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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: K102786

1. Submitter's Identifications:

Well Life Healthcare Limited
1F., No. 16, Lane 454, Jungjeng Road, Yunghe City, Taipei County 234, Taiwan, ROC

Contact: Jenny Hsieh
Telephone: + 886 2 2928 2112

Date of Summary Preparation: May 25,2011

2. Name of the Device:

Trade Name : Well-Life OTC EMS Systems / Model : WL-2412(A)
Common Name : Powered Muscle Stimulator, OTC
Classification Name: Stimulator, muscle, Powered, for muscle conditioning
Product Code : NGX
Regulation Class : II
Regulation Number : 890.5850

3. Information of the 510(k) Cleared Device (Predicate Device):
1> Slendertone EnerVive, Type 561- muscle stimulator (K071666)
2> Ultrastim Electrode – K000947

4. Device Description:

The Well Life OTC EMS System , model no. WL-2412(A) is intended for use by healthy adults for the stimulation of healthy muscles in order to improve or facilitate muscle performance ; it is not intended as a therapy for any medical condition .

Basically the model WL-2412(A), powered by 4.5V (3xAAA/Alkaline battery), is muscle stimulation device and identical to the SE predicate device – Slendertone EnerVive , Type 561, with the following features:

<1> It is a portable two-channel, battery operated neuromuscular electronic stimulation system.
<2> It contains 6 programs as the predicate device; the output waveform is selectable pre-programming change among P1~P6
<3>The output strength is adjustable at 0~80mA via regulated voltage, with variable setting time 5~60 minutes counting from switching ON.
<4>The LCD display is provided for the indication of operation status including operation mode, output program mode, output intensity, time to cut-off, and battery low indication.
<5> The device uses exactly Ultrastim Electrode (K000947) same as predicate device , providing as stimulation transmission media.

5. Intended Use:

The Well-Life OTC EMS System / model no. WL-2412(A) is intended for use by healthy adults for the stimulation of healthy muscles in order to improve or facilitate muscle performance .

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

Compliance to applicable voluntary standards includes ANSI/AAMI, NS4-1985, as well as EN 60601-1, and EN 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.

7. Conclusions

The Well-Life OTC EMS System / model no. WL-2412 (A) , by applying the same stimulus parameters and used with same type of stimulation transmission media by Ultrastim Electrode (K000947), has the same intended use as the cleared device- Slendertone EnerVive 561(K071666).

A summary of the technological characteristics of WL-2412(A) side-by side comparison to the predicate device is given below :

510(K) Summary

Attribute		SLENDERTONE EnerVive 561 510(k)K071666	Well-Life OTC System, WL-2412(A) (this submission)	Discussion of Difference
Design		Muscle Stimulator Size: 104×63.4×30 mm	Muscle Stimulator Size: 90×52.5×18.9 mm	same
Waveform		Symmetrical biphasic square	Symmetrical biphasic square	Same
Channels		Dual	Dual	Same
Power supply		9V	4.5V	same
Material		Unit Housing –ABS plastic	Unit Housing –ABS plastic	same
Number of Self-Adhesive Electrodes		2 pairs of butterfly gel pads type 719	2 pairs of ULB 355	Same supplier 510(k) 000947 cleared
Nos. of Programs		6	6	Same
Amplitude (mA)		0~80	0~80	Same
Pulse rate (Hz)		4~99	4~99	Same
Pulse width (μS)		200~300	200~300	Same
Power ON indicator		LCD	LCD	Same
Pulse Width (μS)		200~300	200~300	Same
Frequency (Hz)		4~99	4~99	Same
Maximum Phase charge (μC) @500Ω		28.4	28.4	Same
Maximum Current Density (mA/cm^2) @500Ω		0.1485	0.1485	Same
Maximum Power Density (W/cm^2) @500Ω		0.00594	0.00594	Same
RMS Voltage (RMSV) (±20%)	@ 500Ω	7.5V	8.8 V	The max. deviation between WL-2412(A) and K071666 is 17.3%, within the acceptable deviation range ((±20%). *Deviation 17% at @ 500Ω , *Deviation 9.6% at @ 1kΩ *Deviation 1.1% at @ 1.5 kΩ
	@ 1kΩ	12.5V	11.7V	
	@ 1.5kΩ	13.7V	13.8V	
	@ 2kΩ	-	16.3V	
	@ 10kΩ	-	27.2V	
RMS Current (RMSA) (±20%),	@ 500Ω	15mA	17.6mA	
	@ 1kΩ	12.5mA	11.7mA	
	@ 1.5kΩ	9.1mA	9.2mA	
	@ 2kΩ	-	8.15mA	
	@ 10kΩ	-	2.72mA	
Prescription or OTC		OTC	OTC	Same

The verification and validation tests contained in this submission demonstrate that the WL-2412(A) 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Well-Life Healthcare, Limited
% Ms. Jenny Hsieh
1Fl., No. 16, Lane 454, Jungjeng Road
Yunghe City, Tiapei County
China (Taiwan) 234

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Re: K102786
Trade/Device Name: Well-Life OTC EMS System/Model WL-2412(A)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: June 30, 2011
Received: June 30, 2011

Dear Ms. Hsieh:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K102786

Device Name: Well-Life OTC EMS System / Model : WL-2412(A)

Indications For Use:

The Well-Life OTC EMS System / model no. WL-2412(A) is intended for use by healthy adults for the stimulation of healthy muscles in order to improve or facilitate muscle performance .

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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102786