December 23, 2019

UMEHEAL Ltd.
% Randy Jiang
Senior Consultant
Emergo Global Consulting , LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K192733
Trade/Device Name: RelieforMe TENS/EMS Device Model UPK-GE01
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ, NUH
Dated: September 3, 2019
Received: September 27, 2019

Dear Randy Jiang:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Vivek Pinto, Ph.D.
Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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)*
K192733

Device Name
RelieforMe TENS/EMS Device Model UPK-GE01

Indications for Use *(Describe)*
TENS:
1. It is intended for temporary relief of pain associated with sore and aching muscles in the shoulder, neck, back, waist, abdomen, lower extremities (legs), upper extremities (arms) due to strain from exercise or normal household and work activities.
2. It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.
EMS:
3. To stimulate healthy muscles to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the intended areas on the body.
4. To be used for relaxation of muscle spasm, increase of blood flow circulation, prevention or retardation of disuse atrophy, muscle re-education, maintaining or increasing range of motion, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

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

1. Submission Sponsor

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3. Date Prepared

11/20/2019

4. Device Identification

Trade or Proprietary Name: RelieforMe TENS/EMS Device Model UPK-GE01
Common or Usual Name: Powered Muscle Stimulator
Regulation Number: 890.5850, 882.5890
Product Code: IPF, GZJ, NUH
Class: Class 2
Panel: Neurology

5. Legally Marketed Predicate Device(s)

Device name: Mini TENS DEVICE (Model KRES102), TENS & EMS DEVICE (Model KRES100B)
Model: KRES100B
510(k) number: K172933
Manufacturer: Shenzhen Conree Technology Co.,Ltd

Device name: Electronic Pulse Stimulator
510(k) number: K162517
Manufacturer: JKH Health Co., Ltd.

Device name: Pulserelief
510(k) number: K151035
Manufacturer: PHILIPS CONSUMER LIFESTYLE

Reference devices:

Device name: JIAJIAN self-adhesive electrode
510(k) number: K090198
Manufacturer: WUXI JIAJIAN MEDICAL INSTRUMENT CO., LTD.

Device name: SYNAPTIC 3000
510(k) number: K940954
Manufacturer: THE SYNAPTIC CORP.

6. Indication for Use Statement

TENS:

1. It is intended for temporary relief of pain associated with sore and aching muscles in the shoulder, neck, back, waist, abdomen, lower extremities (leg), upper extremities (arm) due to strain from exercise or normal household and work activities.

2. It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

EMS:

3. To stimulate healthy muscles to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the intended areas on the body.

4. To be used for relaxation of muscle spasm, increase of blood flow circulation, prevention or retardation of disuse atrophy, muscle re-education, maintaining or increasing range of motion, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

7. Device Description

RelieforMe TENS/EMS Device model UPK-GE01 is designed to focus on pain relief, muscle strengthening and recovery features with TENS/EMS treatment techniques driven and controlled by intelligent programs/software.

RelieforMe TENS/EMS Device, a TENS/EMS combination device, is intended for temporary relief of pain associated with sore and aching muscles in the shoulder, neck, back, waist, abdomen, lower extremities (leg), upper extremities (arm) due to strain from exercise or normal household and work activities. The device is for 18 and older.

The device provides pain relief based on the intelligent use of the key pain-killer mechanisms of TENS (Transcutaneous Electrical Nerve Stimulation).

8. Substantial Equivalence Discussion

The following table compares the RelieforMe TENS/EMS Device Model UPK-GE01 to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 5A – Comparison of Characteristics

Attribute	**SUBJECT DEVICE** RelieforMe TENS & EMS DEVICE Model:UPK-GE01	**PREDICATE DEVICE 1** Mini TENS DEVICE (Model KRES102), TENS & EMS DEVICE Model KRES100B	**PREDICATE DEVICE 2** Electronic Pulse Stimulator	**PREDICATE DEVICE 3** Pulserelief
510(k) Number	N/A	K172933	K162517	K151035
Product Code	IPF, GZJ, NUH	IPF, GZJ, NUH	NUH, NGX, NYN, IRT	NUH, NGX
Regulation Number	890.5850, 882.5890	890.5850, 882.5890	882.5890	890.5850,882.5890
Intended Use	TENS: It is intended for temporary relief of pain associated with sore and aching muscles in the shoulder, neck, back, waist, abdomen, lower extremities (leg), upper extremities (arm)due to strain from exercise or normal household and work activities. It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. EMS: To stimulate healthy muscles to improve and	Mini TENS Device (Model KRESl02) is to be used for the temporary relief of pain associated with sore and aching muscles in the arm, shoulder, neck, back, waist, abdomen, and leg due to strain from exercise or normal household and work activities. TENS & EMS Device (Model KRESl00B) has two functions and can be used for arm, shoulder, neck, back, waist, abdomen, and leg. TENS: It is used for the symptomatic relief of chronic intractable pain and the temporary relief of pain associated with sore and aching muscles in the arm, shoulder, neck, back, waist,	TENS (Modes 1, 2, 4, 5, 6, 8) To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities. It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. PMS (also called EMS, Modes 1, 3, 7) To stimulate healthy muscles in order to improve and facilitate	The OTC TENS/EMS stimulator PulseRelief is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities(arm) and lower extremities (leg) due to strain from exercise or normal household work activities. It should be applied to normal, healthy, dry and clean skin of adult patients, and is to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

Attribute	SUBJECT DEVICE RelieforMe TENS & EMS DEVICE Model:UPK-GE01	PREDICATE DEVICE 1 Mini TENS DEVICE (Model KRES102), TENS & EMS DEVICE Model KRES100B	PREDICATE DEVICE 2 Electronic Pulse Stimulator	PREDICATE DEVICE 3 Pulserelief
	facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the intended areas on the body. To be used for relaxation of muscle spasm, increase of blood flow circulation, prevention or retardation of disuse atrophy, muscle re-education, maintaining or increasing range of motion, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.	abdomen, and leg due to strain from exercise or normal household and work activities. EMS: It is used for relaxation of muscle spasm, increase of blood flow circulation, prevention or retardation of disuse atrophy, muscle re-education, maintaining or increasing range of motion, and immediate post-surgical stimulation of calf muscles to prevent venous thrombosis	muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases. It is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities. Heating Mode Temporary relief of minor aches and pains.	
Power Sources	Lithium Ion Polymer battery	3.0V\210mAh Button lithium manganese battery	Rechargeable battery	Li-ion 3.7V 500mAh
Software/Firmware/Microprocessor control	Yes	Yes	Yes	Yes
Automatic Overload Trip	Yes	Yes	Unknown	Yes
Automatic No- load Trip	Yes	Yes	Unknown	Yes
Automatic Shut Off	Yes	Yes	Unknown	Yes
Maximum Output Voltage	61V ± 20%@ 500Ω 65V ± 20%@@ 2kΩ 65V± 20%@ @ 10kΩ	28.2V@500Ω 48.4V @ 2kΩ 82V @ 10kΩ	@ 500Ω: Mode 1: This mode cycles the following modes Mode 2: 36.4V ± 20% Mode 3: 47.6V ± 20% Mode 4: 57.6 V± 20%	Both TENS & EMS: 31V ± 20% @ 500Ω 69V ± 20% @ 2kΩ 70V ± 20% @ 10kΩ

Attribute	SUBJECT DEVICE RelieforMe TENS & EMS DEVICE Model:UPK-GE01	PREDICATE DEVICE 1 Mini TENS DEVICE (Model KRES102), TENS & EMS DEVICE Model KRES100B	PREDICATE DEVICE 2 Electronic Pulse Stimulator	PREDICATE DEVICE 3 Pulserelief
			Mode 5: 29.6V ± 20% Mode 6: 29.6V ± 20% Mode 7: 40.8V ± 20% Mode 8: 24.0V ± 20% @ 2kΩ: Mode 1: This mode cycles the following modes Mode 2: 80.8V ± 20% Mode 3: 96.0V ± 20% Mode 4: 93.6V ± 20% Mode 5: 66.4V ± 20% Mode 6: 66.4V ± 20% Mode 7: 86.4V ± 20% Mode 8: 53.6V ± 20% @ 10kΩ: Mode 1: This mode cycles the following modes Mode 2: 134V ± 20% Mode 3: 132V ± 20% Mode 4: 108V ± 20% Mode 5: 126V ± 20% Mode 6: 126V ± 20% Mode 7: 129V ± 20% Mode 8: 105V ± 20%	
Maximum output Current	122mA ± 20%@ 500Ω 32.5mA ± 20%@ 2kΩ 6.5mA ± 20%@ 10kΩ	56.4mA@500Ω 24.2mA @2kΩ 8.2mA@10kΩ	@ 500Ω: Mode 1: This mode cycles the following modes Mode 2: 72.8mA ± 20% Mode 3: 95.2mA ± 20% Mode 4: 115.2mA ± 20% Mode 5: 59.2mA ± 20% Mode 6: 59.2mA ± 20% Mode 7: 81.6mA ± 20% Mode 8: 48.0mA ± 20%	Both TENS & EMS: 62mA± 20% @ 500Ω 34mA± 20% @ 2kΩ 7mA± 20% @ 10kΩ

Attribute	SUBJECT DEVICE RelieforMe TENS & EMS DEVICE Model:UPK-GE01	PREDICATE DEVICE 1 Mini TENS DEVICE (Model KRES102), TENS & EMS DEVICE Model KRES100B	PREDICATE DEVICE 2 Electronic Pulse Stimulator	PREDICATE DEVICE 3 Pulserelief
			@ 2kΩ: Mode 1: This mode cycles the following modes Mode 2: 40.4mA ± 20% Mode 3: 48.0mA ± 20% Mode 4: 46.8mA ± 20% Mode 5: 33.2mA ± 20% Mode 6: 33.2mA ± 20% Mode 7: 43.2mA ± 20% Mode 8: 26.8mA ± 20% @ 10kΩ: Mode 1: This mode cycles the following modes Mode 2: 13.4mA ± 20% Mode 3: 13.2mA ± 20% Mode 4: 10.8mA ± 20% Mode 5: 12.6mA ± 20% Mode 6: 12.6mA ± 20% Mode 7: 12.9mA ± 20% Mode 8: 10.5mA ± 20%	
Frequency range	For TENS: 1~1200HZ For EMS: 1~100HZ	1~117.3Hz	Mode 1: This mode cycles the following modes Mode 2: 62.5HZ Mode 3: 12.8~54.3HZ Mode 4: 1.19HZ Mode 5: 104.1HZ Mode 6: 104.1HZ Mode 7: 19.8HZ	For TENS: 1~100HZ For EMS: 40 ~ 65 HZ

Attribute	**SUBJECT DEVICE** RelieforMe TENS & EMS DEVICE Model:UPK-GE01	**PREDICATE DEVICE 1** Mini TENS DEVICE (Model KRES102), TENS & EMS DEVICE Model KRES100B	**PREDICATE DEVICE 2** Electronic Pulse Stimulator	**PREDICATE DEVICE 3** Pulserelief
			Mode 8: 156.2HZ PS: TENS (Modes 1, 2, 4, 5, 6, 8), PMS (also called EMS, Modes 1, 3, 7)	
Pulse width range	TENS:4~300μs; EMS:250~400μs	TENS:96~260μs; EMS:150~260μs sss	Unknown	TENS: 60 ~ 350 μs EMS: 150 ~ 350 μs
Patient Leakage Current	<1uA	N/A	N/A	<10uA
Method of Channel Isolation	N/A (1 output channel)	Unknown	Unknown	N/A (1 output channel)
Maximum Phase Charge (μC)	TENS： 36.6μC @ 500Ω 9.75μC @ 2kΩ 1.95μC @ 10kΩ EMS： 48.8μC @ 500Ω 13.0μC @ 2kΩ 2.6μC @ 10kΩ	N/A	@ 500Ω: Mode 1: This mode cycles the following modes Mode 2: 14.6μC Mode 3: 19.0μC Mode 4: 23.0μC Mode 5: 11.8μC Mode 6: 11.8μC Mode 7: 16.3μC Mode 8: 9.6μC	TENS: 1.6~6.8μC@500Ω EMS: 4.7~10.9μC@ 500Ω
For interferential modes only: - Beat Frequency (Hz)	N/A	N/A	N/A	N/A
For multiphasic waveforms only: - Symmetrical phases?	YES	Unknown	Unknown	YES
Phase Duration	TENS:4~300μs EMS:250~400μs	Unknown	Unknown	TENS:25~175μs EMS: 75~175μs
Biocompatibility	Compliant with requirements of ISO10993-5 and ISO10993-10 standards	Compliant with requirements of ISO10993-5 and ISO10993-10 standards	Unknown	Unknown
Electrical Safety	Compliant with requirements of IEC60601-1, IEC60601-	Compliant with requirements of IEC60601-1, IEC60601-2-	Unknown	IEC 60601-1, IEC 60601-2-10, ISO10993-5/10

Attribute	SUBJECT DEVICE RelieforMe TENS & EMS DEVICE Model:UPK-GE01	PREDICATE DEVICE 1 Mini TENS DEVICE (Model KRES102), TENS & EMS DEVICE Model KRES100B	PREDICATE DEVICE 2 Electronic Pulse Stimulator	PREDICATE DEVICE 3 Pulserelief
	2-10, IEC60601-1-2 safety standards	10, IEC60601-1-2 safety standards		
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Unknown	IEC 60601-1-2
Sterility	N/A	N/A	N/A	N/A

Reference Devices Summary:

Reference device K090198:

- The material of electrode pad in contact with patient is identical to that material cleared under K090198 JIAJIAN self-adhensive electrode, the subject device's biocompatibility of material contacted with patient was evaluated under K090198. Therefore, we chose K090198 as reference device to demonstrate biocompatibility safety.

Reference device K940954:

- Similar to the subject device, Synaptic 3000 (cleared under K940954) in the market, which is also indicated for pain relief. The frequency band of the Synaptic 3000 is 250HZ~60KHZ of which 250Hz~1KHz is named as the TENS frequency band. The subject device's frequency band is within the Synaptic 3000's frequency band. All our TENS programs are within or very close to the conventional TENS band plus the high frequency TENS band in Synaptic 3000.

Review of Differences

Frequency range

Like many high frequency TENS comparable devices in the market, high frequency pulses from the RelieforMe TENS/EMS Device Model UPK-GE01 are used in bursts outputted with lower frequencies similar to the conventional TENS' frequencies. This way is equivalent to TENS with the wider pulse (burst in high frequency TENS case). The advantages of high frequency TENS include more comfortable sensation, deeper penetration to relieve deeper pain, and using less current or power. One of the TENS programs for the RelieforMe TENS/EMS Device Model UPK-GE01 uses the high TENS band in the same way that is equivalent to use a wider pulse (burst in our case) with conventional TENS frequency. This difference doesn't raise new questions of safety and effectiveness.

Pulses per burst

The burst of subject device contains more pulses than the predicate devices due to the higher frequency used. Higher frequency normally can penetrate deeper into the body to have better stimulation on the nerve trunk

to relieve deeper pain. The pain relief treatment is as safe and effective as the predicate device. This difference doesn't raise new questions of safety and effectiveness.

Pulses per second

The subject device has more bursts per second than Predicate Device III to eliminate the potential stimulation resistance better due to the body may be used to fewer bursts. But the efficacy and safety are maintained. The way this burst TENS program is used is equivalent to the use of a wider pulse (burst in the case of the subject device) with conventional TENS frequency. The pain relief treatment is as safe and effective as the predicate device 3. This difference doesn't raise new questions of safety and effectiveness.

Burst duration

The subject device has lower burst duration than Predicate Device III due to the higher frequencies used. It results in the similar energy applied. The way this burst TENS program is used is equivalent to the use of a wider pulse (burst in the case of the subject device) with conventional TENS frequency. The pain relief treatment is as safe and effective as the predicate device 3. This difference doesn't raise new questions of safety and effectiveness.

Duty Cycle

The duty cycles of the subject device are higher than those of the predicate devices due to the higher frequency pulse used. However, the subject device uses lower burst duration than the predicate device III. Therefore, the conclusion is the same as Note 5. This difference doesn't raise new questions of safety and effectiveness.

The RelieforMe TENS/EMS Device model UPK-GE01 has the same intended use and the same or similar technological characteristics and functionality as the predicate devices, and therefore is substantially equivalent to the predicate devices. The minor differences do not raise new questions of safety and effectiveness as compared to the predicate devices.

Maximum Phase Charge

The reason that the subject device's phase charge is higher than the predicate is because the allowed voltage is higher than predicate device's at 500Ω. However, the subject device's phase charge is still in the safety range. In addition, the negative phase charge and the positive phase charge are always balanced out. Therefore, the difference does not raise new questions of safety and effectiveness as compared to the predicate devices.

Phase Duration

The difference in phase duration between the subject device and the predicate device may or may not have different sensation to different people. It will not impact the safety and efficacy. The phase difference is due to difference in pulse ramp and ramp down time in the circuitry. Like many predicate devices, the subject device uses pulse with 0 ramp up and ramp down time. So the phase duration of the subject device is greater than the predicate device with nonzero ramp up and ramp down time, but the difference is not significant to have significant sensation. Therefore, the difference does not raise new questions of safety and effectiveness as compared to the predicate devices.

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of RelieforMe TENS/EMS Device model UPK-GE01 and to show substantial equivalence to the predicate device, UMHEAL completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The UPK-GE01 passed the testing in accordance with international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- Electrical safety testing per IEC 60601-1 – Passed
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2 – Passed
- Software verification and validation per FDA Guidance – results /conclusion
- Treatment Programs Performance Verification Testing
- Stability Verification Testing
- HFE Validation Testing
- FCC Testing
- Transportation Testing per ASTM D4169 – Demonstrates package integrity maintained

10. Clinical Performance Data

Not applicable.

11. Statement of Substantial Equivalence

The RelieforMe TENS/EMS Device model UPK-GE01 has the same intended use as the predicate devices and the same or similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Performance testing has demonstrated the RelieforMe TENS/EMS Device model UPK-GE01 is as safe and effective as the predicate device. Therefore, the UPK-GE01 is substantially equivalent to the predicate device.