March 14, 2020

Shenzhen OSTO Technology Company Limited
℅ Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
Room 2231, Building 1, Rui Feng Center, Kaichuang Road
Huangpu District, Guangzhou
Guangdong, 51006 China

Re: K190783
Trade/Device Name: Health Expert Electronic Stimulator (model: AST-300L)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: February 7, 2020
Received: February 10, 2020

Dear Cassie Lee:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Vivek Pinto, PhD
Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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)*
K190783

Device Name
Health Expert Electronic Stimulator (model: AST-300L)

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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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: 3011564440
- 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. Application Correspondent:

- Contact Person: Ms. Cassie Lee
- Guangzhou GLOMED Biological Technology Co., Ltd.
- Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China
- Tel: +86 20 8266 2446
- Email: regulatory@glomed-info.com

3. Subject Device Information

- Trade Name: Health Expert Electronic Stimulator (model: AST-300L)
- Common Name: Transcutaneous electrical nerve stimulator for pain relief
- Classification name: Stimulator, Nerve, Transcutaneous, Over-the-Counter
- Review Panel: Neurology, Physical Medicine
- Product Code: NUH, NGX
- Regulation Class: II
- Regulation Number: 882.5890, 890.5850

2. Predicate Device Information

Predicate Device 1:

510(K) Number: K133929

Company Name: Shenzhen OSTO Technology Company Limited

Trade Name: Health Expert Electronic Stimulator

Model: AST-300C and AST-300D

Common Name: Transcutaneous electrical nerve stimulator for pain relief

Regulation Number: 882.5890, 890.5850

Regulatory Class: II

Product Code: NUH, NGX

Use: Over-The-Counter Use

Predicate Device 2:

510(K) Number: K160115

Company Name: Omron Healthcare, Inc.

Trade Name: Heat Pain Pro

Common Name: Transcutaneous electrical nerve stimulator for pain relief

Regulation Number: 882.5890

Regulatory Class: II

Product Code: NUH

Use: Over-The-Counter Use

3. 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.

The electronic stimulatory module has the operating elements of ON/OFF Switch, remote control ON/OFF key, Display screen, Heating adjust key, 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 Heating adjust key can help user to select a temperature for warming sensation of the foot range 30 to 40 degree C, the superficial heating time is same as the treatment time you selected. The superficial heating and electrical stimulation can apply simultaneously or apply alternatively.

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.

4. 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.

5. 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, IEC 60601-1-11 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 62366-1 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

6. 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 1**	**Predicate Device 2**	**Remark**
Device Name and Model	Health Expert Electronic Stimulator Model: AST-300L	Health Expert Electronic Stimulator Model: AST-300C and AST-300D	Heat Pain Pro	--
510(k) Number	K190783	K133929	K160115	--
Intended 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	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	The Heat Pain Prois intended for: The relief of pain associated with sore or aching, muscles of the lower back, arms, legs, shoulder, or foot due to strain from exercise or normal household work activities.	SE

Elements of Comparison		Subject Device	Predicate Device 1	Predicate Device 2	Remark
		current to stimulate nerve.	current to stimulate nerve.		
Power Source(s)		Adaptor Input: 100-240Vac, 50-60Hz, 0.1A Output: 5Vdc, 2A Unit Input: 5Vdc, 2A	Adaptor Input: 100-240Vac, 50-60Hz, 0.1A Output: 5Vdc, 1A Unit Input: 5Vdc, 1A	External supply Lithium-ion battery AC adaptor/ Rechargeable battery (Lithium Ion)	SE Note 1
-Method of Line Current Isolation		Type BF Applied Part	Type BF Applied Part	Type BF Applied Part	SE
Patient Leakage Current	NC	AC: 54.5μA, DC: 0.5μA	AC: 54.5μA, DC: 0.5μA	1 μA	SE
	SFC	AC:120.0μA, DC: 0.6μA	AC:120.0μA, DC: 0.6μA	5.25μA max	
Average DC current through electrodes when device is on but no pulses are being applied		﹤ 0.01μA	﹤ 0.01μA	0 (uA)	SE
Number of Output Channel		2	2	1	SE
Number of Output Modes		25	25	-3 Therapies (2 TENS with HEAT combination therapies and 1 TENS therapy) -9 TENS Stimulation Modes -2 Heat Level Settings	SE
Heating Setting		Adjustable	--	High and low	SE Note 3
Heating		30-40°C	--	High: 43 °C maximum	SE

Elements of Comparison		Subject Device	Predicate Device 1	Predicate Device 2	Remark
temperature				Low: 42 °C maximum	Note 3
Output Intensity Level		99 steps	99 steps	unknown	SE
Synchronous or Alternating?		Synchronous	Synchronous	unknown	SE
Method of Channel Isolation		Voltage Transform Isolation “Body+” and “Body-” buttons for body channel, “ Sole+” and “Sole-” buttons for feet channel	Voltage Transform Isolation “Body▼” and “Body▼” buttons for body channel, “ Sole▲” and “Sole▼” buttons for feet channel	--	SE
Regulated Current or Regulated Voltage?		Voltage Control	Voltage Control	Regulated Current	SE
Software/Firmware/Microprocessor Control?		Yes	Yes	Yes	SE
Automatic Overload Trip		No	No	No	SE
Automatic No-Load Trip		No	No	Yes	SE
Automatic Shut Off		Yes	Yes	Yes	SE
User Override Control		Yes	Yes	Yes	SE
Indicator Display	On/Off Status	Yes	Yes	Yes	SE

Elements of Comparison		Subject Device	Predicate Device 1	Predicate Device 2	Remark
	Low Battery	No	No	Yes	SE
	Voltage/ Current Level	Yes	Yes	Yes	SE
Timer Range		25 to 60 min	25min	30 min	SE Note 1
Weight		2.1Kg (Without accessories)	2Kg (Without accessories)	Approx. 200g (incl. batteries)	SE Note 2
Dimensions		429.2mm x 401mm x 152.8mm	428mm x 428.8mm x 185mm	71(W)x165(H)x30.5(D)mm	SE Note 2
Housing Materials and Construction		Main unit: ABS plastic	Main unit: ABS plastic	Unknown	SE
Waveform		Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	biphasic	SE
Shape		Rectangular, with interphase interval	Rectangular, with interphase interval	Rectangular	SE
Maximum Output Voltage		44V±10% @ 500Ω	44V±10% @ 500Ω	67.2 V @ 500Ω	SE
		80V±10% @ 2KΩ	80V±10% @ 2KΩ	85.6 V @ 2KΩ	
		112V±10% @ 10KΩ	112V±20% @ 10KΩ	95.9 V @ 10KΩ	
Maximum Output Current		88mA±10% @ 500Ω	88mA±10% @ 500Ω	134.4 mA @ 500Ω	SE
		40mA±10% @ 2KΩ	40mA±10% @ 2KΩ	42.8 mA @ 2KΩ	
		11.2mA±10% @ 10KΩ	11.2mA±10% @ 10KΩ	9.6 mA @ 10KΩ	
Pulse Duration		120μs	120μs	96μs	SE
Pulse frequency		77.3Hz	77.3Hz	1-20.13Hz	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
Net Charge (per pulse)	0μC @ 500Ω Method: Balanced waveform	0μC @ 500Ω Method: Balanced waveform	0μC @ 500Ω Method: Balanced waveform	SE
Maximum Phase Charge	10.56μC @ 500Ω	12.78μC @ 500Ω	4.3 μC @ 500Ω	SE
Maximum Average Current	1.63mA @ 500Ω	0.968mA @ 500Ω	8.43 mA @ 500Ω	SE
Maximum Current Density (r.m.s)	0.0326mA/cm² @ 500Ω	0.235mA/cm2 @500Ω	0.08 mA/cm2 @500Ω	SE Note 1
Maximum Average Power Density	0.0000266mW/cm² @ 500Ω	1.38mW/cm² @ 500Ω	5.219E-09W/cm² @ 500Ω	SE Note 1
ON Time	240 us	240 us	3.00s	SE Note 1
OFF Time	12700 us	12700 us	0.10s	SE Note 1
Environment for operating	Temperature: 5 ~ 45° C Humidity: 20 ~ 65% RH	Temperature: 5 ~ 45°C Humidity: 20 ~ 65% RH	Temperature: 10 to 40°C Humidity: 30 to 80 %RH	SE
Environment for storage	Temperature: 0 ~ 45°C, Humidity: 10 ~ 90% RH Electrode Pad: 10~20°C	Temperature: 0 ~ 45°C, Humidity: 10 ~ 90% RH Electrode Pad: 10~20°C	Temperature: 0 to 40°C Humidity: 30 to 80 %RH	SE
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	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
			requirements.	
Electrical Safety	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	ES60601-1, IEC60601-1-2, IEC60601-2-10	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”, “Maximum Output Current”, ““Maximum Phase Charge”, “Maximum Average Current”, “Maximum Current Density”, “Maximum Average Power Density” and “time range” are a little different from the predicate device, but it is complying with the IEC 60601-1 and IEC 60601-1-2 requirements. Therefore, the differences will not raise any safety or effectiveness issue.

Note 2:

Although the “Weight” and “Dimensions” are a little different from the predicate device, but the differences will not raise any safety or effectiveness issue.

Note 3:

Although the “Heating Setting” and “Heating temperature” are a little different from the predicate device, but it is complying with the IEC 60601-1 requirements. Therefore, the differences will not raise any safety or effectiveness issue.

Finial Conclusion:

The subject devices “Health Expert Electronic Stimulator, model AST-300L” are Substantial Equivalent to the predicate device K133929 and K160115.

8. Date of the summary prepared: March 12, 2020