November 22, 2021

Shenzhen OSTO Technology Co., Ltd.
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District
Guangzhou, Guangdong 510700
China

Re: K212989
Trade/Device Name: Low-frequency Stimulator (Model: AST-645, AST-646)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH, NGX, NYN, GZJ, IPF, IRT
Dated: September 15, 2021
Received: September 20, 2021

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,

Amber Ballard, PhD
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212989

Device Name
Low-frequency Stimulator (Model: AST-645, AST-646)

Indications for Use *(Describe)*
TENS:
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.

It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

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

Heating:
It is intended for temporary relief of minor aches and pains.

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 for K212989

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
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- Contact Person: Li Yang (General Manger)
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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:	Low-frequency stimulator (Model AST-645, AST-646)
Common Name:	Over-the-counter Transcutaneous Electrical Nerve Stimulator
Classification name:	Transcutaneous Electrical Nerve Stimulator For Pain Relief
Review Panel:	Physical Medicine
Product Code:	NUH, NGX, NYN, GZJ, IPF, IRT
Regulation Class:	II
Regulation Number:	882.5890

4. Predicate Device Information

Primary Predicate Devic Information

Sponsor	Jkh Usa, LLC
Device Name and Model	JKH Stimulator Plus
510(k) Number	K191151

- Product Code NUH, NGX, NYN, GZJ, IPF, IRT
- Regulation Number 882.5890
- Regulation Class II

Secondary Predicate Device Information

- Sponsor Shenzhen OSTO Technology Company Limited
- Device Name and Model Health Expert Electronic Stimulator (Model: AST-300L)
- 510(k) Number K190783
- Product Code NUH, NGX
- Regulation Number 882.5890, 890.5850
- Regulation Class II

2. Device Description

The Low-frequency stimulator is a portable device. It has 10 modes: 9 stimulation modes each has 99 levels of intensity and 1 heating mode has 3 levels of heating intensity, which can give certain stimulation to help the users relax their muscle and relief their pain.
The Low-frequency stimulator has 7 buttons on the main unit:
Press Power button to turn on/off the device.
Press “Mode+” and “Mode-” buttons to select 9 stimulation modes;
Press "Intensity+" and "Intensity-" to increase or decrease the stimulus intensity, there are a total of 99 intensities to choose from;
Press "Heat" to adjust the heating temperature, there are three temperatures(38℃, 40℃ and 43℃) that can be adjusted.
Press "Time" to adjust the treatment time, increasing by five minutes each time, up to 60 minutes. It will automatically shut down in 30 minutes by default when it is turned on.
The LCD screen can show stimulation mode, stimulation intensity, heating intensity and time remaining of an application mode.
All the functions of the device can only be controlled by the button on the main unit. The device is equipped with an adapter, bandage, a pair of electrode pads and electrode wire. The electrode wire is used to connect the electrode pads to the main unit. There are four conductive heads on the main unit, which are mainly composed of stainless steel sheets and giving users stimulation and heating functions, and help users relieve knee pain. The stimulation and heating functions can happen simultaneously or independently by control the button on the main unit. When in use, the main unit is fixed with a bandage, and the electrode sheet is placed at the relevant treatment site according to the instructions. The electrode pads can be used on the guidance site for stimulation only when connected to the host.
There are two models of the device, which differ only in appearance.
The electrode pads are complying with the biocompatibility standards ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation and Sensitization), are interchangeable.

5. Intended Use / Indications for Use

TENS:

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.

It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

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

Heating:
It is intended for temporary relief of minor aches and pains.

6. Test Summary

6.1 Non-clinical testing was conducted to verify that the subject device met all design specifications, demonstrated safety based on current industry standards, and to demonstrate substantial equivalence to the predicate. The following tests were performed:

Low-frequency 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

6.2 Summary of Clinical Performance Test

No clinical study is included in this submission.

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, Mode of operation, and intended use of Low-frequency 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	Primary Predicate Device	Secondary Predicate Device	Remark
Device Name	Low-frequency stimulator (Model: AST-645, AST-646)	JKH Stimulator Plus	Health Expert Electronic Stimulator Model: AST-300L	--
510(k) Number	K212989	K191151	K190783	--

Elements of Comparison	Subject Device	Primary Predicate Device	Secondary Predicate Device	Remark
Intended Use	TENS: 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. It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. PMS: It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance. Heating: It is intended for temporary relief of minor aches and pains.	TENS: PL-029K5BL, PL-029K15, and PL-029T are used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities. PL-029K5BL, PL-029K15, and PL-029T are also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. The device of PL-029K5BL and PL-029K15 may be used during sleep. The device of PL- 029K5BL and PL-029K15 is labeled for use only with its own compatible electrodes. PMS: PL-029K5BL, PL-029K15, and PL-029T are used to stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases. PL-029K5BL, PL-029K15, and PL-029T are also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities. Heating:	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

Elements of Comparison		Subject Device	Primary Predicate Device	Secondary Predicate Device	Remark
			The device of PL-029T is intended for temporary relief of minor aches and pains.		
Power Source(s)		Powered by adapter, 100-240VAC, 50-60Hz Output: 9Vdc, 2A Unit Input: 9Vdc, 2A	Rechargeable or non-rechargeable battery	Adaptor Input: 100-240Vac, 50-60Hz, 0.1A Output: 5Vdc, 2A Unit Input: 5Vdc, 2A	SE Note 1
-Method of Line Current Isolation		Type BF Applied Part	Battery Supply	Type BF Applied Part	SE
-Patient Leakage Current	NC	DC: ＜1μA	N/A	AC: 54.5, DC: 0.5μA	SE Note 1
	SFC	DC: ＜1μA	N/A	AC: 54.5, DC: 0.5μA	
Number of Output Channels:		2	1-2	2	SE
Number of Output Modes		For stimulation: 9 modes For heating: 1 mode	PL-029K5BL: 6-8 PL-029K15: 1-4 PL-029T: 8	25	SE Note 2
Output Intensity Level		For stimulation: 99 levels For heating: 3 levels (38℃, 40℃ and 43℃)	N/A	99 steps	SE Note 2
Synchronous or Alternating		Synchronous	N/A	Synchronous	SE
Method of Channel Isolation		2	N/A	2	SE
Regulated Current or Regulated Voltage?		Voltage	Voltage	Voltage Control	SE
Software/Firmware/ Microprocessor Control?		Yes	Yes	Yes	SE
Automatic Overload Trip		No	No	No	SE
Automatic No-Load Trip		No	Yes	No	SE
Automatic Shut Off		Yes	Yes	Yes	SE

Elements of Comparison		Subject Device	Primary Predicate Device	Secondary Predicate Device	Remark
User Override Control		Yes	Yes	Yes	SE
Indicator Display	On/Off Status	Yes	Yes	Yes	SE
	Low battery	No	Yes	No	SE
	Voltage / current level	Yes	Yes	Yes	SE
Timer Range		5-60 min	PL-029K5BL: 10-540 minutes PL-029K15: 10-60 minutes PL-029T: 10-60 minutes	25 to 60 min	SE Note 2
Dimensions(mm) [L x W x D]		Model AST-622 and Model AST-645: 306.2mm*179.3mm*159.4mm Model AST-646: 306.0mm*179.3mm*161.0mm	PL-029K5BL: 66x56x18 PL-029K15:70x62x16 PL-029T: 95x55x15	429.2mm x 401mm x 152.8mm	SE Note 2
Housing Materials and Construction		Main unit: ABS Plastic	Silicone & ABS	Main unit: ABS plastic	SE
Maximum skin temperature		43℃	43℃	Not Publicly Available	SE
Waveform		Symmetrical Biphasic	Biphasic	Pulsed,Symmetric Biphasic	SE
Shape		Rectangular	Rectangular	Rectangular, with interphase interval	SE
Maximum Output Voltage		44V±10% @ 500Ω	PL-029K5BL: 65 PL-029K15: 36 PL-029T: 46	44V±10% @ 500Ω	SE
		80V±10% @ 2KΩ	PL-029K5BL: 132 PL-029K15: 72 PL-029T: 92	80V±10% @ 2KΩ	
		112V±10% @ 2KΩ	PL-029K5BL: 180 PL-029K15: 125 PL-029T: 136	112V±10% @ 2KΩ	
Maximum Output Current		88mA±10% @ 500Ω	PL-029K5BL: 130 PL-029K15: 72	88mA±10% @ 500Ω	SE

Elements of Comparison	Subject Device	Primary Predicate Device	Secondary Predicate Device	Remark
		PL-029T: 92		
	40mA±10% @ 2KΩ	PL-029K5BL: 66 PL-029K15: 36 PL-029T: 47	40mA±10% @ 2KΩ	
	11.2mA±10% @ 10KΩ	PL-029K5BL: 18 PL-029K15: 12.5 PL-029T: 13.6	11.2mA±10% @ 10KΩ	
Pulse Duration	120μs	PL-029K5BL: 50~500 PL-029K15: 100 PL-029T: 104	120μs	SE
Pulse frequency (Hz)	77.3Hz	PL-029K5BL: 1~500 PL-029K15: 1~100 PL-029T: 1.2~167	77.3Hz	SE
Net Charge (per pulse)	0μC @ 500Ω Method: Balanced waveform	N/A	0μC @ 500Ω Method: Balanced waveform	SE
Maximum Phase Charge(μC) at 500Ω	10.56μC @ 500Ω	PL-029K5BL: 78 PL-029K15: 14.5 PL-029T: 19.3	10.56μC @ 500Ω	SE
Maximum Current Density	1.63mA @ 500Ω	N/A	1.63mA @ 500Ω	SE
Maximum Power Density	0.0000266mW/cm² @ 500Ω	PL-029K5BL: 28 PL-029K15: 1.68 PL-029T: 2.22	0.0000266mW/cm² @ 500Ω	SE
ON Time	2s	1~20 s	240 us	SE
OFF Time	2s	0~10 s	12700 us	SE
Biocompatibility	ISO 10993-5, ISO 10993-10	ISO 10993-5, ISO 10993-10	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	SE
Electrical Safety	IEC 60601-1, IEC 60601-1-11, IEC 60601-2-10	ANSI AAMI ES60601-1, IEC 60601-1-11, IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	SE
EMC	IEC 60601-1-2	IEC 60601-1-2	Comply with IEC 60601-1-2	SE

Comparison in Detail(s):
Note 1:

Although the "Power Source(s)" and "Patient Leakage Current" of subject device are a little different from the predicate device, but they all meet the requirements by IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-10 standards required. So the differences will not raise any safety or effectiveness issue.

Note 2:
Although the "Dimensions(mm) [L x W x D]", “Timer Range”, "ON Time" and "OFF Time" of subject device are a little different from the predicate device, but the differences will not raise any safety or effectiveness issue.

8. Finial Conclusion:
The subject devices "Low-frequency stimulator, model AST-645, AST-646" are Substantial Equivalent to the predicate device K191151 and K190783.