December 7, 2018

Shenzhen OSTO Technology Co., Ltd.
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion, No.121 Science Road
Guangzhou Science Park
Guangzhou, 510006 China

Re: K172897
Trade/Device Name: Neck Care Therapy, Model: SYK-509B
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: November 2, 2018
Received: November 8, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -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)*
K172897

Device Name
Neck Care Therapy (model: 905B)

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 in back of neck.
- Meridian Pad is used in shoulder, waist, back, and arm.

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
K172897

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 Co., Ltd.
Establishment Registration Number: Applying
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: Suite 306, Kecheng Mansion, No.121 Science Road, Guangzhou Science Park, Guangzhou 510663, China
Tel: +86-20-61099984
Email: regulatory@glomed-info.com

2. Subject Device Information

Trade Name: Neck Care Therapy
Common Name: Electronic Stimulator
Classification name: Transcutaneous electrical nerve stimulator for pain relief, Transcutaneous Electrical Nerve Stimulator, Muscle, Powered, For Muscle Conditioning
Review Panel: Neurology
Product Code: NUH, NGX
Regulation Class: II
Regulation Number: 21 CFR 882.5890, 890.5850

3. Predicate Device Information

Sponsor: Shenzhen OSTO Technology Company Limited
Trade Name: Health Expert Electronic Stimulator
Common Name: Electronic Stimulator
Classification name: Stimulator, Nerve, Transcutaneous, Muscle, Powered, For Muscle Conditioning, Over-The-Counter
510(k)number: K133929
Review Panel: Neurology, Physical Medicine
Product Code: NUH, NGX
Regulation Number: 882.5890, 890.5850
Regulation Class: II

4. Device Description

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

The device has one operation modes which has 2 modes and 50 output Intensity Level, so the device can give certain electrical pulse through 2 pairs of electrode pads or the Neck Pad on the skin to help users to enjoy body massage and sole massage.

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

The device is equipped with accessories of electrode pads and an electrode wire. The electrode wire is used to connect the pads to the main unit.

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

The device can be successfully opened only when switch button of the remote control and Neck Pad turned on at the same time.

The remote control is the only controller to select the pulse modes, pulse intensity and adjust the treatment time.

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 in back of neck.
- Meridian Pad is used in shoulder, waist, back, and arm.

6. Test Summary

Neck Care Therapy, Model: AST-905B 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
- 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”.

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 K172897**	**Predicate device K133929**	**Remark**
Device name and model	Neck Care Therapy AST-905B or SYK-509B	Health Expert Electronic Stimulator	
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 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.	Similar intended use and IFU
Power Source(s)	Main Unit: Power Adaptor: Input:100~240Vac, 50/60Hz, 0.2A; Output: 5Vdc, 1A	Adaptor Input: 100- 240Vac, 50-60Hz, 0.1A Output: 5Vdc, 1A Unit Input: 5Vdc, 1A	Similar
	Battery: 3.7Vdc, 500mAh	Battery: 3.7Vdc, 500mAh	Identical
	Remote Control: Battery: 3Vdc, AAA x 2 Unit Input: 5Vdc, 1A	Remote Control: Battery: 3Vdc, AAA x 2 Unit Input: 5Vdc, 1A	Identical
Method of Line Current Isolation	Type BF Applied Part	Type BF Applied Part	Identical
Patient Leakage Current	NC: AC: 54.5uA DC: 0.5uA SFC: AC: 120uA	NC: AC: 54.5uA DC: 0.5uA SFC: AC: 120.0uA	Identical

	DC: 0.6uA	DC: 0.6uA	
Average current through electrodes when device is on but no pulses are being applied	<0.01uA	<0.01uA	Identical
Number of Output Modes	2	25	Doesn't affect safety and effectiveness *See note 1
Output Intensity Level	50 steps	99 steps	Doesn't affect safety and effectiveness *See note 1
Synchronous or Alternating?	Synchronous	Synchronous	Identical
Method of Channel Isolation	Voltage Transform Isolation	Voltage Transform Isolation	Identical
Regulated Current or Regulated Voltage?	Voltage Control	Voltage Control	Identical
Software/Firmware/Microprocessor Control?	Yes	Yes	Identical
Automatic Overload Trip	No	No	Identical
Automatic No-Load Trip	No	No	Identical
Automatic Shut Off	Yes	Yes	Identical
User Override Control	Yes	Yes	Identical
Timer Range	5-30 min	25 min	Similar *See note 1
Weight	Main Unit: AST-905B: 222g Electrode: Patch Electrode: 44g	2kg (Without accessories)	Doesn't affect safety and effectiveness
Dimensions	Main Unit: AST-905B: 187.2*169*67.3 mm Electrode: Patch Electrode: 8.9 cm *5.8 cm	428mm x 428.8mm x 185mm Electrode: Patch Electrode: 8.9 cm *5.8 cm	Identical electrode area
Electrode pads	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	Identical

	Sticky metal sheet: Stainless steel	PP conductive plastic	Complies with IEC 10993-5 and 10993-10.
Housing unit	ABS plastic	ABS plastic	Identical
Waveform	Pulsed, symmetric, biphasic	Pulsed, symmetric, biphasic	Identical
Shape	Rectangular, with interphase interval	Rectangular, with interphase interval	Identical
Maximum Output Voltage	44V±10% @ 500Ω 80V±10% @ 2KΩ 112V±10% @ 10KΩ	44V±10% @ 500Ω 80V±10% @ 2KΩ 112V±10% @ 10KΩ	Identical
Maximum Output Current	88mA±10% @ 500Ω 40mA±10% @ 2KΩ 11.2mA±10% @ 10KΩ	88mA±10% @ 500Ω 40mA±10% @ 2KΩ 11.2mA±10% @ 10KΩ	Identical
Pulse Duration (μs)	120μs	120μs	Identical
Pulse frequency	77.3Hz	77.3Hz	Identical
Net Charge (per pulse)	0μC @ 500Ω Method: Balanced waveform	0μC @ 500Ω Method: Balanced waveform	Identical
Maximum Phase Charge @ 500Ω	12.78μC	12.78μC	Identical
Maximum Average Current@ 500Ω	0.968 mA	0.968 mA	Identical
Maximum Current Density (r.m.s) @ 500Ω	0.235 mA/cm^2	0.235 mA/cm^2	Identical
Maximum Average Power Density @ 500Ω	1.38 mW/cm^2	1.38 mW/cm^2	Identical
Operating Environment	Temperature: 5~40°C Humidity: 15% - 90%RH Atmospheric Pressure: 700 hPa to 1060 hPa	Temperature: 5 ~ 45°C Humidity: 20 ~ 65% RH	Similar
Storage Environment	Temperature: -25 - +70℃Humidity: ≤90% RH, Atmospheric Pressure: 700 hPa to 1 060 hPa	Temperature: 0 ~ 45°C, Humidity: 10 ~ 90% RH Electrode Pad: 10~20°C	Similar
Biocompatibility	Biocompatibility test according to ISO 10993-5 and ISO 10993-10	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	Identical
Electrical Safety	Comply with IEC 60601-1 and IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	Identical
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Identical

Comparison in Detail(s):

Note 1 (Time Range, Number of Output Modes, Output Intensity Level):

The design of the time range, Number of Output Modes and Output Intensity Level is basing on the intended use. And according to the output specification comparing with the predicated devices, we set the default treatment time is 15min and the user could adjust the levels which could meet the requirements in the energy aspect. Thus, the subject device is actually the same as predicated ones.

Finial Conclusion:

Based on the above analysis and tests performed, it can be concluded that Neck Care Therapy device is effective, and it is Substantially Equivalent (SE) to the predicate device.

8. Date of the summary prepared: December 7, 2018