February 27, 2019

Marchan Medical, LLC
Mark Chandler
Managing Partner
165 S Ashe St.
Southern Pines, North Carolina 28387

Re: K182267
Trade/Device Name: PAT (Pain Alleviation Technologies)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: January 18, 2019
Received: January 28, 2019

Dear Mark Chandler:

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

Digitally signed by Pamela D. Scott -S
Date: 2019.02.27 21:10:33 -05'00'

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)*
K182267

Device Name
PAT

Indications for Use *(Describe)*
Temporary relief of pain associated with sore and aching muscles and joints due to strain from exercise or normal household and work activities.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Marchan Medical LLC
marchanmedical.com

510(K) Summary

PAT is an OTC medical device. This device is used for temporary relief of pain of sore and aching muscles and joints, due to strain from exercise or normal household and work activities. The device consists of a small battery operated enclosure with an LCD screen and user buttons to control the device. A monophasic micro-current waveform is transmitted to the affected body part through a cable connected via snaps to skin surface electrodes. There are 8 non-programmable modes representing 8 different body areas to treat.

Sponsor: Marchan Medical, LLC
165 S Ashe St
Southern Pines, NC 28387

Contact Person: Mark Chandler, MD

Phone: 910-783-5285

Email: Markmd@marchanmedical.com

Date of Original Submission: August 15, 2018

Proprietary Name: PAT

Common Name: Transcutaneous electrical nerve stimulator (TENS)

Classification Name: Stimulator, nerve, Transcutaneous, Over-the-Counter

Regulation Number: 21 CFR 882.5890

Regulatory Class: II

Product Code: NUH

Classification Panel: Neurology

Predicate Device: Painmaster MCT Patch (K130114)

Indications for Use:

Temporary relief of pain associated with sore and aching muscles and joints due to strain from exercise or normal household and work activities.

Basic Unit Characteristics

PAT uses Painmaster MCT Patch as the predicate device.

Parameter	Painmaster MCT Patch Predicate Device (K130114)	PAT Proposed Device (K182267)
Manufacturer Specifications Developer	Newmark, Inc.	Shenzhen Bless Electronic Technology Co., Ltd. Marchan Medical, LLC
Product Code	NUH	NUH
Environment of use	Clinics, hospital and home environment	Clinics, hospital and home environment
Indications for Use	Temporary relief of pain associated with sore and aching muscles in the upper and lower extremities due to strain from exercise or normal household and work activities.	Temporary relief of pain associated with sore and aching muscles and joints due to strain from exercise or normal household and work activities.
Patient Population	Adult	Adult
Operation Mode	Waveform: monophasic square wave with 50% duty cycle. Amplitude: 42 µA Frequency: 0.5 Hz	Waveform: monophasic square wave. with 50% duty cycle. Amplitude:40 µA Frequency: 3 Hz
Power Source	Primary battery only. One time use.	Primary battery only. 3 replaceable AAA batteries, not rechargeable.
Operational Indicator	Yes, LED light	Yes, LCD screen
Time Range	Not adjustable, up to 300 hours	40-55 minutes depending on area treated
Housing Materials and Construction	Plastic (ABS) enclosure	Plastic (ABS) enclosure

Marchan Medical LLC
marchanmedical.com

Body contact material	Electrode, CE certified	Electrode, FDA cleared
Maximum Average Current	42 µA	40 µA
OTC Use	Yes	Yes
Dimensions (in.) W x H xD	1.6 x 0.3 x 1	6 x 2.75 x 1
Weight	0.03 lb.	0.25 lb.
Operating Temperature and Humidity	10-45°C, 20%-90%	10-45°C, 20%-90%
Method of Line Current Isolation	N/A	N/A
Patient Leakage Current	Type BF	Type BF
Normal Condition	0	0
Single Fault Condition	50 µA	50 µA
Average DC current through electrodes when device is on but no pulses being applied	N/A (Pulse is always applied when on)	0
Number of Output Modes	1	1 (8 different timings based on body part being treated but only one preset waveform)
Number of Output Channels	1	1
Regulated Current of Voltage	Regulated Current	Regulated Current
Software/Firmware/ Microprocessor Control?	Yes	Yes
Automatic Overload Trip	Yes	Yes
Automatic No-Load Trip	Yes	Yes
Automatic Shut-Off	Yes	Yes
Indicator Display: On/Off Status?	Yes	Yes
Indicator Display: Low Battery?	No	No
Indicator Display: Voltage/Current Level	No	No
Compliance with Voluntary Standards?	EN 60601-1 HA60601-1-11 IEC 60601-1-2 IEC 60601-2-10	AAMI ES 60601-1 IEC 60601-1-2 IEC 60601-2-10
Compliance with 21 CFR 898	N/A	N/A
Electrode cable	4 Inch snap	40 inch double snap, 3.5mm

Output Specifications

Parameter	Predicate Device	Proposed Device
Product Name	Painmaster MCT Patch	PAT
510(K) number	K130114	K182267
Number of output modes	1	1 (8 different timings based on body part being treated but only one preset waveform)
Number of output channels	1	1
Waveform	Square monophasic, 50% duty cycle	Square monophasic, 50% duty cycle
Maximum output Voltage (max) 500 Ω 2K Ω 10K Ω	500 Ω : 22mV 2K Ω: 84mV 10K Ω: 370mV	500 Ω :20.8 mV 2K Ω: 82.0 mV 10K Ω: 416 mV
Maximum output Current (max) 500 Ω 2K Ω 10K Ω	500 Ω : 42 μA 2K Ω: 42 μA 10K Ω: 37 μA	500 Ω : 41.6μA 2K Ω: 41.0 μA 10K Ω: 41.6 μA
Max. Phase charge @500 Ω (Phase charge=pulse duration X current amplitude)	44 microcoulombs	6.9 microcoulombs
Max. Average Current @500Ω	42 μA	41.6 μA
Max. Current density @500 Ω)	0.002 mA/ cm^2	0.0016 mA/cm^2 (using included 5X5cm electrodes)
Maximum Power Density (500 Ω)	0.00005mW/cm^2	0.000035 mW / cm^2 (using included 5X5cm electrodes)

Frequency (Hz)	0.5Hz	3 Hz
Pulse Duration	1.0 sec	0.166 sec
Burst Mode	N/A	N/A
Timer range (min)	0-300 hours, depending on battery life	40-55 min selectable by MODE.

The conclusions drawn from the nonclinical tests described above demonstrate that the device is as safe and effective as the predicate device. The waveform used in both devices is similar with a square waveform with a 50% duty cycle as discovered with oscilloscope readings. The indications for use are very similar, both devices met the same test standards, and both use very low frequency pulses.