBA Newmark Inc.)**
K number	Not yet assigned	K090042 & K130114	K013167
Product Code	NUH	NUH	GZJ
Indication for Use	Temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities. Temporary relief of pain associated with sore and aching muscles in the upper and lower extremity (arm and/or leg) due to strain from exercise or normal household and work activities. Symptomatic relief of chronic, intractable pain.	Temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities. Temporary relief of pain associated with sore and aching muscles in the upper and lower extremity (arm and/or leg) due to strain from exercise or normal household and work activities.	To be used for the symptomatic relief of chronic, intractable pain.
Prescription or OTC	OTC	OTC	Prescribed
Power Source	3 V Li Battery	3 V Li Battery	3 V Li Battery
Number of Channels	1	1	1
Regulated Current or Regulated Voltage?	Current	Current	Current
Waveform	Continuous, monophasic only	Continuous, monophasic only	Continuous, monophasic only
Shape	Rectangular	Rectangular	Rectangular
Max output voltage (+/- %)	21mV@500 ohms	21mV@500 ohms	21mV@500 ohms
Max output current-specify units (+/- %)	42µA @500 ohms	42µA @500 ohms	42µA @500 ohms
Frequency[t] (Hz) [or Rate[t] (pps)]	0.5pps	0.5pps	0.5pps

Conclusion

The Painmaster MCT Patch as the same intended use and technological characteristics as the cleared devices (K090042, K130114, and K013167). Minor revisions to labeling to include the indications for over-the-counter use do not impact the safety or effectiveness. Differences in the Painmaster MCT Patch and the predicate devices do not present new issues of safety and effectiveness.