DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 12, 2014

Shenzhen OSTO Technology Company Limited
Li Yang, General Manager
No.43 Longfeng Road
Xinsheng Community, Longgang Street Longgang District,
Shenzhen City Guangdong Province
CHINA

Re: K133929
Trade/Device Name: Health Expert Electronic Stimulator, Model AST-300C and AST-300D
Regulation Number: 21 CFR 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: October 07, 2014
Received: October 10, 2014

Dear LiYang:

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, PhD, MS
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)*
K133929

Device Name
Health Expert Electronic Stimulator, Model: AST-300C and AST-300D

Indications for Use *(Describe)*
PMS (Mode 1~8)
It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.
TENS (Mode 9~25)
To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve.

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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Chapter 5. 510(k) Summary

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: Shenzhen OSTO Technology Company Limited
- Establishment Registration Number: Applying
- Address: No.43 Longfeng Road, Xinsheng Community, Longgang Street, Longgang District, Shenzhen City, Guangdong Province, China
- Tel: +86-755-29769546
- Fax: +86-755-29769540
- Contact Person: Li Yang (General Manger)
- Email: annaosto@163.com

2. Subject Device Information

- Trade Name: Health Expert Electronic Stimulator
- Common Name: Electronic Stimulator
- Classification name: Stimulator, Nerve, Transcutaneous, Muscle, Powered, For Muscle Conditioning, Over-The-Counter
- Review Panel: Neurology, Physical Medicine
- Product Code: NUH, NGX
- Regulation Class: II
- Regulation Number: 882.5890, 890.5850

3. Predicate Device Information

Sponsor	Hong Qiangxing (Shenzhen) Electronics Limited	Prospera Cprporation
Device Name and Model	SM TENS & PMS Model: SM9128	Prospera OTC TENS Electronic Pulse Massager Model: PL029
510(k) Number	K121719	K122744
Product Code	NUH, NGX	NUH, NGX
Regulation Number	882.5890, 890.5850	882.5890
Regulation Class	II	II

4. Device Description

Health Expert Electronic Stimulator is a portable and adapter powered multifunctional device, offering both Transcutaneous Electronic Nerve Stimulator (TENS) and Powered Muscle Stimulator (PMS) qualities.

Health Expert Electronic Stimulator has 25 operation modes, which can give certain electrical pulse through 4 pcs of electrode pads placed on the skin to help users to enjoy body stimulation and 2 big electrode pads in Electrode Silicon Area for feet placed on the main unit to help users to enjoy sole stimulation, as well as certain non-electrical rolling massage through one massage roller.

The electronic stimulatory module has the operating elements of ON/OFF Switch, Display screen, Mode Selection key and Intensity Modification keys.

The LCD display screen can show selected mode, output intensity of body and/or sole, and time remaining of an application mode.

The device is equipped with accessories of electrode pads, electrode wire, adapter, remote controller. The electrode wire is used to connect the pads to the main unit; the adapter wire is used to connect the adapter to the device.

The electrode pads, which are provided by Shenzhen Context Kang Technology Company Limited complying with the biocompatibility standards ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation and Sensitization), are interchangeable.

5. Intended Use / Indications for Use

PMS (Mode 1~8)

It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.

TENS (Mode 9~25)

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve.

6. Test Summary

Health Expert Electronic Stimulator has been evaluated the safety and performance by lab bench 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
- Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards
- Usability test according to IEC 62366 standard
- Software verification and validation test according to the requirements of the FDA “Guidance for Pre Market Submissions and for Software Contained in Medical Devices”
- The waveform test report has also been conducted to verify the output specifications of the device according to Guidance for Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use and Guidance for Powered Muscle Stimulator for Muscle Conditioning

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Electronic Muscle Stimulator is 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**
Device Name and Model	Health Expert Electronic Stimulator Model: AST-300C and AST-300D	SM TENS & PMS Model: SM9128	Prospera OTC TENS Electronic Pulse Massager Model: PL029	--
510(k) Number	Applying	K121719	K122744	--
Intended Use & Indications for Use	PMS (Mode 1~8) It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance. TENS (Mode 9~25) To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve.	TENS (Mode 1, 3, 4, 5, 6): To be used for temporary relief of pain associated with sore and aching muscle in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (legs) due to strain from exercise or normal household work activities. PMS (Mode 1, 2, 3, 6): It is intended to be used to stimulate healthy muscle in order to improve and facilitate muscle performance.	To be used for temporary relief of pain associated with sore and aching muscle in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (legs) due to strain from exercise or normal household work activities.	SE
Basic Unit Characteristics				
Power Source(s)	Adaptor Input: 100-240Vac, 50-60Hz, 0.1A Output: 5Vdc, 1A Unit Input: 5Vdc, 1A	DC 3.7V Lithium Battery	DC 3V Lithium Battery	SE Note1
-Method of Line Current Isolation	Type BF Applied Part	Type BF Applied Part	Type BF Applied Part	SE

Elements of Comparison		**Subject Device**	**Predicate Device**		**Remark**
Patient Leakage Current	NC	AC: 54.5μA, DC: 0.5μA	2.0μA	2.0μA	SE Note 1
	SFC	AC:120.0μA, DC: 0.6μA	< 10μA	3.3μA	
Average DC current through electrodes when device is on but no pulses are being applied		< 0.01μA	< 0.01μA	0μA	SE Note 1
Number of Output Channels:		2	2	2	SE
Number of Output Modes		25	6	8	SE Note 2
Output Intensity Level		99 steps	20 steps	--	SE Note 2
Synchronous or Alternating?		Synchronous	Synchronous	Alternating	SE Note 2
Method of Channel Isolation		Voltage Transform Isolation "BODY▼" and " BODY▼" buttons for body channel, " SOLE▲" and "SOLE▼" buttons for feet channel	Voltage Transform Isolation	By software	SE Note 2
Regulated Current or Regulated Voltage?		Voltage Control	Voltage Control	Voltage Control	SE
Software/Firmware/Microprocessor Control?		Yes	Yes	Yes	SE
Automatic Overload Trip		No	No	No	SE
Automatic No-Load Trip		No	No	No	SE

Elements of Comparison		**Subject Device**	**Predicate Device**		**Remark**
Automatic Shut Off		Yes.	--	Yes	SE
User Override Control		Yes	Yes	Yes	SE
Indicator Display	On/Off Status	Yes	Yes	Yes	SE
	Low Battery	No	--	No	SE
	Voltage/ Current Level	Yes	Yes	--	SE
Timer Range		25min	10-60 minutes, 10 min/step	5min, 10min	SE Note 2
Weight		2Kg (Without accessories)	--	0.18Kg	SE Note 2
Dimensions		428mm x 428.8mm x 185mm	--	707mm x 2398mm x 253mm	SE Note 2
Housing Materials and Construction		Main unit: ABS plastic	--	Enclousure: ABS	SE
Output Specifications					
Waveform		Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Monophasic	SE
Shape		Rectangular, with interphase interval	Rectangular, with interphase interval	Rectangular	SE
Maximum Output Voltage		44V±10% @ 500Ω	42V±10% @ 500Ω	49.6V±20% @ 500Ω	SE Note 3
		80V±10% @ 2KΩ	84V±10% @ 2KΩ	99.2V±20% @ 2KΩ	
		112V±10% @ 10KΩ	130V±10% @ 10KΩ	114V±20% @ 10KΩ	
Maximum Output Current		88mA±10% @ 500Ω	84mA±10% @ 500Ω	18mA±20% @ 500Ω	SE Note 3
		40mA±10% @ 2KΩ	42mA±10% @ 2KΩ	3.2mA±20% @ 2KΩ	
		11.2mA±10% @ 10KΩ	13mA±10% @10KΩ	0.6mA±20% @ 10KΩ	
Pulse Duration		120μs	100μs	100~200μs	SE Note 3
Pulse frequency		77.3Hz	1~110Hz	0.5~86Hz	SE Note 3

Elements of Comparison	**Subject Device**	**Predicate Device**		**Remark**
Net Charge (per pulse)	0μC @ 500Ω Method: Balanced waveform	0μC @ 500Ω, Method: Balanced waveform	18000μC @ 500Ω	SE Note 3
Maximum Phase Charge	12.78μC @ 500Ω	16.80μC @ 500Ω	23.00μC @ 500Ω	SE Note 3
Maximum Average Current	0.968mA @ 500Ω	0.924mA @ 500Ω	--	SE Note 3
Maximum Current Density (r.m.s)	0.235mA/cm² @ 500Ω	0.462mA/cm^2 @500Ω	1.4mA/cm^2 @500Ω	SE Note 3
Maximum Average Power Density	1.38mW/cm² @ 500Ω	9.702m W/cm^2 @500Ω	0.23W/cm² @ 500Ω	SE Note 3
ON Time	0.6s	--	40ms	SE Note 3
OFF Time	0.6s	--	18ms	SE Note 3
Additional Features				
Environment for operating	Temperature: 5 ~ 45°C Humidity: 20 ~ 65% RH	Temperature: 5 ~ 40°C Humidity: ≤80% RH	--	SE Note 1
Environment for storage	Temperature: 0 ~ 45°C, Humidity: 10 ~ 90% RH Electrode Pad: 10~20°C	Temperature: -20 ~ 55°C Humidity: ≤93% RH	--	SE Note 1
Standards				
Biocompatibility	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	SE
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 " 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 2:

Although the " Number of Output Modes" "Output Intensity Level", " Method of Channel Isolation", " Timer Range", "Weight" and "Dimensions" 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 3:

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", "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.

Finial Conclusion:

The subject device "Health Expert Electronic Stimulator" is Substantial Equivalent to the predicate devices.

8. Date of the summary prepared: November 1, 2014