DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 5, 2014

Hong Qiang Xing (Shenzhen) Electronics Limited
Mr. Xu Jianhua, General Manager
4F, JingCheng Building,
Xicheng Industrial Zone, Xixiang Road, Bao'an District
Shenzhen, Guangdong Province 518102
CHINA

Re: K133108
Trade/Device Name: Fitness Belt, Model SM9065
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: June 20, 2014
Received: July 3, 2014

Dear Mr. Xu Jianhua:

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" (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 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, Ph.D., M.S.
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)*
K133108

Device Name
Fitness Belt, Model SM9065

Indications for Use *(Describe)*
The SM9065 Fitness Belt is indicated for the improvement of muscle tone, for strengthening of muscles and for the development of firmer muscles.
- The big belt is intended for use on the muscles in abdomen.
- The small belt is intended for use on the muscles in arms and thighs areas.

Contraindicated use on injured or otherwise impaired muscles.
Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.08.05 10:02:54 -04'00'

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Chapter 6. 510(k) Summary

Date of the summary prepared: August 4, 2014

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

- 510(k) Owner's Name: Hong Qiang Xing (Shenzhen) Electronics Limited
- Address: 4F.,Jingcheng Building, Xicheng Industrial Zone, Xixiang Road, Bao'an District, Shenzhen, Guangdong Province, PRC
- Phone: 86-755-26423615
- Fax: 86-755-29915485-818
- Contact Person (including title): Mr. Xu Jianhua (General Manager)
- E-mail: info@sunmas.com

2. Subject Device Information

- Trade Name: Fitness Belt, Model: SM9065
- Common Name: Powered muscle stimulator
- Classification name: Stimulator, Muscle, Powered, For muscle conditioning
- Review Panel: Physical Medicine
- Product Code: NGX
- Regulation Class: 2
- Regulation Number: 890.5850

3. Predicate Device Information

Sponsor	Red Lemon Incorporation	SPORT-ELEC S.A.
Device Name	X2ABS Dual Channel Fitness Belt	SPORT-ELEC® Body Control System '4M'
510(k) Number	K102295	K092476
Product Code	NGX	NGX
Regulation Number	890.5850	890.5850

Regulation Class	2	2

4. Device Description

SM9065 Fitness Belt is a two channels battery operated muscle stimulation system to achieve the purpose of exercise and relaxation. It is comprised of a main device for signal generation, four belts for fixation, and series electrodes.

The big belt is intended for use on muscles in abdomen. The two small belts are intended for use on muscles in arms and thigh areas.

Power is derived from 2 “AAA” batteries located in a compartment protected by a removable battery cover.

The stimulator sends gentle electrical current to targeted muscle group through the electrodes placed on the skin. The parameters of the unit are controlled by the buttons. Its intensity level and frequency level can be adjusted by user.

5. Intended Use & Indication for Use

Intended Use:

The SM9065 Fitness Belt is intended for use by healthy persons to apply trans-coetaneous electrical muscle stimulation (EMS) through skin contact electrodes for the following purposes:

- Improvement of muscle tone of the muscles in the abdomen, arms and thighs.

Indication for Use:

The SM9065 Fitness Belt is indicated for the improvement of muscle tone, for strengthening of muscles and for the development of firmer muscles.

- The big belt is intended for use on the muscles in abdomen.
- The small belt is intended for use on the muscles in arms and thighs areas.

Contraindicated use on injured or otherwise impaired muscles.

Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

6. Design

SM9065 Fitness Belt is a two channels battery operated muscle stimulation system to achieve the purpose of exercise and relaxation. It is comprised of a main device for signal generation, four belts for fixation, and series electrodes.

The big belt is intended for use on muscles in abdomen. The two small belts are intended for use on muscles in arms and thigh areas.

Power is derived from 2 “AAA” batteries located in a compartment protected by a removable battery cover.

The stimulator sends gentle electrical current to targeted muscle group through the electrodes placed on

the skin. The parameters of the unit are controlled by the buttons. Its intensity level and frequency level can be adjusted by user.

7. Materials

There are four user directly contracting components in the subject device as the following list.

Component of Device Requiring Biocompatibility	Material of Component	Body Contact Category (ISO 10993-1)	Contact Duration (ISO 10993-1)
Belt	Non-woven (synthetic) fabric in 100% polyester	Surface-contacting device: skin	Maximum 45 minutes (< 24hours)
Electrode	--	Surface-contacting device: skin	Maximum 45 minutes (< 24hours)

The Nature of body contact is surface, skin contact. And the contact duration is less than 24 hours. According to Table 1 - Initial evaluation tests for consideration in ISO 10993-1, the applicable biological effect is:

- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity

The electrodes used in the Fitness Belt (Model: SM9065) are the ones of Top - Rank Adhesive Electrode manufactured by Top - Rank Health Care Equipment Co., Ltd and legally marketed in K132588. So, we do not provide the ISO 10993-5 and ISO 10993-10 test reports on electrodes.

The non-woven fabric of belt used in the Fitness Belt (Model: SM9065) has been tested in accordance with the standards ISO 10993-5, ISO 10993-10.

8. Physical characteristics

Power Source	2 x 1.5V AAA batteries
Number of channels	Two channels
Number of programs	Six modes
Output	From 0 V to 90 V
Output intensity level	10 level
Frequency	1~50 Hz
Pulse width range	200μs (Constant)
Contraction and relaxation time	Adjustable, due to different modes. (See below “Program Specification Table”)

Treatment time	30 minutes (default)
Indicator display	Indicate the following information: on/off status, modes, intensity & frequency levels and time.
Electrode size	Small (one piece): about 56.7 cm² ; Big (one piece): about 96.04 cm²
Control unit dimension	106.6 mm (L) x 77.9 mm (W) x 31.3 mm (H)
Weight	Control unit (except for batteries): 83 g Big belt: 84 g Small belt: 49 g x 2 piece Electrode pad (big): 22 g Electrode pad (small): 14 g x 6 piece
Environment for operation	Temperature: 5~40 °C Humidity: ≤80% RH
Environment for storage	Temperature: 0~45 °C Humidity: ≤93% RH

9. Safety & EMC Test Summary

SM9065 Fitness Belt has been evaluated the safety and EMC testing as following:

- Electrical safety test according to IEC 60601-1 and IEC 60601-2-10 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard

10. Non-Clinical Test Conclusion

Bench tests have been conducted to verify that the subject device meets all design specifications as predicate devices per the following:

- Software verification and validation test according to the requirements of the FDA “Guidance for Pre Market Submissions and for Software Contained in Medical Devices”
- Waveform test report has also been conducted to verify the output parameters (waveform, shape, voltage, pulse width, frequency and so on) and output waveforms (for each mode and each channel under loads of 500, 2k, and 10k ohms) according to the requirements of the FDA “Guidance Document for Powered Muscle Stimulator 510(k)s”

11. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of SM9065 Fitness Belt are substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device	Remark

Elements of Comparison		Subject Device	Predicate Device		Remark
Device Name and Model		SM9065 Fitness Belt, Model: SM9065	X2ABS Dual Channel Fitness Belt	SPORT-ELEC® Body Control System '4M'	--
510(k) Number		K133108	K102295	K092476	--
Manufacturer		Hong Qiang Xing (Shenzhen) Electronics Limited	Leto Enterprises Incorporation	SPORT-ELEC S.A.	--
Intended Use		The SM9065 Fitness Belt is intended for use by healthy persons to apply trans-coetaneous electrical muscle stimulation (EMS) through skin contact electrodes for the following purposes: - Improvement of muscle tone of the muscles in the abdomen, arms and thighs.	The X2ABS Dual Channel Fitness Belt is intended for use by healthy persons to apply trans-coetaneous electrical muscle stimulation (EMS) through skin contact electrodes for the following purposes: - Improvement of muscle tone of the muscles in the abdomen.	The Body Control '4M' is intended for use by healthy persons to apply trans-coetaneous electrical muscle stimulation (EMS) through skin contact electrodes for the following purposes. - Improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs and buttocks areas.	SE Note 1
Basic Unit Characteristics					
Power Source(s)		2 x 1.5V AAA batteries	2 x 1.5V AAA batteries	3 x 1.5V AA batteries	SE Note 2
-Method of Line Current Isolation		Type BF Applied Part	Type BF Applied Part	Type BF Applied Part	SE
Patient Leakage Current	NC	0.586μA	3μA	--	SE Note 2
	SFC	24.017μA	8μA	--	
Average DC current through electrodes when device is on but no pulses are being applied		< 0.01μA	< 0.01μA	< 0.01μA	SE
Number of Output Channels:		Two channels	Two channels	Two channels	SE
Number of Output Modes		6 modes	8 modes	4 modes	SE Note 3

Elements of Comparison		Subject Device	Predicate Device		Remark
Output Intensity Level		10 steps	28 steps	--	SE Note 3
Synchronous or Alternating?		Alternating	Alternating	--	SE
Method of Channel Isolation		Voltage Isolation	Voltage Isolation	--	SE
Regulated Current or Regulated Voltage?		Current Control	Current Control	--	SE
Software/Firmware/Microprocessor Control?		Yes	Yes	Yes	SE
Automatic Overload Trip		Yes	Yes	Yes	SE
Automatic No-Load Trip		Yes	Yes	Yes	SE
Automatic Shut Off		Yes	Yes	Yes	SE
Patient Override Control		Yes	Yes	Yes	SE
Indicator Display	On/Off Status	Yes	Yes	No	SE Note 3
	Low Battery	No	Yes	No	SE Note 3
	Voltage/ Current Level	No	No	No	SE
Timer Range		Default time is 30 minutes	Default time is 10 minutes, minimum time is 5 minutes	--	SE Note 3
LCD display		Indicate the following information: on/off status, modes, intensity & frequency levels and time.	Indicate the following information: Sound on/off, Keylock, Low battery, Channel indication, Intensity level, Mode selection.	Indicate the following information: indicator of power, indicator of electrodes or of contact, indicator of weak and/or defective battery, indicator absence contact belt, indicator of the	SE

Elements of Comparison	Subject Device	Predicate Device		Remark
			programs.	
Compliance with Voluntary Standards	Yes Comply with IEC 60601-1 and IEC 60601-2-10, IEC 60601-1-2	Yes Comply with IEC 60601-1 and IEC 60601-2-10, IEC 60601-1-2	Yes Comply with IEC 60601-1 and IEC 60601-2-10, IEC 60601-1-2	SE
Compliance* with 21 CFR 898	Yes	Yes	Yes	SE
Weight	Control unit (except for batteries): 83 g Big belt: 84 g Small belt: 49 g x 2 piece Electrode pad (big): 22 g Electrode pad (small): 14 g x 6 piece	81.2g	106g	SE Note 3
Dimensions	106.6 mm (L) x 77.9 mm (W) x 31.3 mm (H)	82mm (L) x 62mm (W) x 23mm (H)	69mm (L) x 43mm (W) x 87mm (H)	SE Note 3
Electrode Size	Small: about 56.7 cm^2; Big: about 96.04 cm^2	32 cm^2	Small: 25 cm^2 Big: 32 cm^2	SE Note 4
Housing Materials and Construction	ABS plastic	ABS plastic	ABS plastic	SE
Output Specifications				
Waveform	Pulsed monophasic	Pulsed monophasic	Pulsed monophasic	SE
Shape	Rectangular	Rectangular	Rectangular	SE
Maximum Output Voltage(+/- 10%)	90V@ 500Ω	30V@ 500Ω	--	SE Note 4
	132V@ 2KΩ	90V@ 2KΩ	--	
	170V@ 10KΩ	150V@ 10KΩ	-	
Maximum Output Current(+/- 10%)	180mA@ 500Ω	60mA@ 500Ω	--	SE Note 4
	66mA@ 2KΩ	45mA@ 2KΩ	--	
	17mA@ 10KΩ	15mA@10KΩ	--	
Pulse Duration	200 μs (Constant)	220 μs (Constant)	200 μs (Constant)	SE Note 4
Pulse frequency	1 to 50 Hz	8.5 to 64 Hz	50 to 70 Hz	SE Note 4
Net Charge (per pulse)	16.72μC @ 500Ω	16.0μC @ 500Ω	--	SE Note 4

Elements of Comparison	Subject Device		Predicate Device		Remark
Maximum Phase Charge	0.12μC@ 500Ω		13.2μC@ 500Ω	--	SE Note 4
Maximum Average Current	0.836μA@ 500Ω		1.024μA@ 500Ω	--	SE Note 4
Maximum Current Density (r.m.s)	I_{AVR} = C F_{Max} Where C= Charge, F= Maximum Frequency I_{AVR} = 16.72μC x 50Hz = 836 μA = 0.836 mA Max Current Density = I_{AVR} / Square of one electrode = 0.836 mA / 56.7 cm² = 0.015 (mA/cm²) 0.015 mA/cm^2 @ 500Ω (for the smallest size electrode about 56.7 cm^2)		I_{AVR} = C F_{Max} Where C= Charge, F= Maximum Frequency I_{AVR} = 16.0μC x 64Hz = 1024μA = 1.024mA Max Current Density = I_{AVR} / Square of one electrode = 1.024mA / 32.0cm² = 0.032 (mA/cm²) 0.032 mA/cm^2 @ 500Ω (for the smallest size electrode 32.0 cm^2)	--	SE Note 4
Maximum Average Power Density	Max Power Density = I_{AVR}^2 R / Square of one electrode = (0.836mA) ² x 500Ω / 56.7cm² = 6.16 μW/cm²＜0.25 (W/cm²) 6.16 μW/cm²@ 500Ω		Max Power Density = I_{AVR}^2 R / Square of one electrode = (1.024mA) ² x 500Ω / 32.0cm² = 16.4 μW/cm²＜0.25 (W/cm²) 16.4 μW/cm²@500Ω	--	SE Note 4
Burst Mode					
a. Pulse per burst	Mode 1	310 - 2500	--	--	SE Note 4
	Mode 2	10 - 124			
	Mode 3	61 - 686			
	Mode 4	81 - 820			
	Mode 5	81 - 820			
	Mode 6	127.5			
b. Bursts per second	Mode 1	2 -16	--	--	SE Note 4
	Mode 2	0.32 - 4.16			
	Mode 3	0.02 - 0.27			
	Mode 4	0.018 - 0.22			
	Mode 5	0.018 - 0.22			

Elements of Comparison	Subject Device		Predicate Device		Remark
	Mode 6	39.7			
c. Burst duration (unit: ms)	Mode 1	62 - 500	--	--	SE Note 4
	Mode 2	2 - 24.8			
	Mode 3	12.2 - 137			
	Mode 4	16.2 - 163.8			
	Mode 5	16.2 - 163.8			
	Mode 6	25.2			
d. Duty Cycle	Mode 1	100%	--	--	SE Note 4
	Mode 2	0.27% - 0.30%			
	Mode 3	0.30% - 0.32%			
	Mode 4	0.25%- 0.36%			
	Mode 5	0.25%- 0.36%			
	Mode 6	100%			
ON Time	1s		2s	2.5s	SE Note 4
OFF Time	1s		2s	2.5s	SE Note 4
Contraction and Relaxation time	Adjusted by FRE-UP and FRE-DOWN buttons, due to different frequencies.		Adjustable, due to different modes.	Adjustable, due to different modes.	SE
Additional Features					
Environment for operating	Temperature: 5 ~ 40° C Humidity: ≤80% RH		Temperature: 5 ~ 40° C Humidity: 20 ~ 65% RH	Temperature: 5 ~ 45° C Humidity: 20 ~ 65% RH	SE Note 2
Environment for storage	Temperature: 0 ~ 45° C Humidity: ≤93% RH		Temperature: 0 ~ 40° C Humidity: 10 ~ 90% RH	Temperature: 0 ~ 45° C Humidity: 10 ~ 90% RH	SE Note 2
Standards					
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and		All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10	All user directly contacting materials are compliance with ISO10993-5 and	SE

Elements of Comparison	Subject Device	Predicate Device		Remark
	ISO10993-10 requirements.	requirements.	ISO10993-10 requirements.	
Electrical Safety	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	SE
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	SE

Comparison in Detail(s):

Note 1:

Although the muscles for intended use of subject device are different from predicate devices, we can find that the predicate devices can also be used on the same muscles according to the device description of 510(k) summary. So the subject device and predicate devices have the same intended use aspect.

Note 2:

Although the “Power Source(s)”, “Patient Leakage Current”, “Average DC current through electrodes when device is on but no pulses are being applied”, “Operating Environment”, “Storage Environment” are a little different from the predicate devices, they all comply with IEC 60601-1 requirements. So the differences will not raise any safety or effectiveness issue.

Note 3:

Although the “ Number of Output Modes” “Output Intensity Level”, “ Method of Channel Isolation”, “ Timer Range”, “Weight”, “Dimensions” and “the electrode size” of subject device are different from the predicate devices, they are all comply with IEC 60601-1 and IEC 60601-2-10 requirements. So the differences of the function specifications will not raise any safety or effectiveness issue.

Note 4:

Although the “Maximum Output Voltage”, “Maximum Output Current”, “Pulse Duration”, “Maximum pulse frequency”, “Net Charge (per pulse)”, “Maximum Phase Charge”, “Maximum Average Current”, “Maximum Current Density”, “Maximum Average Power Density of subject device”, “Burst Mode” “ON Time” and “OFF Time” are a little different from the predicate devices, they all comply with IEC 60601-1, IEC 60601-2-10 requirement, FDA guidance requirement for Transcutaneous Electrical Nerve Stimulator for Pain Relief and FDA guidance requirement for Powered Muscle Stimulator for Muscle Conditioning. So the differences of function specification will not raise any safety or effectiveness issue.

Conclusion

The SM9065 Fitness Belt was evaluated with Safety, EMC, Biocompatibility and Waveform Test. The conclusions from testing of the SM9065 Fitness Belt demonstrate that the device is as safe and effective as the legally marketed predicate devices.