DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 12, 2015

Gemore Technology Co., Ltd.
Boden Lai
Official Correspondent
11 Fl., No.29-5, Sec.2, Chung Cheng E. Rd.,
Tan Shui, New Taipei City, 251 TW

Re: K150681
Trade/Device Name: Gemore OTC TENS,
Models GM310PP/GM320PP/GM321PP/GM330PP
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: NUH
Dated: March 16, 2015
Received: March 17, 2015

Dear Boden Lai:

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 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" (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 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 yours,

Felipe Aguel -S

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

Indications For Use

510(k) Number (if known): K150681

Device Name: Gemore OTC TENS, Model GM310PP/GM320PP/GM321PP/GM330PP

Indications For Use:

The Gemore OTC TENS, Model GM310PP/GM320PP/GM321PP/GM330PP, is intended for temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities

Prescription Use ____ OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (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)

510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K 150681 .

1. Submitter's Identifications:

Company Name :	GEMORE TECHNOLOGY CO., LTD.
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Date of Summary Preparation: April 27, 2015.

2. Name of the Device:

Trade/Device Name: Gemore OTC TENS, Model: GM310PP/GM320PP/GM321PP/GM330PP.
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator.
Regulatory Class: II
Product Code: NUH

3. Information of the 510(k) Cleared Device (Predicate Device):

K133723: OTC Patch/ Model WL-2406.
K091757: OTC TENS For Arm & Leg Pain Relief/ Model WL-2407

4. Device Description:

The Gemore OTC TENS, model GM310PP/GM320PP/GM321PP/GM330PP is a dual channel transcutaneous electrical nerve stimulator used for pain relief by applying an electrical current to electrodes, which are attached on the user's skin. The output and waveform characteristic is fixed for every operation mode, only the intensity is adjustable within specified limit.

The Gemore OTC TENS, model GM310PP/GM320PP/GM321PP/GM330PP, consist mainly of two parts: the stimulus generator, electrode. The stimulus generator generates the output current specified as the input of controller. The output port transmits the output current to the electrode, which is attached to the user's skin so as to transmit this stimulus current for pain relief.

The stimulation modes for Gemore OTC TENS is pre-program modes with fixed pulse width, pulse rate, frequency. The timer and amplitude for each program are adjustable. This operation way is considered the simplification from the pre-program modes of comparison clear model, OTC TENS For Low Back Pain Relief/ Model GM310PP/GM320PP /GM321PP/ GM330PP (K060222). Every operation mode of Gemore OTC TENS, model GM310PP/GM320PP/ GM321PP/GM330PP has its individual stimulation operation cycle.

For the device included in this submission, we use the following of our 510(K) legally marketed electrodes:K062675, "Gemore Reusable Self Adhesive Electrode", Wire Series/ model no. FA5050, size 50x50mm, wire type.

With the combination of the main device parts, the device can be placed on the treatment locations as recommended in the user manual for temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

5. Intended Use:

The Gemore OTC TENS, Model GM310PP/GM320PP/GM321PP/GM330PP, is intended for temporary relief of pain associated with sore and aching muscles in the low back and/or upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

6. Summary of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:

Compliance to applicable voluntary standards includes IEC 60601-2-10, IEC 60601-1, and IEC 60601-1-2 as well as ISO 10993-5 and ISO 10993-10 requirements. In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

Summary: The Compliance to applicable voluntary standards as above mentioned indicates that the new device in this submission used the same standards as that of predicate device. Therefore; we consider that the compliance of standards included in our submission is adequate for the determination of substantial equivalence.

7. Comparison of Significant device features

Features	510(K) Cleared Models		New Model
Model	WL-2406	WL-2407	GM310PP/GM320PP/ GM321PP/GM330PP
510(K) No.	K133723	K091757	Unknown
Prescription or OTC	OTC	OTC	OTC
Indication for use	temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/ or leg) due to strain from exercise or normal House-hold 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 House-hold and work activities	temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/ or leg) due to strain from exercise or normal House-hold and work activities
FDA product code	NUH	NUH	NUH
Electrode Used	Self Adhesive Electrode (13x7 cm)/K082065	Belt Electrode and/or Self Adhesive Electrode (5 X 5 cm)/K082065	Self Adhesive Electrode (5x5 cm)/K062675

8. Significant output characteristics comparison table:

Comparison feature		510(K) Cleared Model		New Model
		WL-2406(K133723)	WL-2407(K091757)	GM310PP/GM320PP/ GM321PP/GM330PP
Net charge		0	0	0
Max. phase charge		13 uc	20.8 uc	20.8 uc
Max. current Density		0.549 mA/cm^2	3.2 mA/cm^2	3.2 mA/cm^2
Max. Average current (RMSA)	500Ω	50 mA	80 mA	80 mA
	2KΩ	22.5 mA	30 mA	40 mA
	10KΩ	7.5 mA	10 mA	10 mA
Max. Power Density		0.001219 Watts/ cm^2	0.00200 Watts/ cm^2	0.00399 Watts/ cm^2
Burst Mode		Yes	Yes	Yes

9. Comparison of Unit Characteristics & Output Specification

		Predicate Device		New Device
Mode or Program Name		WL-2406	WL-2407	GM310PP/GM320PP/ GM321PP/GM330PP
510(K) Number		K133723	K091757	Unknown
Waveform (e.g., pulsed monophasic, biphasic)		Biphasic	Biphasic	Pulsed monophasic
Shape (e.g., rectangular, spike, rectified sinusoidal)		Rectangular	Rectangular	Rectangular
Maximum Output Voltage (volts) (+/-_20 %)		25V @500Ω 45V @2KΩ 75V @10KΩ	40V @500Ω 60V @2KΩ 100V @10KΩ	40V @500Ω 80V @2KΩ 100V @10KΩ
Maximum Output Current (mA) (+/-_20 %)		50mA @500Ω 22.5mA @2KΩ 7.5mA @10KΩ	80mA @500Ω 30mA @2KΩ 10mA @10KΩ	80mA @500Ω 40mA @2KΩ 10mA @10KΩ
Duration of primary phase (*u*sec)		260 max	260 max	260 max
Pulse Duration (*u*sec)		8333 max	16666 max	8333 max
Frequency (Hz) [or Rate (pps)]		120 max	60 max	120 max
For multiphasic waveforms only:	Yes	Yes	Yes	Yes
	Not applicable	Not applicable	Not applicable	Not applicable
Power Source(s)		1.5Vx2 (AAA Size)	1.5Vx3 (AAA Size)	9V x 1 (6F22 Size)
- Method of Line current Isolation		Type BF	Type BF	Type BF
- Patient Leakage Current		---	---	---
- Normal condition (*u*A)		Under 0.1	Under 0.1	Under 0.1
- single Fault condition (*u*A)		Under 0.5	Under 0.5	Under 0.5
Average DC current through electrodes when device is on but no pulses are being applied (*u*A)		Not applicable	Not applicable	Not applicable
Number of Output Modes		8	8	8
Number of Output Channels:	Synchronous	Synchronous	Synchronous	Synchronous
	Output Coil	Output Coil	Output Coil	Transformer
Regulated Current or Regulated Voltage?		Voltage	Voltage	Current
Software/Firmware/Microprocessor control?		Yes	Yes	Yes
Automatic Overload Trip?		No	No	No
Automatic No-Load Trip?		Yes	Yes	No
Automatic Shut Off?		Yes	Yes	Yes
User Override control?		No	No	No
Indicator Display:	Yes	Yes	Yes	Yes
	Yes	Yes	Yes	Yes
	Yes	Yes	Yes	Yes
Timer Range (Minutes)		10-60	5-60	10-60 and Continuous
Compliance with Voluntary Standards?		IEC 60601-2-10	IEC 60601-2-10	IEC 60601-2-10
Compliance with 21 CFR 898?		Yes	Yes	Yes
Weight (g) including battery		51.6	125.5	140
Dimensions (mm.) [W x H x D]		68×60×17.5	90×50.8×12.7	108×61.5×25
Housing Materials and construction		ABS	ABS	ABS
Pulse per burst		9	9	9
Burst per second		2	2	2
Bust duration		260*u*s	260*u*s	260*u*s
Duty Cycle		Same for each program	Same for each program	Same for each program
Method of achieving zero net charge for net charge/pulse		Biphasic symmetric wave for each pulse	Biphasic symmetric wave for each pulse	Biphasic asymmetric wave for each pulse

10. Summary for the technology comparison.

Basically the Gemore OTC TENS, Model GM310PP/GM320PP/GM321PP/GM330PP has the same technological characteristics with the predicate device in the product design, material, energy source type, main program mode and the main output waveform…etc. There exists some difference in the device outlook and dimensions. Through the detailed calculation comparison of stimulation output energy for each operation mode(in particular the output current density and power density), we found the output level in each operation mode for Gemore OTC TENS, Model GM310PP/GM320PP/GM321PP/GM330PP and predicate device are very close and within the acceptable range as specified in FDA guidance. So we believe the difference in detailed output parameters does not affect the determination of substantial equivalence.

11. Conclusions

The Gemore OTC TENS, Model GM310PP/GM320PP/GM321PP/GM330PP have the same intended use and the similar technological characteristics as the cleared devices. Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted models could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device.