DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 21, 2015

TrioWave Technologies
Attn: Ms. Parul Chansoria
Regulatory Consultant for TrioWave Technologies
3984 Washington Blvd. #166
Fremont, CA 94538

Re: K151034
Trade Name: PainKARE
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: October 20, 2015
Received: October 23, 2015

Dear Ms. Chansoria:

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 27f 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 contact 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. 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,

Carlos L. Pena -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151034

Device Name
PainKARE

Indications for Use *(Describe)*
The PainKARE is indicatied for Temporary relief of pain of sore and aching muscles, joints, and tissues 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.

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5. 510 (K) Summary

This 510(k) Summary has been created per the requirements of the Safe Medical Device Act (SMDA) of 1990, and the content is provided in conformance with 21 CFR Part 807.92.

5.1 Submitter's Information

Table 1-Submitter's Information	
Submitter's Name: Company: Address:	Huiyou Zhu, Founder TrioWave Technologies. 3984 Washington Blvd., #166 Fremont, CA 94538
Contact Person:	Parul Chansoria, Elexes; Elexes Medical Consulting Pvt Ltd.
Phone:	650-528-2445
Fax:	---------
Email:	parul@elexes.com
Date of Summary Preparation:	October 20, 2015

5.2 Device Information

Table 2-Device Information	
Trade Name:	PainKARE
Common Name:	Transcutaneous electrical nerve Stimulator
Classification Name:	Stimulator, nerve, Transcutaneous, Over-the-counter
Classification Number:	Class II per 21 CFR 882.5890(b)
Product Code:	NUH
Classification Panel:	Neurology

5.3 Predicate Device Information

Painmaster MCT Patch (K090042; K130114)

5.4 Device Description

PainKARE is an OTC medical device intended to temporarily relieve pain due to strain from exercise or normal household work or activities via electro-therapy. The Device consists two Stimulator pads connected by a USB cable for Electrotherapy.

PainKARE's Stimulator pads operate in a programmable micro-current mode and deliver Biphasic waveforms which in turn provide electrical stimulation to the body that aids in relieving pain.

5.5 Indications for Use

The PainKARE system is indicated for "temporary relief of pain of sore and aching muscles, joints, and tissues due to strain from exercise or normal household and work activities".

5.6 Technological Characteristics

The PainKARE (Subject Device) makes use of two Predicate Devices; Painmaster MCT Patch (K090042; K130114) for the Stimulator pads (for electrotherapy).

5.6.1 PainKARE (Stimulator pads) vs. Painmaster MCT Patch (K090042; K130114)

Table 3-PainKARE (Stimulator pads) vs. Painmaster MCT Patch (K090042; K130114)

Parameter	Painmaster MCT Patch (Predicate Device) K090042	Painmaster MCT Patch (Predicate Device) K130114	Proposed Device (Subject Device) PainKARE Stimulator
Manufacturer	Newmark Inc.	Newmark Inc.	TrioWave Technologies
Indications 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 extremities (arm and/or leg)** due to strain from exercise or normal household and work activities.	Temporary relief of pain of sore and aching muscles, joints, and tissues due to due to strain from exercise or normal household and work activities.
Operation Mode	Waveform: pulsed square wave. Amplitude: 50µA Frequency: 0.5Hz Polarity: Mono-phasic	Waveform: pulsed square wave. Amplitude: 50µA Frequency: 0.5Hz Polarity: Mono-phasic	Waveform: pulsed square wave. Amplitude: 50µA Frequency: 0.3Hz Polarity: Biphasic (Alternating Mono-phasic)
Power Source(s)†	Primary battery only. One time use	Primary battery only. One time use	Primary Battery only. Rechargeable
Micro-processor Control	Yes	Yes	Yes

Table 3-PainKARE (Stimulator pads) vs. Painmaster MCT Patch (K090042; K130114)			
Parameter	**Painmaster MCT Patch (Predicate Device) K090042**	**Painmaster MCT Patch (Predicate Device) K130114**	**Proposed Device (Subject Device) PainKARE Stimulator**
Automatic Overload Protection	Yes	Yes	Yes
Automatic No Load Alarm	Yes	Yes	Yes
User Override Control	No	No	Yes
Operational Indicator	Yes	Yes	Yes
Time Range	Not adjustable. Up to 250 hours	Not adjustable. Up to 250 hours	30 minutes to 4 hours, depending on pain
Housing Materials and Construction	Plastic (ABS) enclosure	Plastic (ABS) enclosure	Plastic (ABS) enclosure
Body contact material	Electrode, CE certified	Electrode, CE certified	Electrodes, FDA approved
Maximum Average current	50 µA	50µA	50µA
OTC use	Yes	Yes	Yes
Dimensions (in.) [W x H x D]	1.55 x 0.29x1	1.55 x 0.29x1	1.2” x0.6” x1.6”
Weight	0.03 lb.	0.03 lb.	0.1 lb.
Operating temperature and humidity	10-45°C, 20%-90%	10-45°C, 20%-90%	10-45°C, 20%-90%
- Method of Line Current Isolation	N/A	N/A	N/A
- Patient Leakage Current††	Type CF	Type CF	Type BF
- Normal Condition (µA)	Unspecified	Unspecified	0
- Single Fault Condition (µA)	Unspecified	Unspecified	50µA
Average DC current through electrodes when device is on	0	0	N/A (Pulse always applied when on)

Table 3-PainKARE (Stimulator pads) vs. Painmaster MCT Patch (K090042; K130114)				
Parameter		**Painmaster MCT Patch (Predicate Device) K090042**	**Painmaster MCT Patch (Predicate Device) K130114**	**Proposed Device (Subject Device) PainKARE Stimulator**
but no pulses are being applied (µA)				
Number of output modes		1	1	2
Number of Output Channels ††††:	**Synchronous or Alternating?**	1 channel, monophasic	1 channel, monophasic	1 channel, biphasic (alternating monophasic)
	Method of Channel Isolation	NA	NA	NA
Regulated Current or Regulated Voltage?		Regulated Current	Regulated Current	Regulated Current
Software/Firmware /Microprocessor Control?		Yes	Yes	Yes
Automatic Overload Trip?		No	No	Yes
Automatic No-Load Trip?		Yes	Yes	Yes
Automatic Shut Off?		Yes	Yes	Yes
Indicator Display:	**On/Off Status?**	Yes	Yes	Yes
	Low Battery?	No	No	Yes
	Voltage/ Current Level?	No	No	No

Table 3-PainKARE (Stimulator pads) vs. Painmaster MCT Patch (K090042; K130114)			
Parameter	**Painmaster MCT Patch (Predicate Device) K090042**	**Painmaster MCT Patch (Predicate Device) K130114**	**Proposed Device (Subject Device) PainKARE Stimulator**
Compliance with Voluntary Standards?	Yes, UL260, EN60601-2 Part1, A1 & A2 EN 60601-2-10, Part 2-10 EN 60601-1-2 EMI	Yes, UL260, EN60601-2 Part1, A1 & A2 EN 60601-2-10, Part 2-10 EN 60601-1-2 EMI	Yes, AAMI ES 60601-1, AAMI HA60601-1-11, IEC 60601-1-2 IEC 60601-1-6, IEC 60601-2-10,
Compliance with 21 CFR 898[7]?	N/A	N/A	N/A

Similarities:

- The Subject and the Predicate devices have the same intended use and indications for use.
- Both the Subject and Predicate devices have similar technological characteristics, namely, number of output channel and output current (50µA), and have the same operating temperature and humidity ranges.
- Both devices are microprocessor controlled, and utilize certified/cleared electrode pads.
- The Subject and the Predicate Devices also have same features like the automatic overload trip protection, automatic no load trip, automatic shut off, operational Indicator and no current display.
- The subject device has rechargeable battery whereas the Predicates do not have a rechargeable battery.

Differences:

- The Subject device operates in biphasic waveforms/modes, whereas the Predicates only operates in monophasic mode/waveform.
- There are some minor technological differences namely user override control etc.

5.7 Performance Data

The following Performance testing has been performed on the Subject Device in accordance with appropriate FDA guidance documents and relevant standards, to support the determination of substantial equivalence. The test data showed that the Subject device is safe and effective for its intended use as compared to the Predicate.

- The Subject Device was tested to conform to the electrical and safety requirements established in AAMI ES 60601-1 and the electromagnetic compatibility requirements in IEC 60601-1-2.
- The Subject Device was also tested to conform to IEC 60601-1-6, and AAMI HA60601-1-11 and IEC 60601-2-10.

5.8 Conclusion

Based on the comparison of intended use and key technological characteristics, the PainKARE (Subject Device) is substantially equivalent to the Predicate Device.