June 11, 2021

Shenzhen OSTO Technology Company Limited
% Cassie Lee
Submission Correspondent
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District,
Guangzhou, Guangdong, China 510663

Re: K210756
Trade/Device Name: Neck Care Therapy, Model: AST-905A, AST-905D, AST-905H
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: March 10, 2021
Received: March 15, 2021

Dear Ms. 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210756

Device Name
NECK CARE THERAPY (Model: AST-905A, AST-905D, AST-905H)

Indications for Use *(Describe)*
To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back of neck, back, arm, and leg, due to strain from exercise or normal household and work activities.
- Neck Pad is used on back of neck.
- Meridian Pad is used on shoulder, waist, back, arm and leg.

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 of K210756

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
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Contact Person: Li Yang (General Manager)
Email: annaosto@163.com

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

2. Subject Device Information

Common Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter, Stimulator
Trade Name: NECK CARE THERAPY, Model: AST-905A, AST-905D, AST-905H
Classification Name: Transcutaneous electrical nerve stimulator for pain relief,
Review Panel: Neurology
Product Code: NUH
Regulation Number: 882.5890
Regulation Class: II

3. Predicate Device Information

Predicate Device 1:
510(K) Number: K172897
Company Name: Shenzhen OSTO Technology Co., Ltd.
Address: No.43 Longfeng Road, Xinsheng Community, Longgang Street Longgang District, Shenzhen City Guangdong Province, CHINA
Trade/Device Name: Neck Care Therapy, Models: SYK-509B
Common Name: Electronic Stimulator
Regulation Number: 882.5890
Regulatory Class: II
Product Code: NUH

Predicate Device 2:
510(K) Number: K190783
Company Name: Shenzhen OSTO Technology Company Limited
Address: No.43 Longfeng Road, Xinsheng Community, Longgang Street, Longgang District,

Shenzhen City, Guangdong Province, China
Trade/Device Name: Health Expert Electronic Stimulator (model: AST-300L)
Common Name: Transcutaneous electrical nerve stimulator for pain relief
Regulation Number: 882.5890, 890.5850
Regulatory Class: II
Product Code: NUH, NGX

4. Device Description

For Model AST-905A and AST-905H:

This instrument is a new generation of a household multifunctional device based on physics, modern microelectronics and clinical practices, it uses low-frequency electronic therapy, and circular traction vibration to temporarily alleviate the pain associated with sore and aching muscles in the shoulder, waist, neck, back, arm, and leg. The main unit is used for the back of the neck and the streamlined ring design follows the physiological curvature of the human body. The Meridian Pad is used on the shoulder, waist, back, arm and leg.

The device has 2 operation modes: Stimulation and heating. The stimulation has 2 modes for stimulating, and 50 output Intensity Levels. The heating only has 1 mode for heating and 3 temperature levels. The device can give a certain electrical pulse through 2 pairs of electrode pads that are placed on the skin to help users to enjoy stimulation on the shoulder, waist, back, arm, and leg when using the individual Meridian pads or on the back of the neck when using the Neck Pad.

The remote control of this device is user-friendly controlled because it has the operating elements of the ON/OFF button, left or right button, and increase or decrease button.

The device is equipped with accessories of electrode pads and an electrode wire.

The LCD display screen can show the selected mode, the output intensity of the stimulation, and the time remaining of an application mode.

The device can be successfully opened only when both the switch button of the remote control and the main unit turned on.

When the device connected to the remote control, the remote control is the only controller to select the pulse modes, temperature modes, pulse intensity, temperature levels and adjust the treatment time.

For Model AST-905D:

This instrument is a new generation of a household multifunctional device based on physics, modern microelectronics and clinical practices, it uses low-frequency electronic therapy, and circular traction vibration to temporarily alleviate the pain associated with sore and aching muscles in the shoulder, waist, neck, back, arm, and leg. The main unit is used for the back of the neck and the streamlined ring design follows the physiological curvature of the human body. The Meridian Pad is used on the shoulder, waist, back, arm and leg.

The device has 2 operation modes: Stimulation and heating. The stimulation has 2 modes for stimulating, and 50 output Intensity Levels. The heating only has 1 mode for heating and 3 temperature levels. The device can give a certain electrical pulse through 2 pairs of electrode pads that are placed on the skin to help users to enjoy stimulation on the shoulder, waist, back, arm, and leg when using the individual Meridian pads or on the back of the neck when using the Neck Pad..

The user can control the device effectively by the buttons on the main unit. There are 5 operation buttons: switch button, "M" button, "℃" button, "＋" button and "－" button. The switch button can help user to turn on/off the device, the "M" button intended to select the pulse mode, the "℃" button intended to select the temperature mode and the "＋" button and "－" button intended to increase or decrease the Intensity Levels or temperature levels.

The device is equipped with accessories of Meridian pads and an electrode wire.

5. Intended Use / Indications for Use

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

- Neck Pad is used on back of neck.
- Meridian Pad is used on shoulder, waist, back, arm and leg.

6. Test Summary

NECK CARE THERAPY, Model: AST-905A, AST-905D, AST-905H 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
- Usability test according to IEC 62366 standard
- Software verification and validation test according to the requirements of the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
- The waveform test 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".
- Biocompatibility:
  The body-contacting components of this device are Electrode Pads and Neck Pad. And the Electrode Pads and Neck Pad comply with biocompatibility standards ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation and Sensitization) because the Electrode Pads and Neck Pad of the subject device are identical to those that had been cleared under K172897 (which clearance as K172897 on 12/07/2018) and been marketed to US market.
  So, we have reason to believe that the Electrode Pads and Neck Pad are safe for the users. The Electrode Pads and Neck Pad comply with the following standards.
  - ISO 10993-5, Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity;
  - ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of NECK CARE THERAPY (Model: AST-905A, AST-905D, AST-905H) 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	NECK CARE THERAPY Model: AST-905A, AST-905D and AST-905H	Neck Care Therapy AST-905B or SYK-509B	Health Expert Electronic Stimulator (model: AST-300L)	--
510(k) Number	K210756	K172897	K190783	--

Intended Use & Indications for Use		To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back of neck, back, arm, and leg, due to strain from exercise or normal household and work activities. - Neck Pad is used on back of neck. - Meridian Pad is used on shoulder, waist, back, arm and leg.	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back of neck, back, arm, and leg, due to strain from exercise or normal household and work activities. — Neck Pad is used in back of neck. — Meridian Pad is used in shoulder, waist, back, and arm.	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)		Main Unit: 3.7Vdc, 2200mAh lithium battery Power Adaptor: Input: 100~240Vac, 50/60Hz, 0.2A; Output: 5Vdc, 1A Remote Control: Battery: 3Vdc, 1.5V AAA x 2	Main Unit: Power Adaptor: Input:100~240Vac, 50/60Hz, 0.2A; Output: 5Vdc, 1A Battery: 3.7Vdc, 2200mAh Remote Control: Battery: 3Vdc, AAA x 2 Unit Input: 5Vdc, 1A	Adaptor Input: 100-240Vac, 50-60Hz, 0.1A Output: 5Vdc, 2A Unit Input: 5Vdc, 2A	SE
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	AC: 54.5μA, DC: 0.5μA	SE
	SFC	AC:120.0μA, DC: 0.6μA	AC:120.0μA, DC: 0.6μA	AC: 120.0μA, DC: 0.6μA	
Average current through electrodes when device is on but no pulses are being applied		＜ 0.01μA	＜ 0.01μA	＜ 0.01μA	SE
Number of Modes		3	2	25	SE Note 1

Number of Output Channel		1	1	2	SE
Output Intensity Level		For stimulating: 50 For heating: 3	50 steps	99 steps	SE Note 1
Heating temperature		30-40°C	N/A	30-40°C	SE
Synchronous or Alternating?		Synchronous	Synchronous	Synchronous	SE
Method of Channel Isolation		Voltage Transform Isolation	Voltage Transform Isolation	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	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
Automatic Shut Off		Yes	Yes	Yes	SE
User Override Control		Yes	Yes	Yes	SE
Indicator Display	On/Off Status	Yes	Yes	Yes	SE
	Low Battery	Yes	Yes	No	SE
	Voltage/ Current Level	Yes	Yes	Yes	SE
Timer Range		5-30 min	5-30 min	25 to 60 min	SE

Weight	For Main Unit: AST-905A: 193g; AST-905D: 229g; AST-905H: 178g For Electrode: Patch Electrode: 44g	Main Unit: SYK-509B: 222g Electrode: Patch Electrode: 44g	2.1Kg (Without accessories)	SE Note 2
Dimensions	For Main Unit: AST-905D: 166.0*159.5*55.6 mm AST-905H: 173.4*156.3*43.4 mm For Electrode: Meridian Pad: 8.9*5.8 cm Effective area: 50.04 cm^2 Neck Pad: 42.3 mm x 29.5 mm	Main Unit: SYK-509B: 187.2*169*67.3 mm Patch Electrode: 8.9*5.8 cm	429.2mm x 401mm x 152.8mm	SE Note 2
Housing Materials and Construction	For Electrode Pads: White silica gel, Black conductive silicone, Transparent conductive adhesive silicone, Transparent PET silicone	Electrode Pads: White silica gel, Black conductive silicone, Transparent conductive adhesive silicone, Transparent PET silicone	Main unit: ABS plastic	SE
	For Neck Pad: Stainless steel	Sticky metal sheet: Nickel plating	No publicly available	
	For Unit Housing: ABS plastic	Unit Housing: ABS plastic	No publicly available	
Waveform	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	SE
Shape	Rectangular, with interphase interval	Rectangular, with interphase interval	Rectangular, with interphase interval	SE
Maximum Output Voltage	44V±10% @ 500Ω	44V±10% @ 500Ω	44V±10% @ 500Ω	SE
	80V±10% @ 2KΩ	80V±10% @ 2KΩ	80V±10% @ 2KΩ	SE
	112V±10% @ 10KΩ	112V±10% @ 10KΩ	112V±10% @ 10KΩ	SE

Maximum Output Current	88mA±10% @ 500Ω	88mA±10% @ 500Ω	88mA±10% @ 500Ω	SE
	40mA±10% @ 2KΩ	40mA±10% @ 2KΩ	40mA±10% @ 2KΩ	SE
	11.2mA±10% @ 10KΩ	11.2mA±10% @ 10KΩ	11.2mA±10% @ 10KΩ	SE
Pulse Duration	120μs	120μs	120μs	SE
Pulse frequency	77.3Hz	77.3Hz	77.3Hz	SE
Net Charge (per pulse)	0μC @ 500Ω Method: Balanced waveform	0μC @ 500Ω Method: Balanced waveform	0μC @ 500Ω Method: Balanced waveform	SE
Maximum Phase Charge @ 500Ω	10.56μC	12.78μC	10.56μC	SE
Maximum Average Current@ 500Ω	1.63 mA	0.968 mA	1.63 mA	SE
Maximum Current Density (r.m.s) @ 500Ω	0.0326 mA/cm^2	0.235 mA/cm^2	0.0326 mA/cm^2	SE
Maximum Average Power Density @ 500Ω	0.0000266 mW/cm^2	1.38 mW/cm^2	0.0000266 mW/cm^2	SE
Operating Environment	Temperature: 10~40℃ Humidity: 30% - 75%RH Atmospheric Pressure: 860 hPa to 1060 hPa	Temperature: 10~40℃ Humidity: 30% - 75%RH Atmospheric Pressure: 860 hPa to 1060 hPa	Temperature: 5~45℃ Humidity: 20% - 65%RH Atmospheric	SE
Storage Environment	Temperature: -25 - +70℃ Humidity: ≤90% RH, Atmospheric Pressure: 860 hPa to 1060 hPa	Temperature: -25 - +70℃ Humidity: ≤90% RH, Atmospheric Pressure: 860 hPa to 1060 hPa	Temperature: 0~45℃ Humidity: 10% - 90%RH	SE
Biocompatibility	Biocompatibility test according to ISO 10993-5 and ISO 10993-10	Biocompatibility test according to ISO 10993-5 and ISO 10993-10	All user directly contacting materials are compliance with ISO 10993-5 and ISO 10993-10	SE

			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

Note 1:
Although the "Number of Modes", and “Output Intensity Level" of subject device a little different from the predicate devices, they all meet the IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-10 requirements. Therefore, the differences will not raise any safety or effectiveness issue.

Note 2:
Although the "Weight" and "Dimensions" of subject device a little different from the predicate devices, they all meet the requirements by safety standards IEC 60601-1, IEC 60601-1-11, IEC 60601-2-10 and IEC 60601-1-2 required. Therefore, the differences will not raise any safety or effectiveness issue.

Final Conclusion:
The subject device "NECK CARE THERAPY, Model: AST-905A, AST-905D, AST-905H " is Substantial Equivalent to the predicate devices K172897 and K190783.

8. Date of the summary prepared: June 11, 2021