December 12, 2019

Shenzhen OSTO Technology Company Limited
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
Room 2231, Building 1, Ruifeng Center, Kaichuang Road
Huangpu District
Guangzhou, 51006 CN

Re: K190673
Trade/Device Name: Health Expert Electronic Stimulator, Models AST-300F, AST-300H, AST-300J
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: September 7, 2019
Received: September 13, 2019

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,

Pamela D. Scott
Assistant 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)*
K190673

Device Name
Health Expert Electronic Stimulator (model: AST-300F, AST-300H, AST-300J)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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
- 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

4. Predicate Device Information

Sponsor	Shenzhen OSTO Technology Company Limited
Device Name and Model	Health Expert Electronic Stimulator Model: AST-300C and AST-300D
510(k) Number	K133929
Product Code	NUH, NGX
Regulation Number	882.5890, 890.5850

Regulation Class	II

2. 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, 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, 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

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-300F, AST-300H, AST-300J	Health Expert Electronic Stimulator Model: AST-300C and AST-300D	--
510(k) Number		Applying	K133929	--
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 current to stimulate nerve.	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.	SE
Power Source(s)		Adaptor Input: 100-240Vac, 50-60Hz, 0.1A Output: 5Vdc, 1A Unit Input: 5Vdc, 1A	Adaptor Input: 100-240Vac, 50-60Hz, 0.1A Output: 5Vdc, 1A Unit Input: 5Vdc, 1A	SE
-Method of Line Current Isolation		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	SE
	SFC	AC:120.0μA, DC: 0.6μA	AC:120.0μA, DC: 0.6μA	
Average DC current through electrodes when device is on but no pulses are being applied		< 0.01μA	< 0.01μA	SE

Elements of Comparison		Subject Device	Predicate Device	Remark
Number of Output Channels:		2	2	SE
Number of Output Modes		25	25	SE
Output Intensity Level		99 steps	99 steps	SE
Synchronous or Alternating?		Synchronous	Synchronous	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	SE
Software/Firmware/Microprocessor Control?		Yes	Yes	SE
Automatic Overload Trip		No	No	SE
Automatic No-Load Trip		No	No	SE
Automatic Shut Off		Yes.	Yes	SE
User Override Control		Yes	Yes	SE
Indicator Display	On/Off Status	Yes	Yes	SE
	Low Battery	No	No	SE
	Voltage/ Current Level	Yes	Yes	SE
Timer Range		25min	25min	SE

Elements of Comparison	Subject Device	Predicate Device	Remark
Weight	1.9Kg (Without accessories)	2Kg (Without accessories)	SE Note 1
Dimensions	429.1mm x 426.6mm x 153.8mm	428mm x 428.8mm x 185mm	SE Note 1
Housing Materials and Construction	Main unit: ABS plastic	Main unit: ABS plastic	SE
Waveform	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	SE
Shape	Rectangular, with interphase interval	Rectangular, with interphase interval	SE
Maximum Output Voltage	44V±10% @ 500Ω	44V±10% @ 500Ω	SE
	80V±10% @ 2KΩ	80V±10% @ 2KΩ	
	112V±10% @ 10KΩ	112V±20% @ 10KΩ	
Maximum Output Current	88mA±10% @ 500Ω	88mA±10% @ 500Ω	SE
	40mA±10% @ 2KΩ	40mA±10% @ 2KΩ	
	11.2mA±10% @ 10KΩ	11.2mA±10% @ 10KΩ	
Pulse Duration	120μs	120μs	SE
Pulse frequency	77.3Hz	77.3Hz	SE
Net Charge (per pulse)	0μC @ 500Ω Method: Balanced waveform	0μC @ 500Ω Method: Balanced waveform	SE
Maximum Phase Charge	10.56μC @ 500Ω	12.78μC @ 500Ω	SE
Maximum Average Current	1.63mA @ 500Ω	0.968mA @ 500Ω	SE
Maximum Current Density (r.m.s)	0.0326mA/cm² @ 500Ω	0.235mA/cm² @500Ω	SE
Maximum Average Power Density	0.000651mW/cm² @ 500Ω	1.38mW/cm² @ 500Ω	SE
ON Time	0.6s	0.6s	SE
OFF Time	0.6s	0.6s	SE

Elements of Comparison	Subject Device	Predicate Device	Remark
Environment for operating	Temperature: 5 ~ 45° C Humidity: 20 ~ 65% RH	Temperature: 5 ~ 45°C Humidity: 20 ~ 65% 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	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.	SE
Electrical Safety	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	SE

Comparison in Detail(s):
Note 1: Although the " Weight" and "Dimensions"are a little different from the predicate device, but the differences will not raise any safety or effectiveness issue.

Finial Conclusion:
The subject devices "Health Expert Electronic Stimulator, model AST-300F, AST-300H, AST-300J" are Substantial Equivalent to the predicate device K133929.

8. Date of the summary prepared: December 4, 2019