510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being prepared in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 at June 15, 2011.

The assigned 510(k) number is: K162744.

1. Submitter's Identifications:
   Establishment: EVERYWAY MEDICAL INSTRUMENTS CO., LTD.
   Address: 3Fl., No. 5, Lane 155, Sec. 3, Beishen Rd., Shenkeng Dist, New Taipei City 222, Taiwan
   Registration Number: 9616877
   Operations: Manufacturer

   Owner/Operator: EVERYWAY MEDICAL INSTRUMENTS CO., LTD.
   Address : 3Fl., No. 5, Lane 155, Sec. 3, Beishen Rd., Shenkeng Dist., New Taipei City 222, Taiwan
   Contact Person: Robert Tu
   Phone: 886-2-2662-0038
   Fax No.: 886-2-2664-5566
   e-mail : robert@everyway-medical.com

2. Name of the Device:
   Everyway OTC EMS, Model EV-805

3. Information of the 510(k) Cleared Device (Predicate Device):
   K102926: Gemore Muscle Conditioner/ Model GM320PE

4. Classification Information:

   Trade/Device Name: Everyway OTC EMS, model: EV-805
   Regulation Number: 21 CFR 890.5850
   Regulation Name: Powered Muscle Stimulator
   Regulatory Class: II
   Product Code: NGX

5. Device Description:

   The Everyway OTC EMS, model EV-805 is a dual channel powered muscle stimulator intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The various types of muscle work that Everyway OTC EMS can impose on the stimulated muscles are able to improve or facilitate muscle performance by applying an electrical current to electrodes, which are attached on the user's skin.

   The device measures 101mm(H)x 68mm(W)x21.5mm(D). Its outer housing is made of injection molded thermoplastic resin with the output contact probes consist of chrome-plated spheres. The device is powered by a 9-Volt battery to generate output pulses that is discharged through the two adhesive electrode placed on the patient's skin for treatment and muscle training.

   The device is operated in such a way that turn on the intensity control knob and adjust the intended intensity or turn off the device during operation through the same control knob. While device is turned on for operation. User then follow the instruction for use to get appropriate stimulation treatment and/or training on the healthy muscles .

With the combination of the main device parts as above mentioned , the device can be used as recommended in manual for muscle stimulation and indicated for over-the-counter (OTC) use to improve or facilitate muscle performance

6. Intended Use:
Everyway OTC EMS is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The various types of muscle work that Everyway OTC EMS can impose on the stimulated muscles are able to improve or facilitate muscle performance. Everyway OTC EMS may therefore be considered a technique of muscle training.

7. Comparison to the 510(k) Cleared Device (Predicate Device):
The following features are completely identical among the predicate device and our devices.

Parameter	New Device	Predicate Device	Substantive Equivalency
Mode or Program Name or 510k	EV-805 OTC EMS	K102926	--
Product Code	NGX	NGX	Identical
Prescription (Rx) or OTC	OTC	OTC	Identical
Indication for use (IFU)	Everyway OTC EMS is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The various types of muscle work that Everyway OTC EMS can impose on the stimulated muscles are able to improve or facilitate muscle performance. Everyway OTC EMS may therefore be considered a technique of muscle training.	The Gemore muscle conditioner, model GM310PE/GM320PE/ GM330PE/GM340PE/GM350PE are intended to stimulate healthy muscles in order to improve or facilitate muscle performance. The Gemore muscle conditioner, model GM310PE/GM320PE/ GM330PE/GM340PE/GM350PE are not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the Gemore muscle conditioned training programs are designed for injured or ailing muscle and it's use on such muscle in contraindicated. The Gemore muscle conditioner, model GM310PE/GM320PE/ GM330PE/GM340PE/GM350PE electrically impulse triggering actions potentials on motoneurones of motor nerves (excitations). The excitations motoneurones are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber response that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different type of muscle work can be imposed on the stimulated muscles. The various types of muscle work that Gemore muscle conditioner can impose on the stimulated muscles are able to improve or facilitate muscle performance. The Gemore muscle conditioner, model GM310PE/GM320PE/ GM330PE/GM340PE/GM350PE may therefore be considered a technique of muscle training.	SE*

Waveform (e.g., pulsed monophasic),		Biphasic	Biphasic	Identical
Shape (e.g., rectangular, spike, rectified sinusoidal)		Rectangular	Rectangular	Identical
Maximum Output Voltage (volts) (+/-20%)		7.66V @500Ω 8.2V @2KΩ 8.2V @10KΩ	7.5V @500Ω 18.0V @2KΩ 23V @10KΩ	SE*
Maximum Output Current (mA) (+/-20%)		15.3mA @500Ω 4.1mA @2KΩ 0.82mA @10KΩ	15.0mA @500Ω 9.0mA @2KΩ 2.3mA @10KΩ	SE*
Duration of primary phase (*u*sec)		210us (single phase)	200-300us (single phase)	SE*
Pulse Duration (*u*sec)		420us	600us	SE*
Frequency (Hz) [or Rate (pps)]		2~99Hz	2~99Hz	Identical
For multiphasic waveforms only:	Symmetrical phases?	Yes	Yes	Identical
Maximum Charge(Microcoulombs per pulse) (if zero, state method of achieving zero net charge for net		15.75uC	22.5uC	SE*
Maximum Phase Charge(*uC*)		15.75uC	22.5uC	SE*
Maximum Current Density		0.0624mA/cm2	0.0716mA/cm2	SE*
Maximum Average Current		3.119mA	4.455 mA	SE*
Maximum Average Power Density		2.34mW/cm2	2.685mW/cm2	SE*
Burst Mode (i.e. pulse trains)	Pulse per burst	No burst mode	No burst mode	Identical
	Burst per	No burst mode	No burst mode	Identical
	Bust duration	No burst mode	No burst mode	Identical
	Duty Cycle	No burst mode	No burst mode	Identical
On Time (Second)		0s, 5s, 6s, All time	0s, 5s, 6s, All time	Identical
Off Time(second)		0s, 1s, 5s, 10s	0s, 1s, 5s, 10s	Identical

SE*= Substantially equivalent to the predicate. Please see section 10 for more information.

8. Discussion of Non-Clinical Tests Verification Activities Performed to Determine the Safety and Performance of the devices are as the followings:
   Compliance to applicable voluntary standards includes IEC 60601-2-10, as well as IEC 60601-1, IEC60601-1-11 and IEC 60601-1-2 requirement. In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

According to the device features, the testing for the following standards were considered required for the device:

- The International Standard IEC 60601-2-10: 2012; Medical Electrical equipment – Part 2-10: Particular requirement for the safety of nerve and muscle stimulators.
- The International Standard ANSI/AAMI ES 60601-1: 2005 – Safety of medical device; Electrical equipment – General safety.
- The International Standard IEC 60601-1-2: 2014; Medical – Electrical equipment – Safety – Electromagnetic Compatibility.
- International Standard ISO 10993-1: 2009; Biological evaluation of medical devices – Part 1: Guidance on selection of tests.
- International standard ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- International standard EN/ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity
- The International Standard IEC 60601-1-11: 2010 – collateral standard: requirement for medical electrical equipment and medical electrical system used in the home healthcare environment.

Discussion: 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.

9. Discussion of Clinical Test Validation Activities Performed to Determine the Effectiveness of Device are as the followings:

No particular Clinical Test was conducted for Everyway OTC EMS, Model EV-805.

10. Summary for the technology comparison.

Basically the Everyway OTC EMS, Model EV-805 has the similar 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 detailed output parameters (mainly in the output intensity and electrode sizes). 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 our OTC EMS, Model EV-805 and predicate device are very close and within the acceptable range. So we believe the difference in detailed output parameters does not affect the determination of substantial equivalence.

11. Conclusions

The Everyway OTC EMS, Model EV-805 has 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.